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Presidential Documents

Title 3—

The President

Proclamation 10559 of April 28, 2023

Asian American, Native Hawaiian, and Pacific Islander Heritage Month, 2023

By the President of the United States of America

A Proclamation

During Asian American, Native Hawaiian, and Pacific Islander Heritage Month, our Nation celebrates the diversity of cultures, breadth of achievement, and remarkable contributions of these communities; of brave immigrants who, motivated by the promise of possibilities, picked up their lives and found new homes here; of native peoples who have stewarded these lands since time immemorial; and of community leaders shaping a brighter future for us all. Throughout our history, they have represented the bigger story of who we are as Americans and embodied the truth that our diversity is our strength as a Nation.

Asian Americans, Native Hawaiians, and Pacific Islanders (AA and NHPIs) represent us at every level of government, including Vice President Kamala Harris, the first Vice President of South Asian descent; Ambassador Katherine Tai, the first Asian American United States Trade Representative; and Dr. Arati Prabhakar, who is the first South Asian American to lead the White House Office of Science and Technology Policy. Earlier this year, I was also proud to nominate Julie Su to serve as the Secretary of Labor. From historic Oscar-winning performances in film to achievements across business, culture, sports, and civil rights, AA and NHPIs shape and strengthen the fabric of this Nation. We see their contributions as business owners and caregivers as well as their service in the military and on the frontlines during the COVID–19 pandemic.

Despite the immeasurable ways AA and NHPIs enrich this country, we continue to see persistent racism, harassment, and hate crimes against these communities. Attacks on Asian American women and elders, have left too many families afraid to leave their homes and too many loved ones traumatized. The devastating murder of eight victims in Atlanta, six of whom were women of Asian descent, pierced the soul of this Nation. This year, after the shootings in Monterey Park and Half Moon Bay, both the Vice President and I visited California to honor the victims; grieve with the community; and witness their resilience, heroism, and courage. Hate must have no safe harbor in America, and every person deserves to be treated with dignity and respect. To address the rising tide of anti-Asian violence, I signed the bipartisan COVID–19 Hate Crimes Act into law—which included the Jabara-Heyer No HATE Act, making it easier for Americans to report hate crimes and to help State, local, and Tribal law enforcement agencies better track these hateful acts.

This year I was proud to launch the first-ever National Strategy to Advance Equity, Justice, and Opportunity for Asian American, Native Hawaiian, and Pacific Islander Communities. This plan reflects my Administration's commitment to improving the lives of AA and NHPIs—ensuring that the census collects accurate data so they are properly reflected when new policy is made; advancing safety, inclusion, and belonging for AA and NHPI communities; promoting language access and preservation; advancing AA and NHPI representation in the Federal workforce; and striving toward an equitable COVID–19 recovery. The White House was proud to host celebrations such

as Diwali, Eid al-Fitr, Lunar New Year, Nowruz, and Vesak so we could celebrate with diverse AA and NHPI communities from across the Nation.

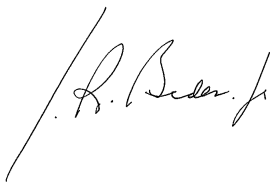
We are also creating economic opportunities for AA and NHPI workers and business owners. The Small Business Administration has distributed nearly $16 billion in loans to AA and NHPI entrepreneurs since I took office. I was proud to sign Executive Orders to ensure the Federal workforce reflects the diversity of the American people. Our efforts are paying off. In the Asian American community, unemployment has fallen by more than half since I took office, and as of 2021, entrepreneurship had risen at the fastest rate in over a decade.

As we make progress to advance equity and opportunity, we know our work is far from done. To help more AA and NHPIs see themselves in the story of America, I signed historic legislation bringing us closer to creating the National Museum of Asian Pacific American History and Culture. To honor the traditional practices and ancestral pathways of Pacific Island voyagers, I expanded protections for the Pacific Remote Islands. To help Americans reckon with and learn from more shameful chapters of our history, I signed into law the Amache National Historic Site Act, which establishes a memorial to the 10,000 Japanese Americans who were unjustly incarcerated at Amache during World War II. Facing past wrongs helps us build a more just and equitable future.

This country's fundamental promise holds that every person is created equal and deserves to be treated equally throughout their lives. We have never fully lived up to that ideal, but we have never walked away from it either. This month, we renew our work to put the American Dream within reach of all people, and we celebrate the vibrancy, contributions, and future of AA and NHPI communities across America.

NOW, THEREFORE, I, JOSEPH R. BIDEN JR., President of the United States of America, by virtue of the authority vested in me by the Constitution and the laws of the United States, do hereby proclaim May 2023 as Asian American, Native Hawaiian, and Pacific Islander Heritage Month. I call upon all Americans to learn more about the history of AA and NHPIs and to observe this month with appropriate programs and activities.

IN WITNESS WHEREOF, I have hereunto set my hand this twenty-eighth day of April, in the year of our Lord two thousand twenty-three, and of the Independence of the United States of America the two hundred and forty-seventh.



[FR Doc. 2023–09522
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Presidential Documents

Proclamation 10560 of April 28, 2023

Jewish American Heritage Month, 2023

By the President of the United States of America

A Proclamation

This month, we celebrate the enduring heritage of Jewish Americans, whose values, culture, and contributions have shaped our character as a Nation. For generations, the story of the Jewish people—one of resilience, faith, and hope in the face of adversity, prejudice and persecution—has been woven into the fabric of our Nation's story. It has driven us forward in our ongoing march for justice, equality, and freedom as we recommit to upholding the principles of our Nation's founding and realizing the promise of America for all Americans.

For centuries, Jewish refugees fleeing oppression and discrimination abroad have sailed to our shores in search of sanctuary. Early on, they fought for religious freedom, helping define one of the bedrock principles upon which America was built. Union soldiers celebrated Passover in the midst of the Civil War. Jewish suffragists fought to expand freedom and justice. And Jewish faith leaders linked arms with giants of the Civil Rights Movement to demand equal rights for all.

Jewish Americans continue to enrich every part of American life as educators and entrepreneurs, athletes and artists, scientists and entertainers, public officials and activists, labor and community leaders, diplomats and military service members, public health heroes, and more. Last year, I was proud to host the White House's first-ever Jewish New Year reception. During our Hanukkah celebration, I was also proud to unveil the first-ever permanent menorah at the White House—reinforcing the permanency of Jewish culture in America. In my own life, the Jewish community has been a tremendous source of friendship, guidance, and strength through seasons of pain and seasons of joy.

But there is also a dark side to the celebrated history of the Jewish people—a history marked by genocide, pogrom, and persecution—with a through line that continues in the record rise of antisemitism today. We have witnessed violent attacks on synagogues, bricks thrown through windows of Jewish businesses, swastikas defacing cars and cemeteries, Jewish students harassed on college campuses, and Jews wearing religious attire beaten and shot on streets. Antisemitic conspiracy theories are rampant online, and celebrities are spouting antisemitic hate.

These acts are unconscionable and despicable. They carry with them terrifying echoes of the worst chapters in human history. Not only are they a strike against Jews, but they are also a threat to other minority communities and a stain on the soul of our Nation. I decided to run for President after I saw this hatred on display during the rally in Charlottesville, when neo-Nazis marched from the shadows spewing the same antisemitic bile that was heard in Germany in the 1930s. These incidents remind us that hate never truly goes away—it only hides until it is given just a little oxygen. It is our obligation to ensure that hate can have no safe harbor in America and to protect the sacred ideals enshrined in our Constitution: religious freedom, equality, dignity, and respect. That is the promise of America.

I have made clear that I will not remain silent in the face of this antisemitic venom, vitriol, and violence. During my first year in office, I signed the bipartisan COVID–19 Hate Crimes Act to help State and local law enforcement better identify and respond to hate crimes. I appointed Deborah Lipstadt, a historian of the Holocaust, as the first Ambassador-level Special Envoy to Monitor and Combat Antisemitism. And my Administration also secured the largest increase in funding ever for the physical security of nonprofits, including synagogues, Jewish Community Centers, and Jewish day schools.

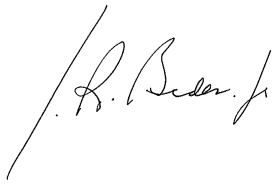
At my direction, we are also developing the first national strategy to counter antisemitism that outlines comprehensive actions the Federal Government will undertake and that reflects input from over a thousand Jewish community stakeholders, faith and civil rights leaders, State and local officials, and more. This strategy will help combat antisemitism online and offline, including in schools and on campuses; improve security to prevent antisemitic incidents and attacks; and build cross-community solidarity against antisemitism and other forms of hate.

But governance alone cannot root out antisemitism and hate. All Americans—including business and community leaders, educators, students, athletes, entertainers, and influencers—must help confront bigotry in all its forms. We must each do our part to put an end to antisemitism and hatred and create a culture of respect in our workplaces, schools, and homes and across social media.

This Jewish American Heritage Month, let us join hands across faiths, races, and backgrounds to make clear that evil, hate, and antisemitism will not prevail. Let us honor the timeless values, contributions, and culture of Jewish Americans, who carry our Nation forward each and every day. And let us rededicate ourselves to the sacred work of creating a more inclusive tomorrow, protecting the diversity that defines who we are as a Nation, and preserving the dignity of every human being—here at home and around the world.

NOW, THEREFORE, I, JOSEPH R. BIDEN JR., President of the United States of America, by virtue of the authority vested in me by the Constitution and the laws of the United States, do hereby proclaim May 2023 as Jewish American Heritage Month. I call upon all Americans to learn more about the heritage and contributions of Jewish Americans and to observe this month with appropriate programs, activities, and ceremonies.

IN WITNESS WHEREOF, I have hereunto set my hand this twenty-eighth day of April, in the year two thousand twenty-three, and of the Independence of the United States of America the two hundred and forty-seventh.



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Presidential Documents

Proclamation 10561 of April 28, 2023

National Building Safety Month, 2023

By the President of the United States of America

A Proclamation

Modern building codes help to ensure that our homes, schools, workplaces, and gathering spots are safely constructed and secure, keeping the power on, our country strong, and our lives moving forward. During National Building Safety Month, we recommit to helping every community in America make all of its structures safer, more sustainable, and more resilient for the future.

From planning and design to construction and renovation, many buildings are safer today than they were decades ago. But nearly two-thirds of Americans live in communities that have not yet adopted the latest building codes, which are designed to avoid damages and keep emerging threats like climate change from further devastating communities with increasingly powerful fires, floods, and storms. We need to do more to help everyone prepare for and prevent disasters; to promote building safety; and to support our too-often overlooked engineers, construction workers, and code enforcement inspectors, who do so much every day to keep Americans safe.

My Administration has taken major steps in that direction. Last year, we launched a new National Initiative to Advance Building Codes, designed to help State, local, Tribal, and territorial governments adopt the latest building standards. With our once-in-a-generation infrastructure law, we are rebuilding the Nation's roads, bridges, ports, water systems, and more; we are investing over $50 billion to weatherize American homes and to help protect communities against droughts, heat, and floods; and we are replacing toxic lead pipes in 10 million homes and 400,000 schools or child care centers so every American can turn on the faucet and drink clean water. We are also investing in training workers to meet and enforce new standards.

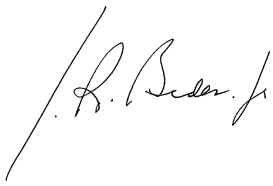
The Inflation Reduction Act, meanwhile, is America's biggest-ever investment in fighting climate change, providing $1 billion to help States and localities adopt building energy codes that reduce greenhouse gas emissions. It invests another nearly $1 billion to improve energy efficiency and indoor air quality in federally-supported housing and make these properties more resilient to climate impacts. At the same time, the Federal Emergency Management Agency has helped rebuild communities devastated by floods, fires, tornadoes, and hurricanes while incentivizing the use of low-carbon materials when rebuilding. Across the board, we have committed to sending 40 percent of the benefits of certain Federal investments—including investments in clean energy, energy efficiency, affordable housing, and pollution reduction—to disadvantaged communities, which too often have been left out and left behind.

Regularly-updated building codes and tough enforcement are key to safety—but we can each do our part to build a stronger, more resilient America. To keep your homes safe, we urge all Americans to change the batteries in your smoke alarms; to regularly check that your appliances, vents, plumbing, and electrical systems are working; and to keep an eye out for mold and pests that can make loved ones sick. If you live in wildfire country, find time to clear the leaves and debris from around your home. While

there are few things more proudly American than do-it-yourself renovations, make sure your work is in line with local requirements designed to save lives or hire qualified contractors to do it for you. Finally, we urge everyone to support their local code enforcement inspectors and to give them the respect and thanks they deserve for keeping us safe and making all our communities more resilient.

NOW, THEREFORE, I, JOSEPH R. BIDEN JR., President of the United States of America, by virtue of the authority vested in me by the Constitution and the laws of the United States, do hereby proclaim May 2023 as National Building Safety Month. I encourage citizens, government agencies, businesses, nonprofits, and other interested groups to join in activities that raise awareness about building safety. I also call on all Americans to learn more about how they can contribute to building safety at home, at work, and in their communities.

IN WITNESS WHEREOF, I have hereunto set my hand this twenty-eighth day of April, in the year of our Lord two thousand twenty-three, and of the Independence of the United States of America the two hundred and forty-seventh.



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Presidential Documents

Proclamation 10562 of April 28, 2023

National Foster Care Month, 2023

By the President of the United States of America

A Proclamation

The more than 391,000 American children and youth living in foster care deserve to grow up in safe and loving homes devoted to their health, happiness, and advancement. This month, we honor the absolute courage of young people in foster care, who too often endure challenges that no child should ever have to confront, and we give thanks to the dedicated kinship and foster parents who care for them during their times of greatest need. We recognize the biological parents and families of foster children who work hard to overcome difficult circumstances so they can safely reunite with their children. We also rededicate ourselves to supporting the volunteers and professionals who help America's foster youth find temporary and permanent homes.

Despite the selflessness and service of loving foster parents across the country, children in foster care often face an uphill battle in achieving their full potential. Many carry lasting physical and emotional scars from trauma they experienced at a young age, which can increase their risk of mental health issues or lead to substance use disorders. These challenges are magnified for children of color, who are disproportionately represented in the child welfare system: 1 in 9 Black children and 1 in 7 Native American children spend part of their childhood in foster care. Meanwhile, recent estimates suggest 30 percent of youth in foster care identify as LGBTQI+.

To fulfill our Nation's responsibility to our children, we need to prevent the conditions that lead to kids entering foster care in the first place. My Administration has invested hundreds of millions of dollars in community-based child abuse and neglect prevention programs, and we are requesting an increase from the Congress for these programs. We are also proposing a $5 billion expansion of evidence-based foster care prevention services to allow more children to remain safely in their own homes with their own families. Because poverty can trigger interventions that unnecessarily remove children from their families, we are fighting to restore the expanded Child Tax Credit, which in 2021 helped slash child poverty to its lowest rate ever. And as a dangerous wave of cynical State investigations targets families with transgender children, we will keep working to stop politicians from weaponizing child protective services against loving families who simply want to support their kids and help them to be their authentic selves.

For children and youth already in the foster care system, we must continue finding them loving temporary homes and, ultimately, safe and supportive permanent homes. My Administration is working to help States place more children with relatives and other trusted adults instead of in group homes. We are seeking to make it easier for biological parents to safely reunite with their children by providing these families with legal representation to help them navigate the complex child welfare system.

To make adoption and legal guardianship more manageable for families who could otherwise create safe and supportive homes, I have called for the adoption tax credit to be made fully refundable and proposed extending it to legal guardians—including grandparents, aunts, uncles, and other relatives. This would provide more breathing room to the kinship caregivers currently raising nearly one-third of all children in the foster care system, and it would also help reduce racial inequities in our country's child welfare system.

To further increase the number of loving families who can take in foster children, I issued an Executive Order removing barriers and combating biases that make it harder for LGBTQI+ families to foster and adopt. At the same time, we are working with State child welfare agencies to make sure LGBTQI+ youth are placed in supportive environments that see and value them for who they are.

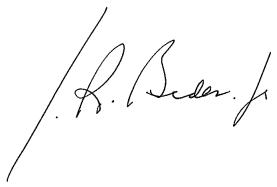
Since coming to office, my Administration has worked hand-in-hand with States to help youth aging out of the foster care system to stay in school, participate in job training programs, pay their bills, and transition to adulthood. I have also expanded the Military Parental Leave Program, which enables service members to spend needed time with their families following a child's birth, adoption, or placement in long-term foster care. My latest Budget calls for $9 billion to provide housing vouchers to all 20,000 youth exiting foster care annually—a key step in helping them secure stable housing during this difficult transition. I have also called for an additional $1 billion to help youth aging out of foster care find a job, enroll in and afford higher education, obtain basic necessities, and access preventative health care.

One of my great privileges during my career in public service has been meeting some of the remarkable young people in foster care and their foster parents. I have seen what good foster care can do. Despite the challenges that no young person should ever have to face, loving foster families can help children become independent, confident, successful members of society and can be a critical resource to children and families in times of need. Ensuring that children who are separated from their families are placed in loving and supportive environments, while ensuring that as many families as possible have the resources they need to remain safely together, is a moral duty we all share and an investment in America's future that will pay dividends for generations to come.

This National Foster Care Month, we express our gratitude to every loving foster parent in America, and we acknowledge every young person navigating the child welfare system, unsure of what the future might hold. You can succeed, and my Administration will do all it can to provide you with the tools and resources you need and the secure, respectable upbringing you deserve to create a meaningful life.

NOW, THEREFORE, I, JOSEPH R. BIDEN JR., President of the United States of America, by virtue of the authority vested in me by the Constitution and the laws of the United States, do hereby proclaim May 2023 as National Foster Care Month. I call upon all Americans to observe this month by reaching out in their neighborhoods and communities to the children and youth in foster care and their families, to those at risk of entering foster care, and to kin families and other caregivers.

IN WITNESS WHEREOF, I have hereunto set my hand this twenty-eighth day of April, in the year of our Lord two thousand twenty-three, and of the Independence of the United States of America the two hundred and forty-seventh.



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Presidential Documents

Proclamation 10563 of April 28, 2023

National Mental Health Awareness Month, 2023

By the President of the United States of America

A Proclamation

During National Mental Health Awareness Month, we honor the absolute courage of the tens of millions of Americans living with mental health conditions, and we celebrate the loved ones and mental health professionals who are there for them every day. Treatment works, and there is no shame in seeking it. Together, we will keep fighting to get everyone access to the care they need to live full and happy lives.

As Americans, we have a duty of care to reach out to one another and leave no one behind. But so many of our friends, colleagues, and loved ones are battling mental health challenges, made worse by the isolation and trauma of COVID–19. Two in five adults report anxiety and depression, and two in five teens describe experiencing persistent sadness or hopelessness, exacerbated by social media, bullying, and gun violence. Drug overdose deaths are also near record highs, and suicide is the second leading cause of death among young people. It does not have to be this way.

As President, I released a new national strategy to transform how we understand and address mental health in America—supporting and training more providers, improving access to care, and building healthy environments that promote mental health. This work is a core pillar of the Unity Agenda that I outlined in my first State of the Union Address. Mental health is health; it affects everyone, regardless of race, gender, politics, or income. Promoting it is one of the big things that we can all agree to do together as Americans to make our country stronger.

The United States has long faced a shortage of mental health providers. It takes an average of 11 years to get treatment after the onset of symptoms, and less than half of Americans struggling with mental illness ever receive the care they need. This is especially true in rural and other underserved communities. That is why the American Rescue Plan made our Nation's biggest-ever investment in mental health and substance use programs—recruiting, training, and supporting more providers at the State and local levels, including in our schools. Last year, when we passed the Nation's first major gun safety law in nearly 30 years, it contained measures to further increase the number of school psychologists and counselors available to our kids, to make it easier for schools to use Medicaid to deliver mental health care, and to expand the Certified Community Behavioral Health Clinics that deliver 24/7 care. Additionally, we have invested in training more first responders to address mental health-related issues.

Last year, we also launched 988 as the Nation's new Suicide and Crisis Lifeline so anyone in the midst of a crisis can receive life-saving confidential help right away. We added dedicated counselors trained in supporting LGBTQI+ youth to the 988 lifeline, and for veterans, we made it easier to reach the Veterans Crisis Line by dialing 988 and pressing 1 to reach trained crisis responders. We created a separate Maternal Mental Health Hotline to help mothers navigate mental health issues like postpartum depression, anxiety, and substance use disorders, which affect one in five pregnant and postpartum women. Far too often, these disorders go undiagnosed and untreated, so we have invested in programs that bolster screening and treatment and call specific attention to them during Maternal Mental Health Awareness Week, which we also observe this month. Finally, we have passed historic laws that further require insurers to cover mental health care as they would any other kind of treatment, that lower prescription drug costs, and that expand health coverage generally. I am proud that we have seen historic health insurance coverage gains since I took office.

At the same time, we are fighting to expand access to prevention and treatment for substance use disorders, including opioid use disorder, which have devastated so many families and communities. This includes expanding access to mental health and substance use treatment in jails and prisons and during reentry to support people when they return home. And last year, we passed a law making it easier for doctors to prescribe effective addiction treatment. Anyone suffering should know they are not alone: We believe in recovery, and we celebrate the courage of the 23 million Americans who have come so far down that road.

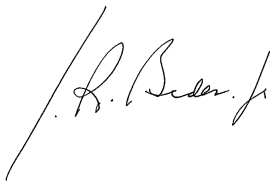
We are also expanding mental health care for service members and veterans, to better honor our sacred obligation to the troops we send into harm's way and to care for them and their families when they are home. We cannot keep losing 17 veterans a day to the silent scourge of suicide. My Administration is increasing access to mental health care, hiring more mental health professionals, and investing in programs that recruit veterans to help one another get the support they need. And we are working to expand rental assistance and job placement programs to help smooth veterans' return to civilian life. I have also signed laws extending counseling, benefits, and other mental health resources to first responders and their families to help them heal from the trauma that they or their loved ones faced on the job.

There is much more to do. For one, we must finally hold social media companies accountable for the experiments they are running on our children for profit. I have called on the Congress to limit the personal data that tech companies collect, to ban targeted advertising directed at minors, and to require social media platforms to put health and safety first, especially for kids.

We all have a role to play in ending the stigma around mental health issues. It starts by showing compassion, so everyone feels free to ask for help. If you are facing a crisis, dial 988 to reach the National Suicide and Crisis Lifeline. If you are a new or expecting mother, you can call 1–833–9–HELP4MOMS for confidential professional advice. If you are feeling overwhelmed or just need someone to talk to, ask your healthcare provider, contact the Substance Abuse and Mental Health Services Administration's National Helpline at 1–800–662–HELP, or visit www.FindSupport.gov. If someone you know is going through a tough time, reach out and tell them you are there for them. We are all in this together.

NOW, THEREFORE, I, JOSEPH R. BIDEN JR., President of the United States of America, by virtue of the authority vested in me by the Constitution and the laws of the United States, do hereby proclaim May 2023 as National Mental Health Awareness Month. I call upon citizens, government agencies, private businesses, nonprofit organizations, and other groups to join in activities and take action to strengthen the mental health of our communities and our Nation.

IN WITNESS WHEREOF, I have hereunto set my hand this twenty-eighth day of April, in the year of our Lord two thousand twenty-three, and of the Independence of the United States of America the two hundred and forty-seventh.



[FR Doc. 2023–09535
Filed 5–2–23; 8:45 am]
Billing code 3395–F3–P

Presidential Documents

Proclamation 10564 of April 28, 2023

National Physical Fitness and Sports Month, 2023

By the President of the United States of America

A Proclamation

Forty years ago, our Nation observed its first National Physical Fitness and Sports Month to promote the benefits of exercising and leading a healthy lifestyle. Since then, we have learned more about how physical activity can improve mental health, reduce the risk of disease, and foster social connection. This month, we recommit to making fitness accessible in every community and encourage all Americans to adopt healthy habits that strengthen our bodies and minds and increase the prospect of a long and healthy life.

Studies show that regular exercise can have a dramatic impact on our health, lowering the likelihood of heart disease, stroke, type 2 diabetes, and some types of cancer. It also improves memory and sleep, increases our ability to focus, and reduces symptoms of depression and anxiety. This is particularly important for people most affected by diet-related diseases, including communities of color, people living in rural areas and territories, people with disabilities, older adults, LGBTQI+ people, military families, and veterans. For young people, sports can also be a great way to build leadership skills, learn teamwork, forge friendships, and foster mental health.

But too often, obstacles prevent Americans from getting the exercise they need. Less than half of Americans live within a half-mile of a park. Adults who work multiple jobs or take care of family members have less time to pursue an active lifestyle. Low-income families typically have less access to safe streets and playgrounds. Youth sports leagues can be unaffordable, leaving students with few fitness options if their school cuts back on physical education.

No one's health should suffer because exercise opportunities are too expensive or because outdoor spaces are too far away. That is why I released a National Strategy on Hunger, Nutrition, and Health to make America a stronger, healthier Nation. I am also working with the Congress to make outdoor spaces more accessible by increasing the number of parks around our country and expanding opportunities for people to travel to national parks and other public lands. We have partnered with State, local, Tribal, and territorial governments to improve community access to parks and spaces within our communities where people can be physically active. And to encourage a healthy lifestyle for our Nation's kids, my Administration has been working with summer schools and after-school programs to expand physical education opportunities. We've also invested $800 million into communities across the country to help redesign roads and make sidewalks and crosswalks safer for people to walk, bike, and roll. My Administration has also partnered with business, civic, academic, and philanthropic leaders who have committed billions of dollars to take on projects like improving physical education curricula and taking children on trips to national parks.

But we must do more. That is why I launched the White House Challenge to End Hunger and Build Healthy Communities. This initiative encourages all sectors of society to make bold and impactful commitments to offer Americans more opportunities to be physically active in their schools and communities. I also recently announced my upcoming appointments to the

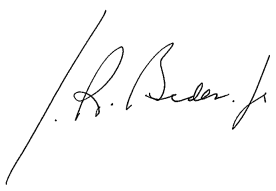
President's Council on Sports, Fitness, and Nutrition, which promotes access to healthy foods and physical activity for all Americans. Those appointees include prominent athletes, anti-hunger and nutrition advocates, health care professionals, and other leaders.

In addition, my Administration continues to support the Centers for Disease Control and Prevention's ''Active People, Healthy Nation'' initiative, which provides local governments, schools, and community organizations with a blueprint to help 27 million Americans become more physically active by 2027. We are also supporting the Department of Health and Human Services' ''Move Your Way'' campaign, which informs Americans about the newest guidance on staying healthy through physical activity.

This month, I encourage all Americans to find ways to be active, whether it is taking a walk or hike, joining a gym, trying a new fitness class, signing up for a local sports team, or registering for a community race. I also call on State, local, Tribal, and territorial governments, as well as business leaders, to make physical activity more accessible to all. When we invest in our health, we foster healthy homes, more productive communities, and a more resilient society for generations to come.

NOW, THEREFORE, I, JOSEPH R. BIDEN JR., President of the United States of America, by virtue of the authority vested in me by the Constitution and the laws of the United States, do hereby proclaim May 2023 as National Physical Fitness and Sports Month. I call upon the people of the United States to make daily physical activity a priority, to support efforts to increase access to sports opportunities in their communities, and to pursue physical fitness as an essential part of healthy living.

IN WITNESS WHEREOF, I have hereunto set my hand this twenty-eighth day of April, in the year of our Lord two thousand twenty-three, and of the Independence of the United States of America the two hundred and forty-seventh.



[FR Doc. 2023–09536
Filed 5–2–23; 8:45 am]
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Presidential Documents

Proclamation 10565 of April 28, 2023

Older Americans Month, 2023

By the President of the United States of America

A Proclamation

On this 60th anniversary of Older Americans Month, we honor our Nation's senior citizens, whose lifetimes of hard work, devotion to family, and commitment to community have laid the foundation for the country we are today. We have a rock-solid responsibility to ensure our Nation's seniors can age with dignity and financial security.

When President John F. Kennedy issued the first proclamation recognizing older Americans, approximately a third of seniors lived in poverty, and close to half were without health insurance. Our Nation rallied together to confront this crisis, passing Medicare to deliver affordable, quality health care to our seniors; strengthening Social Security, the bedrock of American retirement; and ultimately raising so many seniors out of poverty. We extended lifespans and provided critical breathing room to Americans who had worked hard their whole lives. But there is still more work to do to ensure that no senior lies in bed at night wondering how they are going to pay for lifesaving drugs, put food on the table, or support their children and grandchildren.

That is one reason why I signed the Inflation Reduction Act. For those on Medicare, this law caps the cost of insulin at $35 per month and will cap out-of-pocket prescription drug costs at $2,000 per year. That means seniors could save upwards of tens of thousands of dollars on lifesaving drugs—including for cancer, heart disease, Alzheimer's, and more. It also means Americans can get vaccinated for free against shingles, whooping cough, tetanus, and other diseases. And by holding drug companies responsible when they increase prices faster than inflation and finally allowing Medicare to negotiate drug prices, this law is helping bring down prescription drug costs for seniors across our country. Affordable health care is about basic dignity, which is also why I issued an Executive Order calling on the Food and Drug Administration to make hearing aids available over the counter without a prescription. Now, millions of adults with mild-to-moderate hearing loss can save as much as $3,000 per pair by buying hearing aids at a store or online without a prescription.

At the same time, standing by our seniors means honoring our Nation's fundamental promise that when it comes time to retire after working hard and contributing to our economy, Social Security and Medicare will be there for you. I am committed to defending these vital programs—a lifeline for millions of seniors—which is why my newest Budget extends the life of the Medicare Trust Fund by at least 25 years. And I will veto any effort to deny older Americans the benefits they have earned.

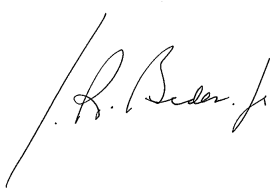
We must keep building on this progress. Older Americans should be able to live, work, and participate in their communities with dignity. That's why I recently signed an Executive Order on Increasing Access to High-Quality Care and Supporting Caregivers. I call on the Congress to expand on the investments we have already made to help seniors receive care in their own homes and to support family caregivers—including aging caregivers—and the home care workers who perform selfless work every day. I also call on the Congress to expand access to nutrition counseling for

seniors and others with Medicare coverage, to increase funding for nutrition services for older adults, and to pilot coverage of medically tailored meals in Medicare—actions that are also part of my Administration's National Strategy on Hunger, Nutrition, and Health. We need to improve the quality and safety of nursing homes and protect vulnerable residents and the health care heroes who care for them. And we must keep pushing to end cancer as we know it and win the fight against other deadly diseases that deny us time with those we love most.

Older Americans are the pillars of our community, and we owe it to them to value their wisdom, celebrate their contributions, and champion their well-being. To older Americans across this Nation, we will always support you.

NOW, THEREFORE, I, JOSEPH R. BIDEN JR., President of the United States of America, by virtue of the authority vested in me by the Constitution and the laws of the United States, do hereby proclaim May 2023 as Older Americans Month. This month and beyond, I call upon all Americans to celebrate older adults for their contributions, support their independence, and recognize their unparalleled value to our Nation.

IN WITNESS WHEREOF, I have hereunto set my hand this twenty-eighth day of April, in the year of our Lord two thousand twenty-three, and of the Independence of the United States of America the two hundred and forty-seventh.



[FR Doc. 2023–09537
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Billing code 3395–F3–P

Presidential Documents

Proclamation 10566 of April 28, 2023

National Hurricane Preparedness Week, 2023

By the President of the United States of America

A Proclamation

Powerful hurricanes, typhoons, and tropical storms can devastate our communities, threaten the lives of our families, and damage everything we have worked so hard to build. During National Hurricane Preparedness Week, we raise awareness about the hazards posed by hurricanes and share resources to help Americans stay safe and protect their property before these storms make landfall. We also celebrate the remarkable first responders and community members who help rescue, recover, and rebuild in the aftermath of these natural disasters.

During last year's hurricane season, especially in Florida and Puerto Rico, we witnessed the overwhelming damage these storms so often leave in their wake. Families lost their homes. Business owners lost their livelihoods. Survivors were left with unimaginable grief. As the climate crisis intensifies, the impacts of storm surges, flooding, mudslides, and heavy rainfall will only increase, and communities that lack the resources to respond and recover will be hit hardest.

That is one reason why I signed the historic Bipartisan Infrastructure Law, which will keep Americans safer from natural disasters by building stronger roads and bridges, improving levees and floodwalls, and making our power grid more resilient. This law includes over $50 billion to shore up our defenses against flooding and other weather and climate disasters. It provides States with billions of dollars to prepare evacuation routes and improve other at-risk coastal infrastructure. It also invests in community-wide planning to ensure that those most impacted by extreme weather have a voice in preparing for the future.

Our Inflation Reduction Act takes these efforts a step further, making the largest investment in our Nation's history to combat climate change. With historic funding for green manufacturing, clean energy development, and climate-smart agriculture, this law puts us on a path to cut America's greenhouse gas emissions in half by 2030. It gives families tax credits to make their homes more energy efficient, saving money and helping ensure that the power stays on when the grid goes down. And it provides the National Oceanic and Atmospheric Administration with billions of dollars to improve weather forecasting and invest in resilience projects in coastal communities that will help them more easily recover from extreme weather events.

These actions build on our efforts to ensure communities consider climate resilience as they plan for the future—from modernizing building codes so that structures are more protective and less pollutive to harnessing the power of ecosystems like reefs, beaches, and wetlands, which keep us safer during storms.

These bold investments will benefit our communities for years to come. But as we enter another hurricane season, every American can do their part to plan, prepare, and protect their families. Check your insurance policies to ensure they are up to date. Put your important documents in a location where they are easy to find. Know your local evacuation route, and have an emergency kit ready to go. Help increase awareness about the risks among your friends, family, and neighbors. And when storms approach,

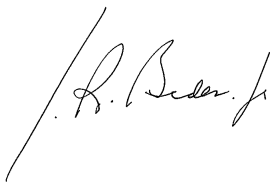
pay attention to storm surge and hurricane warnings, and follow the guidance from your local authorities, including guidance about when it is safe to return to affected areas.

As we prepare, we must also remember and honor the courage, kindness, and resilience of our fellow Americans. As President, I have issued dozens of disaster declarations to support the American people wherever they live, and every time, first responders have worked around the clock to save lives and provide food and shelter. Neighbors, community organizations, and faith groups have opened their doors to people in need. Workers have rebuilt homes, schools, and businesses to make them more resilient to future disasters. Scientists have helped communities adapt and remain safe. Families, having often lost everything, have found the strength to move forward. Time and again, in America's most trying moments, we are reminded that we are a great Nation because we are a good people.

This National Hurricane Preparedness Week, let us each recommit to doing our part to help safeguard our families, our communities, and our Nation from these devastating natural disasters.

NOW, THEREFORE, I, JOSEPH R. BIDEN JR., President of the United States of America, by virtue of the authority vested in me by the Constitution and the laws of the United States, do hereby proclaim April 30 through May 6, 2023, as National Hurricane Preparedness Week. I urge all Americans to help build our climate resilient Nation so that individuals, organizations, and community leaders are empowered to take action to make their communities more resilient to extreme weather and climate change. I call on our Federal, State, Tribal, territorial, and local government agencies to share information that will protect lives and property.

IN WITNESS WHEREOF, I have hereunto set my hand this twenty-eighth day of April, in the year of our Lord two thousand twenty-three, and of the Independence of the United States of America the two hundred and forty-seventh.



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Presidential Documents

Proclamation 10567 of April 28, 2023

National Small Business Week, 2023

By the President of the United States of America

A Proclamation

From barber shops, beauty salons, and pizza parlors to manufacturing companies and mom-and-pop shops, Americans have applied to form a record 10.5 million small businesses in the past 2 years. This week, we celebrate the backbone of our economy and the glue of our communities: our small businesses, which help make our Nation strong.

Nearly half of all private sector workers in our country are employed by small businesses. These businesses also account for almost half of our Nation's gross domestic product. They create many of the goods and services Americans rely on to sustain their everyday lives. For many families, owning a small business is also the fulfillment of their dreams, their path to a better life, their chance to build a family legacy, and a source of community enrichment. But as so many entrepreneurs know well, success can never be taken for granted.

Success requires access to capital to meet payroll, pay rent, buy inventory, and grow. Small businesses need resilient supply chains so products can get out the door and arrive on time, and they need high-speed Internet to process transactions and connect with customers around the world. They also need the confidence that, when the going gets tough, support is close by.

When companies were shuttering their doors and laying off workers at the height of the COVID–19 pandemic, my Administration delivered a capital infusion of more than $450 billion to the small business sector to keep Main Streets across America operating and employees on the payroll. To create long-term benefits for our economy, I signed the Bipartisan Infrastructure Law, the CHIPS and Science Act, and the Inflation Reduction Act. Together, these new laws are creating billions of dollars in contracting opportunities for America's small businesses and investing hundreds of billions of Federal dollars to rebuild our infrastructure, bring manufacturing back to America, and launch a clean energy revolution right here in the United States.

Our historic investment in semiconductors—the tiny computer chips that power everything from smartphones to cars—will create a manufacturing boom, including for small businesses throughout the semiconductor supply chain. Record funding for clean energy development means small businesses have the opportunity to build electric and other fuel cell vehicles and charging stations. My Administration is committed to investing in America and empowering its small businesses to thrive. I underscored that during my State of the Union Address when I announced new standards that require all construction materials used in these new Federal infrastructure projects to be made in America—ensuring our country's future is built right here at home.

We need to make sure all American small business owners benefit from these investments. That is why I am committed to improving access to capital, contracts, technical expertise, and financial and legal assistance for small business owners from historically underrepresented communities. Through our State Small Business Credit Initiative, States, territories, and Tribal governments are helping small business owners, including socially and economically disadvantaged entrepreneurs, access billions of dollars in loans and investments. The Small Business Administration is revamping its existing loan programs to expand access to small-dollar loans and increase the number of lenders that offer guaranteed loans, both of which can make a major difference for the smallest businesses and minority- and women-owned businesses that may have trouble accessing capital.

One of the first actions taken by my Administration was to make the Minority Business Development Agency a permanent part of the Department of Commerce. In March, I hosted the second annual Women's Small Business Summit at the White House, where I announced the establishment of the largest network of Women's Business Centers ever across America. My Administration has invested nearly $70 million in this network, expanding it to all 50 States for the first time in our history. The centers offer training and mentoring to help women entrepreneurs develop business plans, launch new businesses, and access credit and capital.

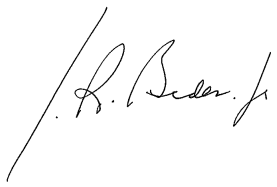
Vice President Kamala Harris has convened small business owners and entrepreneurs across our Nation to inform them about the resources, capital, and support we are offering them. Last year she announced the formation of the new Economic Opportunity Coalition, an alliance of private sector companies and nonprofits committing tens of billions of dollars of investments in community financial institutions and small businesses. In April of this year, she and the Deputy Treasury Secretary Wally Adeyemo announced our new $1.73 billion investment in the Community Development Financial Institutions Fund, which provides historically underserved and often low-income communities access to credit, capital, and financial support to grow their businesses.

We are making progress, but I know there is more we can do. I have set a goal to award 15 percent of all Federal contracts to small disadvantaged businesses by 2025, which will bring an estimated additional $100 billion in Federal contracting money to these companies. My new Budget calls for an additional $341 million for the Community Development Financial Institutions Fund, and I am seeking an additional $30 million for the Community Navigators Pilot Program—which we have already supported with $100 million—so that local nonprofits, government agencies, and organizations can help new entrepreneurs navigate the complex paperwork involved in applying for small business loans.

Building an economy from the middle out and bottom up, not the top down, means investing in America's small businesses. It means opening up doors of opportunity for doers, dreamers, and job creators who represent the restless, bold, and optimistic American spirit. When we make these investments and support these innovators, our Main Streets thrive, our families have good-paying jobs, and America's future truly knows no bounds.

NOW, THEREFORE, I, JOSEPH R. BIDEN JR., President of the United States of America, by virtue of the authority vested in me by the Constitution and the laws of the United States, do hereby proclaim April 30 through May 6, 2023, as National Small Business Week. I call upon all Americans to recognize the contributions of small businesses to the American economy, continue supporting them, and honor the occasion with programs and activities that highlight these important businesses.

IN WITNESS WHEREOF, I have hereunto set my hand this twenty-eighth day of April, in the year of our Lord two thousand twenty-three, and of the Independence of the United States of America the two hundred and forty-seventh.



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Presidential Documents

Proclamation 10568 of April 28, 2023

Law Day, U.S.A., 2023

By the President of the United States of America

A Proclamation

When our Founding Fathers convened to write the Constitution over 235 years ago, they set in motion an experiment that changed the world. America would not be a land of kings but a Nation of laws. Since then, generations of Americans have worked to defend and improve our laws, hold accountable those who break or undermine them, and ensure equal rights and protections for all. On Law Day, we celebrate the rule of law and rededicate ourselves to the pursuit of a more perfect Union.

Our Nation and world are at an inflection point. At home and around the globe, autocrats and dictators threaten the rule of law. Our democracy is under strain, with people's rights, including the sacred right to vote, at risk. We face a choice between moving backward—unravelling so much of the progress our Nation has made—or moving forward toward a future of possibilities and promise.

We must choose to move forward. That is why my Administration is protecting the right to vote—the right from which all others flow, including the power to establish our Nation's laws. Since taking office, I have issued an Executive Order promoting access to voter registration and election information, and signed into law the Electoral Count Reform Act, which establishes clear guidelines for certifying and counting electoral votes to help preserve the will of the people against future attempts to overturn our elections. The Department of Justice has also strengthened its ability to fight unlawful voter suppression in the courts. I continue to call on the Congress to pass the Freedom to Vote Act and the John Lewis Voting Rights Advancement Act to further strengthen our democracy.

Respecting the rule of law also means supporting equal access to justice. My Administration reestablished the Department of Justice's Office for Access to Justice to help ensure that all Americans, regardless of wealth or status, have quality legal aid when they need it and to remove barriers—including language barriers—that prevent people from understanding and navigating the legal system.

We are also working to ensure that hate has no safe harbor in America. I signed the bipartisan COVID–19 Hate Crimes Act into law, making it easier to report hate crimes and helping State, local, and Tribal law enforcement agencies better track these crimes. I secured the largest-ever increase in funding for the physical security of nonprofits, including churches, gurdwaras, mosques, synagogues, temples, and other houses of worship. I convened the first-ever White House Summit on combating hate-fueled violence, bringing together stakeholders from around the country to reaffirm that nobody should fear going to a religious service, wearing a symbol of their faith, or simply being who they are. And I established a new interagency group to counter antisemitism, Islamophobia, and related forms of bias and discrimination within the United States.

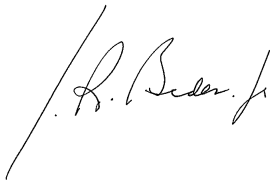
The United States is standing up for the rule of law around the world. We will continue to marshal security, humanitarian, and economic support for Ukraine as they defend themselves against Russia's unjust war, which

is also an attack on the bedrock principle of sovereignty. To support democracy worldwide, I cohosted the second Summit for Democracy in March, bringing together government, civil society, and private sector representatives from around the world to promote transparent and accountable governance, democratic resilience, and respect for human rights. We must support free and independent media, fight the corruption that undermines democratic institutions, ensure new technology is used to strengthen democracy, and defend free and fair elections.

The theme of this year's Law Day, ''Cornerstones of Democracy: Civics, Civility, and Collaboration,'' acknowledges that each of us has a role to play in defending democracy and the guardrails that make it possible. It also recognizes that the rule of law depends on us seeing one another not as enemies but as fellow Americans. This great national experiment only works if we respect each other's differences, protect each other's freedoms, and work together to ensure that ''We, the People,'' get to choose our own fate and make our own future.

NOW, THEREFORE, I, JOSEPH R. BIDEN JR., President of the United States of America, in accordance with Public Law 87–20, as amended, do hereby proclaim May 1, 2023, as Law Day, U.S.A. I call upon all Americans to acknowledge the importance of our Nation's legal and judicial systems with appropriate ceremonies and activities and to display the flag of the United States in support of this national observance.

IN WITNESS WHEREOF, I have hereunto set my hand this twenty-eighth day of April, in the year of our Lord two thousand twenty-three, and of the Independence of the United States of America the two hundred and forty-seventh.



[FR Doc. 2023–09540
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Presidential Documents

Proclamation 10569 of April 28, 2023

Loyalty Day, 2023

By the President of the United States of America

A Proclamation

America was founded on the sacred proposition that we are all created equal; entitled to be treated with dignity and respect; and deserving of equal access to justice, opportunity, and freedom. On Loyalty Day, we rededicate ourselves to delivering that promise of America to all Americans.

We are a Nation that has sought to encourage and inspire loyalty through our actions. We do that by honoring the Constitution, upholding the rule of law, and respecting free and fair elections. As Americans, we are called to unequivocally condemn political violence and hate-motivated attacks; they have no place in our democracy. We must open the doors of opportunity even wider to others because the promise of this country is big enough for everyone to succeed. And we must stand up for truth and resist lies and disinformation that would tear us apart.

Our democracy has endured for generations because Americans have stood together to defend it. That includes brave service members, veterans, and their families, selfless first responders who protect our communities, and hardworking people of all backgrounds who build our Nation and power our prosperity.

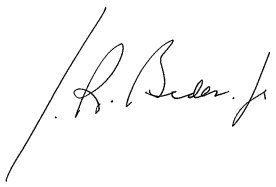
''We, the People,'' are the heirs of a big, complicated country unlike any other in the world. Whoever we are and whatever our job, we all have a part to play in sustaining and advancing this great American experiment by being informed citizens, engaged community members, respectful neighbors, and thoughtful patriots.

Today, we remember that America is a covenant requiring constant care and commitment. Let us agree that upholding democracy must never be a partisan issue but rather an American issue. And let us keep the flame of liberty burning in our time as it did for past generations of Americans—through the fight for our independence; the Civil War; the Great Depression; two World Wars; the Civil Rights Movement; and all the sustained struggles of citizens to make America more prosperous, just, and free.

To celebrate our shared American spirit and the sacrifices so many of our fellow citizens have made, the Congress, by Public Law 85–529, as amended, has designated the first day of May each year as Loyalty Day. On this day, let us reaffirm our commitment to the values that bind us together and honor all those who have defended our freedom and ideals.

NOW, THEREFORE, I, JOSEPH R. BIDEN JR., President of the United States of America, do hereby proclaim May 1, 2023, as Loyalty Day. This Loyalty Day, I call upon the people of the United States to join in this national observance, display the American Flag, and pledge allegiance to our Republic for which it stands.

IN WITNESS WHEREOF, I have hereunto set my hand this twenty-eighth day of April, in the year of our Lord two thousand twenty-three, and of the Independence of the United States of America the two hundred and forty-seventh.



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DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 800

[Doc. No. AMS–FGIS–19–0062]

RIN 0581–AD90

Exceptions to Geographic Boundaries

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule.

SUMMARY: This final rule sets forth a process by which applicants for official grain inspection services (applicants) may request a service exception, allowing an official agency (OA) to cross boundary lines and perform services outside of its assigned geographic area. While four exception types are authorized in the United States Grain Standards Act (USGSA or Act), this final rule focuses on two: the inability to provide services in a timely manner and the nonuse of service from the OA assigned to the applicant's geographic area (assigned OA). This final rule establishes a three-tiered system under which applicants can request a one-time, 90-day, or long-term timely service exception due to untimely service issues. This rule provides that nonuse of service exception requests must be preceded by ninety days without service from the assigned OA. This final rule further amends the regulations to provide criteria the Federal Grain Inspection Service (''FGIS'' or ''the Service'') will use to review, validate, and determine whether to grant service exception requests. This final rule also establishes a process that allows an assigned OA to challenge requests for service exceptions. Finally, this rule provides for FGIS review to ensure the validity of requests.

DATES: Effective August 1, 2023.

FOR FURTHER INFORMATION CONTACT: Karla Whalen, Director, Quality Assurance and Compliance Division, Federal Grain Inspection Service, AMS, USDA: telephone: (202) 720–7312, email: *FGISQACD@usda.gov.*

SUPPLEMENTARY INFORMATION: Under the USGSA (7 U.S.C. 71 *et seq.*), each OA that is designated to provide inspection and weighing services in the United States is assigned a specific geographic area where it performs such services for applicants within that geographic area (7 U.S.C. 79(f)(2)(A)). This ensures effective and efficient delivery of official services to applicants within the assigned OA's geographic area and enhances the orderly marketing of grain. The USGSA also provides that applicants may obtain inspection and weighing services from another OA (gaining OA) under certain circumstances. OAs may cross geographic boundaries to provide services to applicants if: (1) the assigned OA is unable to provide inspection services in a timely manner (timely service exception); (2) the applicant has not been receiving official inspection services from the assigned OA (nonuse of service exception); (3) the applicant requests a probe inspection on a barge-lot basis; or (4) the assigned OA agrees in writing with the adjacent OA to waive the current geographic area restriction at the applicant's request (7 U.S.C. 79(f)(2)(B)). The regulations at 7 CFR 800.117 provide further clarification for requesting these exceptions.

Background on the Nonuse of Service Exception

In the past, under a nonuse of service exception, an applicant who had not obtained official inspection or weighing services from the assigned OA for a specified length of time could obtain services from another designated OA. Over time, the procedural variance on whether a request for nonuse of service exceptions was approved or not caused concern for applicants and OAs.

In 2015, Congress eliminated the nonuse of service exception from the USGSA.[1] FGIS subsequently removed that exception provision from the regulations in 2016.[2] As a result, FGIS terminated existing nonuse of service exceptions. However, in 2018, Congress reinstated authority to allow a nonuse of service exception through an amendment to the USGSA in the 2018 Farm Bill.[3] The 2018 Farm Bill directed USDA to allow for restoration of the terminated nonuse of service exceptions, where appropriate. Interested parties were given an opportunity to submit restoration requests to FGIS, as described in a Notice to Trade published on March 5, 2019.[4]

The amended USGSA also provides that the nonuse of service exception may only be terminated if all parties to the exception jointly agree on the termination. This means that the applicant, the assigned OA, the gaining OA, and FGIS must agree to terminate the exception. Such provision ensures all parties are aware of the change and the assigned OA will resume providing service to the applicant.

On April 1, 2020, FGIS published an advanced notice of proposed rulemaking[5] to solicit industry comments on how FGIS should amend its criteria for reviewing, approving, and implementing exceptions to the USGSA's requirements for geographic boundaries. FGIS received responses from six commenters. FGIS sought to incorporate industry feedback from the advanced notice of proposed rulemaking, along with input received during industry meetings, to develop a proposed rule, which was published on August 19, 2021.[6] FGIS requested comment on proposed options for timely service and nonuse of service exceptions. Particularly, FGIS sought input from industry participants, who use, and OAs, who provide, official services and are familiar with grain inspection services under the USGSA. FGIS received comments from four entities. This final rule includes the AMS review and consideration of those comments on this process.

Amended Exception Provisions: Inability To Provide Timely Service

Applicants may request a timely service exception when service is not timely. Service is not timely when the assigned OA cannot provide the requested official services within 6 hours of request or cannot provide the

[1] 7 U.S.C. Ch. 3 Grain Standards; January 1, 2016.

[2] 81 FR 49855; July 29, 2016.

[3] 7 U.S.C. Ch. 3 Grain Standards; December 11, 2020.

[4] *https://www.ams.usda.gov/content/restoring-certain-exceptions-us-grain-standards-act;* accessed 08/10/2022.

[5] 85 FR 18155; April 1, 2020.

[6] 86 FR 46606; August 19, 2021.

results and certificate in accordance with 7 CFR 800.160(c). The applicant must submit a request for a timely service exception to FGIS. The applicant may make this request orally or in writing. If the applicant orally requests a timely service exception, the applicant must submit a written request to the Service within two business days after the oral request. The applicant must clearly state and support the identified reason for the requested exception.

Applicants may also request an exception for delays caused by weather events or requests for official services that are not offered by the assigned OA, as they would not be able to offer such services in a timely manner. Thus, for the inability to provide timely service, FGIS intends to grant a timely service exception when: (1) the assigned OA is unable to provide official services to an applicant within 6 hours; (2) or the assigned OA is unable to provide results and certificates in accordance with 7 CFR 800.160(c); or (3) a request for official services not offered by the assigned OA would result in an inability to receive timely service; or (4) a weather event or other short term disruption impacts the ability of an assigned OA to provide timely service; with consideration that granting an exception is in the best interest of the official system.

This final rule implements a tiered application process for requesting exceptions when an assigned OA is unable to provide timely service. The first tier is a one-time, timely service exception. In this instance, a one-time exception to use another official agency (gaining OA) may be allowed for applicants that have a pending service request that meets the timely service exception criteria. The second tier is a 90-day timely service exception due to the assigned OA's inability to provide timely service. If, after the first-tier one-time, timely service exception request is granted, a second instance occurs in which an assigned OA is not able to provide timely service within 180 days of the first instance, the applicant may request a 90-day exception. In this instance, a 90-day exception to use the gaining OA may be allowed. Lastly, the third tier is a long-term timely service exception due to the repeated inability of the assigned OA to provide timely service. If there is another occurrence within 365 days of the applicant's return to the assigned OA after their 90-day timely service exception period has expired, the applicant may request a long-term exception, extending until the termination date of the gaining OA's designation. Along with the required data to support their timely service exception request, the applicants may elect to send any supporting documentation they feel would aid in the agency's determination process. FGIS will then review and verify the accuracy and thoroughness of each package.

If the applicant has an urgent timely service exception request, outside of the Service's customary business hours, an OA from outside the geographic area may provide one-time service. When providing an urgent service, the gaining OA must provide written notification to the Service within two business days after service. Upon returning to official office hours, FGIS will review and verify the circumstances of the urgent request, as well as its consistency with the USGSA and implementing regulations.

For 90-day and long-term timely service exception requests, FGIS will have a determination review period. Once the applicant has provided all required information, FGIS will notify the applicant and begin reviewing the service exception request. FGIS will make every attempt to issue a determination within 15 business days of receipt for 90-day and long-term timely service exceptions, barring a challenge from the assigned OA. To challenge a 90-day or long-term timely exception, the assigned OA must submit the challenge and any supporting documents within 14 calendar days of the date of notification of the exception request. The challenge and supporting documentation must clearly identify the objection to the exception request and support the identified reason for the challenge. While awaiting a final decision on 90-day and long-term timely service exceptions, the applicant may receive service from the potential gaining OA.

FGIS will provide its decision in writing to the assigned OA, the applicant, and the potential gaining OA. The assigned OA may challenge a request for a timely service exception for any reason. To challenge a request for a timely service exception, the assigned OA must object, in writing, and submit the challenge and any supporting documents to FGIS within 14 calendar days.

If an applicant submits a request for a timely service exception that FGIS determines to be false or misleading, FGIS will not grant the exception and may elect to limit the applicant from submitting further requests for a period of up to 180 days. If an urgent request for a timely service exception, outside of customary business hours, was granted on the basis of a false or misleading request, FGIS may deny the applicant from future urgent timely service exceptions for a period of up to 180 days.

The applicant maintains the option of returning to the assigned OA within 60 days of notification of termination of the timely service exception to all parties. The applicant must submit a written notification requesting to terminate the exception to FGIS, the assigned OA and the gaining OA. The exception will be cancelled, and future exception requests must be considered at the beginning of successive-tiered system.

If FGIS determines that the assigned OA's inability to provide a specific service is limited due to weather events or the issue of service availability has been resolved, FGIS, in consultation with all the parties, may terminate the 90-day or long-term exception. If FGIS terminates a timely service exception, the applicant, the assigned OA, and the gaining OA, will be notified in writing, via any written form to include email or autogenerated response, and the applicant will resume service with the assigned OA within 60 days of notification. However, if the existing exception was associated with the assigned OA's inability to provide service in 6 hours or less, or with timely issuance of the results and certificate, FGIS might elect not to terminate the exception. During the duration of exceptions caused by a failure of the assigned OA to supply timely service, this exception period gives assigned OAs an opportunity to improve.

Amended Exception Provisions: Nonuse of Service Exceptions

For nonuse of service exception requests, this rule defines the period of nonuse as 90-days prior to application for a nonuse of service exception. The rule defines areas of inquiry but does not limit factors FGIS will take into consideration when reviewing requests for nonuse of service exceptions. These considerations include: (1) the location of the service need(s); (2) the impact of expanding the applicant/customer base for the gaining OA; (3) the types of services requested by the applicant and offered by the assigned OA; (4) whether the applicant has ever utilized the official system (*i.e.,* a facility that has never used the official system before may not qualify for nonuse of service exception, nor may a facility that is under new ownership by a company with no history of use of the official system); and (5) the impact on the applicant in the event it continues services with the assigned OA.

For a nonuse of service exception request, FGIS intends to grant an exception when: (1) the applicant has

not received service from the assigned OA within the established time period, (2) the applicant submits, to FGIS, its request for a nonuse of service exception, and (3) granting an exception is in the best interest of the official system. FGIS will notify the assigned OA in writing upon receipt of the request for a nonuse of service exception. At the completion of the process, FGIS will issue written notification of the determination on the request to the applicant, the assigned OA, and the gaining OA.

If an applicant submits a request that FGIS determines is false or misleading, FGIS will not grant the nonuse of service exception and may elect to limit the applicant from submitting further requests for a period of up to 180 days.

A nonuse of service exception will remain in place during the period of the gaining OA's designation. At the end of the designation, FGIS will review current information concerning the exception. Unless the applicant, the assigned OA, the gaining OA, and FGIS request to terminate the exception, the FGIS will renew the exception for the gaining OA's new designation period, if applicable. In the event the gaining OA is no longer designated, the exception will automatically terminate, and the applicant will return to the assigned OA. If the applicant transfers ownership of its facility, the exception will automatically terminate, and the new applicant/owner of the facility must request a new nonuse of service exception, if it wishes to receive service from an OA other than the assigned OA for that geographic area. At any point in the designation cycle, if the applicant, the assigned OA, the gaining OA, and FGIS agree to terminate the nonuse of service exception, FGIS will terminate the exception. In this case, the assigned OA must resume service within 60 days of notification.

FGIS recognizes there may be instances where granting an exception may impact the assigned OA. For example, in some cases, the cost of the equipment necessary to provide the requested service is more than the assigned OA would be able to recoup, due to the infrequency of the requests for such a special service. Therefore, as stated in the proposed rule, FGIS is establishing a challenge process for requested nonuse of service exceptions. The timeline for the challenge initiates when FGIS notifies the assigned OA of the requested nonuse of service exception. FGIS will consider factors provided by an assigned OA in such challenge. Requests for a challenge must state and support the identified reason for the challenge. FGIS may request additional documentation to support the challenge.

Comment Summary and Analysis

AMS received a total of four comments on the proposed rule, one from a State department of agriculture OA and three industry associations. While generally supportive, three of the commenters offered suggestions for improving or clarifying processes.

Comment: One commenter expressed support and congratulated FGIS on the overall nature of the proposed rule. The commenter noted that multiple revisions to the OA boundary exception provisions of the USGSA and the FGIS regulations had created uncertainty among both applicants and OAs for some time. The commenter suggested that the proposed rule would accomplish FGIS's goal to create a clear, consistent, and fair framework for considering and granting exceptions for customer needs and offered no concerns or suggestions.

Comment: Comments from two associations recommended additional procedural changes. The commenters urged FGIS to develop a template for submitting exception requests due to an inability to provide timely service and nonuse of service. The commenters stated that the template should outline the necessary information for FGIS to review and process the request, as well as identify the persons at FGIS and the respective OAs that should receive the application. The commenters also suggested that such template should be available online.

Further, the commenters recommended that FGIS and the assigned OA be required to acknowledge receipt of the request and determine, within 12 hours, whether services can be provided by an alternate OA. The commenters noted that although the proposed rule states that an applicant can notify FGIS verbally or in writing to request a service exception, it does not offer an alternative contact in the event the applicant cannot reach a live person. Commenters recommended FGIS provide a secondary contact option. The commenters also recommended that the point of contact at the grain handling facility requesting the service exception should be notified by verbal and written communication regarding the decision on the request.

AMS response: In 2023, FGIS will create a web page with instructions and templates for requesting designation service exceptions due to the inability to provide timely service and nonuse of service. For one-time, timely service exception requests, if the request is made during customary business hours, FGIS will provide its decision that day. FGIS will acknowledge receipt of the request in writing, via any written form to include email or autogenerated response. Notably, the newly designed regulations allow applicants to proceed with one-time urgent timely service exception requests outside of business hours without prior approval from FGIS to avoid a delay in the marketing of grain.

Since urgent timely service exception requests submitted outside of business hours can proceed without prior approval, AMS determined it is not necessary to provide a second point of contact in the regulations. Further, the request template is to be submitted to a group recipient office inbox monitored by multiple staff. FGIS will make every effort to issue its determination for 90-day and long-term timely service exceptions within 15 business days, barring a challenge from the assigned OA. To ensure the applicant's receipt of service is not delayed, it may utilize the potential gaining OA while awaiting a final determination from FGIS.

Regarding exception requests for nonuse of service, AMS has determined not to include a 12-hour response time for such requests because of the 14-day challenge period that has been established for the assigned OA to challenge the exception request and the time required for the FGIS to review the matter. AMS intends to reconcile appropriate FGIS directives in conjunction with the release of this rule. However, AMS has included wording in the regulations that addresses the timeline.

Comment: An association asked AMS to explain, in the final rule or in the FGIS Directive, who within the agency is responsible for reviewing exception applications and whether applications would be reviewed by more than one office.

AMS response: 7 CFR 800.0(b) clarifies that the Federal Grain Inspection Service is referred to in the regulations as the ''Service.'' The Service administers the regulations pertaining to Federal grain inspection, including those established by this final rule. The request template will not further define the FGIS representative responsible for receiving these requests as FGIS organizational structure and staffing responsibilities can change rapidly. This also ensures no undue external pressure is placed on an individual staff member while allowing for AMS executives to be consulted and apprised of individual situations. FGIS may have other offices involved in decision making, as appropriate. FGIS

contact information is available on the FGIS website.

Comment: An association commented that, in some cases, an assigned OA can be delayed in providing timely service due to weather conditions over which it has no control. The commenter recommended that FGIS take this factor into consideration and ''not penalize the OA if there is another request from the same grain handling facility for a different reason.''

AMS response: FGIS acknowledges that some situations requiring timely service exceptions may be temporary and out of the control of the assigned OA. Accordingly, FGIS will consider relevant factors related to the reason(s) for the inability to provide timely service during the decision-making process. As stated in the proposed rule, the long-term exceptions may be cancelled by FGIS, in consultation with the parties, if the issue that caused the lack of timely service has been addressed.

Comment: A commenter recommended that nonuse of service exceptions should be strictly limited to situations where the OA is unable to provide the service requested by the facility in a timely manner. The commenter asserted that allowing the requesting facility to receive a nonuse of service exception for the sake of convenience or other arbitrary or subjective reasons undermines the integrity of the grain inspection system, as well as the purpose behind the designated geographic boundaries. The comment supported adding a challenge process to review newly requested and previously issued nonuse of service exceptions. This commenter provided specific situational details regarding four elevators.

AMS response: FGIS concurs that requests for exceptions should be evidence-based and provide the assigned OA an opportunity to demonstrate the ability to deliver timely service. The process takes this need into account through a variety of factors in the revised evaluation criteria that governs how exception requests will be determined. Regarding the commenter's reference to the four applicants that elected to return to out-of-State service providers, those applicants were allowed to revert back to those service providers based on their previously approved nonuse of service exceptions that were reinstated in accordance with amendments to the USGSA.

Comment: A State department of agriculture comment suggested AMS further clarify the definition of ''period of nonuse as 90 days'' in the proposed rule. The commenter also asked AMS to specify what factor determines the start of the 90-day period. The comment further suggested that 120 days would be a more reasonable period for defining nonuse, explaining that 120 days would give the assigned OAs sufficient time to resolve staffing or equipment deficiencies, which, according to the comment, have become more challenging in the last 18 months.

AMS response: FGIS will require an applicant to demonstrate, through documentation, the last date of official inspection service from the assigned OA. FGIS also believes that a period of 90 days nonuse is reasonable and sufficient for establishing a period of nonuse, prior to submission of a nonuse of service exception request and accounting for review time. As a point of reference, the proposed rule stated that the feedback on the number of days without official service (for nonuse of service exceptions) had a wide range, from 30 to 180 days. As stated in the advanced notice of proposed rulemaking, prior ranges allowed were between 90 to 180 days in length. A period of 90 days is within timeframes used for the nonuse of service exceptions in the past and is a compromise based on timeframes suggested in the public comments. FGIS also considered that during the time it takes FGIS to review the request, the applicant must continue with nonuse of service, so the period of nonuse will extend beyond the applicant's original 90 days of nonuse. Due to the strictly defined timely service exceptions criteria, FGIS believes most applicant issues will be satisfied under that category. Allowing this full nonuse of service time period enables the assigned OA additional time to work out any service difficulty with its customer. Applicant requests that meet the requirements of timely service exceptions, may be handled under the timely service exception tiers.

Executive Orders 12866 and 13563

Executive Orders 12866—Regulatory Planning and Review, and 13563—Improving Regulation and Regulatory Review, direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits of reducing costs, harmonizing rules, and promoting flexibility.

This action has been determined to be not significant for the purposes of Executive Order 12866, as supplemented by Executive Order 13563. The final rule is not expected to create any new material costs for industry.

Baseline

Under the USGSA, the USDA regulates the inspection of barley, canola, corn, flaxseed, mixed grain, oats, rye, sorghum, soybeans, sunflower seed, triticale, and wheat. This rule impacts the 41 OAs that provide USDA-regulated grain certification and the over 5,000 commercial entities they serve. In FY2021, OAs performed 3,150,029 grain inspections of 257.8 million metric tons of grain. Based on current data, FGIS expects fewer than one percent of the entities served by OAs to request and be granted exceptions under the two types of exceptions detailed in this rule.

Official inspection costs represent a very small percentage of the total value of grain shipments. In 2021, FGIS calculated the weighted average costs for inspections for different carriers as follows: $18.68 for a semi-truck capable of carrying 58,000 pounds, $30.75 for a railcar capable of carrying 220,000 pounds, and $316.90 for a barge capable of carrying 3,000,000 pounds of grain. For example, if the price of wheat was $8 for a 60-pound bushel, the cost of the inspection would represent 0.24% of the revenue for a truck load, 0.11% of the revenue for a railcar load, and 0.08% of the revenue for a barge load of wheat.

Need for the Rule

Federally regulated grain inspection is designed to remedy two competing sources of market failure—asymmetric information and market power—while preserving the ability of small producers to access markets. This rule increases the flexibility of the existing inspection program without affecting the program's quality standards or the ability of small sellers to access inspection services. The rule's greater flexibility in allowing producers to obtain inspection services, however, will save costs and provide them greater ability to meet potential market opportunities and inspection challenges.

Many agricultural products, including grain, vary in important quality characteristics due to both farm production decisions and idiosyncratic factors. In the absence of a quality verification process, sellers in a transaction may have more knowledge of a product's quality than buyers, a condition called asymmetric

information. Akerlof (1978) showed asymmetric information can cause economic inefficiencies in which producers forego investments that are less costly to implement than the benefit they provide consumers.[7] Third-party inspection that verifies a product's quality resolves this source of market failure.

Grain inspectors certify the protein content, kernel size, and other quality factors related to product's market value to simplify transactions. Since the outcome of grain inspections directly affects the sale price, biases and inconsistences in inspection methods might potentially redistribute the gains to trade from seller to buyer, or vice versa. Market power might exacerbate biases and inconsistencies if, for instance, large sellers or buyers can influence the outcome of quality inspections in their favor. In addition to fairness concerns, such opportunistic behavior creates economic inefficiencies by reducing the returns on investment in quality improvement and creating costs for downstream producers (*i.e.,* bakers and food processors) expecting products of certain quality.

Domestic grain inspection is an optional service. When information asymmetries are a concern, inspection facilitates simpler, more rapid, and less risky transaction of final product. By allowing producers to recoup the costs of quality improvement, grain inspection also encourages investment in quality improvement.

Under its regulatory authority, the USDA approves grain inspection standards and monitors their uniform application by OAs in a variety of ways, including inspection sample review, fee schedule approvals, and periodic OA audits. To promote a competitive market for grain in which all producers have access to inspection services, FGIS requires that OAs provide inspection services to all producers in an assigned area and regulates marketing fee schedules charged by OAs for these services. FGIS approves rates to cover various labor, laboratory, and travel costs and only approves differential rates across geographic areas if the underlying costs differ across assigned regions. For this reason, FGIS does not expect this rule to impact the price paid by inspection users or the fees received by OAs. Instead, FGIS expects this rule will allow the small fraction of inspection users who need timely service and nonuse of service exceptions greater flexibility in obtaining inspections services to meet immediate business requirements.

Benefits and Costs of the Rule

FGIS assesses the economic benefits of this rule as being three-fold. First, the rule provides clarity to grain inspection applicants (*e.g.,* producers, elevators, merchandisers, etc.), as well as OAs, regarding the terms under which exceptions are granted. Second, the rule increases the options to producers, elevators, merchandisers, etc., who require inspection services to market their grain. FGIS expects that this option will be utilized by fewer than one percent of applicants who need inspections services, quickly, but face service constraints by OAs. Third, the rule may heighten attention to service issues among OAs that have received nonuse of service exception requests. The validation process FGIS will establish and maintain to review all exception requests will ensure all granted requests are in the best interest of the official system and confirm an exception will not undermine the congressional policies in Sec. 2 of the USGSA. OAs may offer additional services, such as a broader range of testing, as a result.

FGIS does not ascribe any direct compliance costs to either OAs or producers as a result of the potential increase for timely service and nonuse of service exceptions under this rule. FGIS does not expect that the inspection fees it approves will change as a result of this rule. To the extent that this rule provides greater flexibility to how applicants can obtain inspection services, it will provide improved services or reduce total costs to producers by, for instance, allowing those needing immediate inspections to get them from an OA other than the one to which they are assigned. Moreover, FGIS does not believe the rule will create significant indirect costs, aside from the minor costs to market participants learning the rule and documenting exception requests.

To the extent that some OAs conduct fewer inspections because applicants in their assigned area have requested more exceptions, other OAs will conduct more inspections. FGIS believes that any business losses to an OA will be small and that any losses will be offset by gains to other OAs. This rearrangement of business activity constitutes a transfer of benefits from one OA to another and has a neutral effect on total costs and benefits of the rule.

To summarize, FGIS believes that the total impact of the rule on the grain inspection industry is not economically significant and that the benefits of this rule exceed its costs, which are negligible.

Regulatory Flexibility Analysis

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) requires agencies to consider the impact of their rules on small entities and to evaluate alternatives that would accomplish the objectives of the rule without unduly burdening small entities when the rules impose a significant economic impact on a substantial number of small entities. This rule has an economic impact on farms selling grain that require inspections (classified under North American Industry Classification System, or NAICS, codes 111110, 111120, 111130, 111140, 111150, 111191, 111160, 111191, and 111199), grain elevators and grain certifiers that conduct post-harvest crop activities (NAICS code 115114) and either require or perform inspections. The Small Business Administration considers grain farms to be small if their sales are less than $1 million and grain elevators and grain certifiers (OAs) to be small if their sales are less than $30 million (13 CFR 121.201).

The AMS Administrator certifies that this rule does not have a significant economic impact on small businesses. This determination is made based on the expectation that any small entities requiring grain inspection, including grain farms and grain elevators, or entities performing grain inspection, including OAs, will see neither a change in prices paid or fees charged nor a loss in access to inspection services or change in territorial boundaries for which they can perform inspections. Further, FGIS believes the new challenge process addresses the concern that some small OAs may lose economic viability when exceptions are granted to applicants under the exceptions to geographic boundary requirement. Finally, AMS does not believe that OAs qualifying as small business will be any more likely to be subject to exception requests than those OAs not qualifying as small businesses.

Executive Order 12988

This rule has been reviewed under Executive Order 12988—Civil Justice Reform. This rule is not intended to have retroactive effect. The USGSA provides in sec. 87g that no State or subdivision thereof may require or impose any requirements or restrictions concerning the inspection, weighing, or description of grain under the Act.

This rule will not preempt any State or local laws, regulations, or policies,

[7] Akerlof, George A. ''The market for ''lemons'': Quality uncertainty and the market mechanism.'' *Uncertainty in economics.* Academic Press, 1978. 235–251.

unless they represent an irreconcilable conflict with this rule. No administrative proceedings would be required before parties could file suit in court challenging the provisions of this rule.

Executive Order 13175

This rule has been reviewed in accordance with the requirements of Executive Order 13175, Consultation and Coordination with Indian Tribal Governments. Executive Order 13175 requires Federal agencies to consult and coordinate with Tribes on a government-to-government basis on: (1) Policies that have Tribal implications, including regulations, legislative comments or proposed legislation; and (2) other policy statements or actions that have substantial direct effects on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes.

AMS has assessed the impact of this rule on Indian Tribes and determined that this rule will not have Tribal implications that require consultation under Executive Order 13175. AMS hosts a quarterly teleconference with Tribal leaders where matters of mutual interest regarding the marketing of agricultural products are discussed. Information about the proposed changes was shared during the quarterly call on July 22, 2021, and Tribal leaders were informed about the proposed revisions to the regulation and the opportunity to submit comments. AMS received no questions or requests for additional information or outreach. If requested, AMS will provide additional support and information.

Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), the Office of Information and Regulatory Affairs designated this final rule as not a major rule as defined by 5 U.S.C. 804(2).

Paperwork Reduction Act and E-Government Act

In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), there are no information collection and record keeping requirements implications associated with this rule. Should any changes become necessary, they will be submitted to OMB for approval.

USDA is committed to complying with the E-Government Act (44 U.S.C. 3601 *et seq.*) by promoting the use of the internet and other information technologies to provide increased opportunities for citizen access to Government information and services, and for other purposes.

List of Subjects in 7 CFR Part 800

Administrative practice and procedure, Exports, Grains, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, AMS amends 7 CFR part 800 as follows:

PART 800—GENERAL REGULATIONS

■ 1. The authority citation for part 800 continues to read as follows:

Authority: 7 U.S.C. 71–87k.

■ 2. Amend § 800.117 by:
■ a. Adding paragraph (b) introductory text;
■ b. Revising paragraph (b)(1);
■ c. Redesignating paragraphs (b)(2) and (3) as paragraphs (b)(3) and (4), respectively; and
■ d. Adding a new paragraph (b)(2).

The additions and revisions read as follows:

§ 800.117 Who shall perform original services.

* * * * *

(b) *Exceptions for official agencies to provide service.* Under an exception, an official agency may provide service to an applicant outside of their geographic area. The Service may grant exceptions in instances when: the assigned official agency is unable to provide inspection services in a timely manner; a person requesting inspection services in that geographic area has not been receiving official inspection services from the official agency for that geographic area; a person requesting inspection services in that geographic area requests a probe inspection on a barge-lot basis; or, the assigned official agency for that geographic area agrees in writing with the adjacent official agency to waive the current geographic area restriction at the request of the applicant for service. Excluding requests for probe inspections on a barge-lot basis, applicants requesting an exception must submit requests for a service exception to the Service.

(1) *Timely service.* Service is not timely when an official agency cannot provide the requested official services within 6 hours or cannot provide the results and certificate in accordance with § 800.160(c). Timely service exception requests will also be considered for delays caused by weather events or for official services that the assigned official agency does not offer. The applicant must submit a request for a timely service exception to the Service. The applicant may make this request orally or in writing. If the applicant requests a timely service exception orally, the applicant must submit a written request to the Service within two business days of the request. The applicant must clearly state and support the identified reason for the requested timely service exception. There are three consecutive tiers of timely service exceptions: one-time, 90-day, and long-term. Applicants requesting 90-day or long-term timely service exceptions must progress through each previous tier sequentially. The Service will review timely service exception requests and may contact the applicant, the assigned official agency, or potential gaining official agency with questions during its review.

(i) *One-time.* In the case of an assigned official agency's inability to provide timely service, an applicant may be granted a one-time approval to use another official agency for the associated pending service request, as applicable.

(A) For one-time, timely service exception requests, if the request is made during customary business hours, the Service will provide its decision that day.

(B) If the applicant has an urgent timely service exception request, outside of the Service's customary business hours, an official agency from outside the geographic area may provide one-time service. When providing an urgent service, the gaining official agency must provide written notification to the Service within two business days after service.

(C) Upon returning to official office hours, the Service will review and verify the circumstances of the urgent request, as well as its consistency with the U.S. Grain Standards Act and implementing regulations.

(ii) *90-day.* If there is an occurrence of untimely service within 180 days of the date of the occurrence in paragraph (b)(1)(i) of this section, the applicant may request a 90-day timely service exception. This 90-day window will begin the day the exception is granted.

(iii) *Long-term.* If there is an occurrence of untimely service within 365 days after the applicant's return to service with the assigned official agency, following an exception granted under paragraph (b)(1)(ii) of this section, the applicant may request a long-term timely service exception. When granting this exception, the Service may continue the exception up to the date on which the gaining official agency's designation terminates.

(iv) *Supporting documentation.* The applicant must submit a request for a timely service exception to the Service.

This request may include any associated supporting documentation the applicant feels is warranted. After receipt of the request, the Service will provide the applicant, assigned official agency, and potential gaining official agency an opportunity to submit any additional information in support of the timely service exception request in writing. The Service will request additional information, if needed.

(v) *Review and verification.* Except as provided in paragraph (b)(1)(i) of this section, prior to granting a timely service exception, the Service must review and verify information submitted with the request. When a timely service exception request is received, the Service will issue a written notification to acknowledge the receipt of the request to the applicant, the assigned official agency, and the potential gaining official agency. When possible, the Service should also attempt to make oral contact.

(vi) *Timeline.* Once the applicant's request is received, the Service will notify the applicant and begin the review timeline. The Service will issue a determination within 15 business days for 90-day and long-term timely service exceptions, barring a challenge from the assigned official agency. While awaiting a final decision on 90-day and long-term timely service exceptions, the applicant may receive service from the potential gaining official agency.

(vii) *Notification.* The Service must notify the assigned official agency in writing upon receipt of the request for a timely service exception. At the completion of the request review process, the Service will issue written notification of the determination on the request to the applicant, the assigned official agency, and the gaining official agency. When possible, the Service should also attempt to make oral contact.

(viii) *Challenge.* The assigned official agency may challenge a request for a timely service exception for any reason. To challenge a request for a timely service exception, the assigned official agency must object, in writing, and submit the challenge and any supporting documents to the Service.

(A) Given the urgency of a one-time service request, if the assigned official agency wishes to challenge the request, it must be done in a manner which does not further delay the applicant from receiving the pending service. If the one-time timely service exception has already been granted or used, the assigned official agency may still challenge the Service's determination within 14 calendar days.

(B) To challenge a 90-day or long-term timely service exception, the assigned official agency must submit the challenge and any supporting documents within 14 calendar days of the date of notification of the timely service exception request. The documents must clearly identify the objection and support the identified reason for the challenge.

(ix) *Determination.* In the event the Service determines that the assigned official agency is unable to provide official services in a timely manner, the Service will grant a timely service exception.

(x) *False or misleading requests.* If an applicant submits a request for a timely service exception that the Service determines to be false or misleading, the Service will not grant the exception and may elect to limit the applicant from submitting further requests for a period of up to 180 days. If an urgent request for a timely service exception, outside of customary business hours, was granted on the basis of a false or misleading request, the Service may deny the applicant from future timely service exceptions for a period of up to 180 days.

(xi) *Return to the assigned official agency.* The applicant maintains the option of returning to the assigned official agency within 60 days of notification of termination of the timely service exception to all parties. The applicant must submit a written notification requesting to terminate the timely service exception to the Service, the assigned official agency and the gaining official agency. The timely service exception will be cancelled, and future timely service exception requests must be considered at the beginning of successive-tiered system.

(xii) *Termination.* If the Service determines the assigned official agency's inability to provide a specific service was limited due to weather events or for official services that the assigned official agency does (did) not offer, the cause of which has been resolved, the Service, in consultation with all the parties, may terminate the 90-day or long-term timely service exception. However, if the timely service exception was associated with the official agency's inability to provide service in 6 hours or less, or with its failure to issue the results and certificate in a timely manner, then the Service might elect not to terminate the timely service exception. The Service must notify the applicant, the assigned official agency, and the potential gaining official agency of all timely service exception termination decisions in writing. The assigned official agency must resume service within 60 days of notification.

(2) *Nonuse of service exception.* If an applicant has not received official inspection services from the assigned official agency within the last 90 days, the applicant may request, in writing, a nonuse of service exception. Periods of nonuse resulting from timely service exceptions will not qualify as part of a period of nonuse.

(i) *Supporting documentation.* Along with the request for an exception, the applicant must submit supporting documentation pursuant to paragraph (b)(2)(i)(A) of this section and may submit any additional supporting material the applicant wishes to submit to the Service. After receipt of the request, the Service will provide the applicant, assigned official agency, and potential gaining official agency an opportunity to submit any additional information in writing. The Service will request additional information, if needed.

(A) *Required information.* The applicant's request for a nonuse of service exception must include the following information:

(*1*) The last date of service from the assigned official agency;

(*2*) The reason service has not been received during this time frame; and

(*3*) The identified reason for the request.

(B) *Additional relevant information.* Applicants may submit any additional relevant supporting information. This may include, but is not limited to:

(*1*) The location of the specified service need(s);

(*2*) The types of services requested by the applicant and offered by the assigned official agency;

(*3*) The ability of the assigned official agency to provide the requested service;

(*4*) Whether the applicant's facility has ever used the official system; and

(*5*) The impact on the applicant in the event it continues with the assigned official agency.

(ii) *Review and verification.* The Service will review the request for a nonuse of service exception and supporting documentation, then conduct any necessary analysis to estimate the exception's impact prior to making a determination, as defined in paragraph (b)(2)(vi) of this section. When the Service receives a nonuse of service exception request, the Service will issue a written notification to acknowledge the receipt of the request to the applicant, the assigned official agency, and the potential gaining official agency.

(iii) *Timeline.* The Service will make every attempt to complete the

determination process in a timely manner, during which the applicant must continue with nonuse of service. This time period will include the allotted 14 calendar days in which the assigned official agency may challenge the request. The Service may extend the determination timeline when necessary.

(iv) *Notification.* The Service must notify the assigned official agency in writing upon receipt of the request for a nonuse of service exception. At the completion of the process, the Service will issue written notification of the determination on the request to the applicant, the assigned official agency, and the gaining official agency. When possible, the Service should also attempt to make oral contact.

(v) *Challenge.* The assigned official agency may challenge a request for a nonuse of service exception for any reason. To challenge a nonuse of service exception, the assigned official agency must object in writing and must submit the challenge and any supporting documentation to the Service within 14 calendar days from the date of notification from the Service of receipt of the request for a nonuse of service exception for the applicant. The documents must clearly identify the objection and support the identified reason for the challenge.

(vi) *Determination.* The Service will consider impacts on the applicant, the assigned official agency, and the potential gaining official agency when deciding whether to grant a nonuse of service exception. These impacts may include, but are not limited to, the viability of the assigned official agency given the loss of business. The Service will also consider the impact on the official system and confirm a nonuse of service exception will not undermine the congressional policies in section 2 of the United States Grain Standards Act. The Service will provide its decision, in writing, to the applicant, the assigned official agency, and the potential gaining official agency. If approved, the applicant can receive service from either the originally assigned official agency or the gaining official agency.

(vii) *False or misleading requests.* If an applicant submits a request that the Service determines is false or misleading, the Service will not grant the nonuse of service exception and may elect to limit the applicant from submitting further requests for a period of up to 180 days.

(viii) *Renewal or termination of exception.* The nonuse of service exception is for the period of the gaining official agency's designation. At the end of the designation, the Service will review the nonuse if service exception and verify the information. Unless the applicant, the assigned official agency, the gaining official agency, and the Service all agree to terminate the nonuse of service exception, the Service will renew the nonuse of service exception for the gaining official agency's new designation period. In the event the gaining official agency is no longer designated, the nonuse of service exception will automatically terminate, and the applicant will return to the assigned official agency. If the applicant transfers ownership of its facility, the nonuse of service exception will automatically terminate, and the new applicant/owner of the facility must request a new nonuse of service exception to receive service from an official agency other than the assigned official agency for that geographic area. At any point in the designation cycle, if the applicant, the assigned official agency, the gaining official agency, and FGIS jointly agree to terminate nonuse of service exception in writing, the Service will terminate the exception. In this case, the assigned official agency must resume service within 60 days of notification that the nonuse of service exception has been terminated.

(ix) *Historic exceptions.* All nonuse of service exceptions that were in place as of March 30, 2019, and that are currently active as of the date of effectuation of this rule, are incorporated within the list of active nonuse of service exceptions.

* * * * *

Melissa Bailey,

Associate Administrator, Agricultural Marketing Service.

[FR Doc. 2023–08957 Filed 5–2–23; 8:45 am]

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NUCLEAR REGULATORY COMMISSION

10 CFR Parts 50 and 52

[NRC–2020–0245]

Regulatory Guide: Environmental Qualification of Certain Electric Equipment Important to Safety for Nuclear Power Plants

AGENCY: Nuclear Regulatory Commission.

ACTION: Final guide; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is issuing Revision 2 to Regulatory Guide (RG) 1.89, ''Environmental Qualification of Certain Electric Equipment Important to Safety for Nuclear Power Plants.'' RG 1.89, Revision 2 provides guidance that the staff of the NRC considers acceptable to meet regulatory requirements for environmental qualification (EQ) of certain electric equipment important to safety.

DATES: Revision 2 to RG 1.89 is available on May 3, 2023.

ADDRESSES: Please refer to Docket ID NRC–2020–0245 when contacting the NRC about the availability of information regarding this document. You may obtain publicly available information related to this document using any of the following methods:

- *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2020–0245. Address questions about Docket IDs in *Regulations.gov* to Stacy Schumann; telephone: 301–415–0624; email: *Stacy.Schumann@nrc.gov.* For technical questions, contact the individuals listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *PDR.Resource@nrc.gov.* The ADAMS accession number for each document referenced (if it is available in ADAMS) is provided the first time that it is mentioned in this document.
- *NRC's PDR:* You may examine and purchase copies of public documents, by appointment, at the NRC's Public Document Room (PDR), Room P1 B35, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852. To make an appointment to visit the PDR, please send an email to *PDR.Resource@nrc.gov* or call 1–800–397–4209 or 301–415–4737, between 8 a.m. and 4 p.m. eastern time (ET), Monday through Friday, except Federal holidays.

Revision 2 to RG 1.89 and the regulatory analysis may be found in ADAMS under Accession Nos. ML22272A602 and ML20192A230, respectively.

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FOR FURTHER INFORMATION CONTACT: Michael Eudy, Office of Nuclear Regulatory Research, telephone: 301–415–3104; email: *Michael.Eudy@nrc.gov* and Matthew McConnell, Office of Nuclear Reactor Regulation, telephone: 301–415–1597; email:

Matthew.McConnell@nrc.gov. Both are staff of the U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

SUPPLEMENTARY INFORMATION:

I. Discussion

The NRC is issuing a revision in the NRC's ''Regulatory Guide'' series. This series was developed to describe methods that are acceptable to the NRC staff for implementing specific parts of the agency's regulations, to explain techniques that the staff uses in evaluating specific issues or postulated events, and to describe information that the staff needs in its review of applications for permits and licenses.

Revision 2 to RG 1.89 was issued with a temporary identification of Draft Regulatory Guide, DG–1361 (ADAMS Accession No. ML20183A423).

The staff revised RG 1.89 to endorse, with clarifications, exceptions, and supplements, International Electrotechnical Commission/Institute of Electrical and Electronic Engineers Standard 60780–323, ''Nuclear Facilities—Electrical Equipment Important to Safety—Qualification,'' Edition 1, 2016–02, as this standard reflects almost 40 years of experience gained in implementing regulatory requirements and industry research and testing related to environmental qualification (EQ). Nuclear plant license renewal provides additional motivation for continuing attention to equipment qualification. This revised guide contains information specific for EQ for both older plants and newer reactors licensed under parts 50 and 52 of title 10 of the *Code of Federal Regulations* (10 CFR).

II. Additional Information

The NRC published notices of the availability of DG–1361 in the **Federal Register** on December 17, 2020 (85 FR 81958) and February 18, 2021 (86 FR 10133) for 60-day public comment periods. The public comment periods closed on February 16, 2021, and April 19, 2021, respectively. Public comments on DG–1361 and the staff responses to the public comments are available under ADAMS under Accession No. ML22272A601.

As noted in the **Federal Register** on December 9, 2022 (87 FR 75671), this document is being published in the ''Rules'' section of the **Federal Register** to comply with publication requirements under 1 CFR chapter I.

III. Congressional Review Act

This RG is a rule as defined in the Congressional Review Act (5 U.S.C. 801–808). However, the Office of Management and Budget has not found it to be a major rule as defined in the Congressional Review Act.

IV. Backfitting, Forward Fitting, and Issue Finality

Issuance of RG 1.89, Revision 2, does not constitute backfitting as defined in 10 CFR 50.109, ''Backfitting,'' and as described in NRC Management Directive (MD) 8.4, ''Management of Backfitting, Forward Fitting, Issue Finality, and Information Requests''; affect the issue finality of an approval issued under 10 CFR part 52; or constitute forward fitting as defined in MD 8.4 because, as explained in this RG, licensees are not required to comply with the positions set forth in this RG.

V. Submitting Suggestions for Improvement of Regulatory Guides

A member of the public may, at any time, submit suggestions to the NRC for improvement of existing RGs or for the development of new RGs. Suggestions can be submitted on the NRC's public website at *https://www.nrc.gov/reading-rm/doc-collections/reg-guides/contactus.html.* Suggestions will be considered in future updates and enhancements to the ''Regulatory Guide'' series.

Dated: April 28, 2023.

For the Nuclear Regulatory Commission.

Meraj Rahimi,

Chief, Regulatory Guide and Programs Management Branch, Division of Engineering, Office of Nuclear Regulatory Research.

[FR Doc. 2023–09389 Filed 5–2–23; 8:45 am]

BILLING CODE 7590–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510, 516, 520, 522, 524, 526, 529, 556, and 558

[Docket No. FDA–2023–N–0002]

New Animal Drugs; Approval of New Animal Drug Applications; Withdrawal of Approval of New Animal Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendments.

SUMMARY: The Food and Drug Administration (FDA or we) is amending the animal drug regulations to reflect application-related actions for new animal drug applications (NADAs), abbreviated new animal drug applications (ANADAs), and conditionally approved new animal drug applications (cNADAs) during January, February, and March 2023. FDA is informing the public of the availability of summaries of the basis of approval and of environmental review documents, where applicable. The animal drug regulations are also being amended to improve their accuracy and readability.

DATES: This rule is effective May 3, 2023.

FOR FURTHER INFORMATION CONTACT: George K. Haibel, Center for Veterinary Medicine (HFV–6), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–402–5689, *george.haibel@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Approvals

FDA is amending the animal drug regulations to reflect approval actions for NADAs, ANADAs, and cNADAs during January, February, and March 2023, as listed in table 1. In addition, FDA is informing the public of the availability, where applicable, of documentation of environmental review required under the National Environmental Policy Act (NEPA) and, for actions requiring review of safety or effectiveness data, summaries of the basis of approval (FOI Summaries) under the Freedom of Information Act (FOIA). These public documents may be seen in the office of the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500. Persons with access to the internet may obtain these documents at the CVM FOIA Electronic Reading Room: *https://www.fda.gov/about-fda/center-veterinary-medicine/cvm-foia-electronic-reading-room.* Marketing exclusivity and patent information may be accessed in FDA's publication, Approved Animal Drug Products Online (Green Book) at: *https://www.fda.gov/animal-veterinary/products/approved-animal-drug-products-green-book.*

TABLE 1—ORIGINAL AND SUPPLEMENTAL NADAS, ANADAS, AND CNADAS APPROVED DURING JANUARY, FEBRUARY, AND MARCH 2023 REQUIRING EVIDENCE OF SAFETY AND/OR EFFECTIVENESS

Approval date	File No.	Sponsor	Product name	Effect of the action	Public documents	21 CFR section
January 5, 2023	200–732	Felix Pharmaceuticals Pvt. Ltd., 25–28 North Wall Quay, Dublin 1, Ireland.	Carprofen Tablets (carprofen tablets) Caplets.	Original approval for the relief of pain and inflammation associated with osteoarthritis and for the control of postoperative pain associated with soft tissue and orthopedic surgeries in dogs as a generic copy of NADA 141–053.	FOI Summary	520.304
January 11, 2023	200–611	Akorn Operating Company LLC, 5605 Centerpoint Ct., Suite A, Gurnee, IL 60031.	DETOMISED (detomidine hydrochloride) Injectable Solution.	Original approval as a sedative and analgesic to facilitate minor surgical and diagnostic procedures in horses as a generic copy of NADA 140–862.	FOI Summary	522.536
January 11, 2023	200–738	Aurora Pharmaceutical, Inc., 1196 Highway 3 South, Northfield, MN 55057–3009.	DECTOGARD (doramectin topical solution) Topical Solution.	Original approval for treatment and control of internal and external parasites of cattle as a generic copy of NADA 141–095.	FOI Summary	524.770
January 12, 2023	141–426	Intervet, Inc., 2 Giralda Farms, Madison, NJ 07940.	BRAVECTO (fluralaner) Chewable tablets.	Supplemental approval for the treatment and control of Asian long horned tick infestations for 12 weeks in dogs and puppies.	FOI Summary	520.998
January 12, 2023	200–721	Norbrook Laboratories Ltd., Carnbane Industrial Estate, Newry, County Down, BT35 6QQ, United Kingdom.	MIDAMOX for Cats (imidacloprid and moxidectin) Topical Solution.	Supplemental approval for prevention of heartworm disease and treatment of flea infestations in ferrets as a generic copy of NADA 141–254.	FOI Summary	524.1146
January 12, 2023	200–733	Felix Pharmaceuticals Pvt. Ltd., 25–28 North Wall Quay, Dublin 1, Ireland.	Marbofloxacin Chewable Tablets (marbofloxacin).	Original approval for treatment of infections in dogs and cats associated with bacteria susceptible to marbofloxacin as a generic copy of NADA 141–151.	FOI Summary	520.1310
January 12, 2023	200–734	Do	Praziquantel Tablets (praziquantel).	Original approval for removal or removal and control of certain canine tapeworms as a generic copy of NADA 111–798.	FOI Summary	520.1870
January 13, 2023	200–735	ZyVet Animal Health, Inc., 73 Route 31N, Pennington, NJ 08534.	Dexmedetomidine Hydrochloride (dexmedetomidine hydrochloride) Injectable Solution.	Original approval for use as a sedative, analgesic, and preanesthetic in dogs and cats as a generic copy of NADA 141–267.	FOI Summary	522.558
January 13, 2023	200–736	Do	Marbofloxacin Tablets (marbofloxacin).	Original approval for treatment of infections in dogs and cats associated with bacteria susceptible to marbofloxacin as a generic copy of NADA 141–151.	FOI Summary	520.1310
February 2, 2023	200–737	Do	Enrofloxacin (enrofloxacin) Flavored Antimicrobial Tablets.	Original approval for the management of diseases associated with bacteria susceptible to enrofloxacin in dogs and cats as a generic copy of NADA 140–441.	FOI Summary	520.812
February 2, 2023	200–739	Do	Carprofen (carprofen) Chewable Tablets.	Original approval for the relief of pain and inflammation associated with osteoarthritis and for the control of postoperative pain associated with soft tissue and orthopedic surgeries in dogs as a generic copy of NADA 141–111.	FOI Summary	520.304
February 9, 2023	200–701	Chanelle Pharmaceuticals Manufacturing Ltd., Loughrea, County Galway, Ireland.	PARASEDGE Multi for Cats (imidacloprid and moxidectin) Topical Solution.	Supplemental approval for prevention of heartworm disease and treatment of flea infestations in ferrets as a generic copy of NADA 141–254.	FOI Summary	524.1146

TABLE 1—ORIGINAL AND SUPPLEMENTAL NADAS, ANADAS, AND CNADAS APPROVED DURING JANUARY, FEBRUARY, AND MARCH 2023 REQUIRING EVIDENCE OF SAFETY AND/OR EFFECTIVENESS—Continued

Approval date	File No.	Sponsor	Product name	Effect of the action	Public documents	21 CFR section
February 24, 2023	200–741	Aurora Pharmaceutical, Inc., 1196 Highway 3 South, Northfield, MN 55057–3009.	EPRIGARD (eprinomectin) Topical Solution.	Original approval for treatment and control of internal and external parasites in cattle as a generic copy of NADA 141–079.	FOI Summary	524.814
March 21, 2023	200–743	Provetica LLC, 8735 Rosehill Rd., Suite 300, Lenexa, KS 66215.	MODULIS for Dogs (cyclosporine oral solution) USP MODIFIED.	Original approval for the control of atopic dermatitis in dogs as a generic copy of NADA 141–218.	FOI Summary	520.522
March 21, 2023	200–745	Parnell Technologies Pty. Ltd., Unit 4, 476 Gardeners Rd., Alexandria, New South Wales 2015, Australia.	RESPIRMYCIN 25 (tulathromycin injection) Injectable Solution.	Original approval for the treatment of respiratory disease in swine and calves as a generic copy of NADA 141–349.	FOI Summary	522.2630
March 29, 2023	200–744	Provetica LLC, 8735 Rosehill Rd., Suite 300, Lenexa, KS 66215.	MODULIS for Cats (cyclosporine oral solution) USP MODIFIED.	Original approval for the control of feline allergic dermatitis in cats as a generic copy of NADA 141–329.	FOI Summary	520.522
March 30, 2023	200–746	Norbrook Laboratories Ltd., Carnbane Industrial Estate, Newry, County Down, BT35 6QQ, United Kingdom.	TAURAMOX (moxidectin) Injectable Solution.	Original approval for treatment and control of internal and external parasites in beef and nonlactating dairy cattle as a generic copy of NADA 141–220.	FOI Summary	522.1450
March 31, 2023	200–747	ZyVet Animal Health, Inc., 73 Route 31N, Pennington, NJ 08534.	Maropitant Citrate (maropitant citrate) Tablets.	Original approval for the prevention of acute vomiting and the prevention of vomiting due to motion sickness in dogs as a generic copy of NADA 141–262.	FOI Summary	520.1315

Also, FDA is amending the animal drug regulations to reflect approval of supplemental applications, as listed in table 2, to change the marketing status of dosage form antimicrobial animal drug products from over the counter (OTC) to by veterinary prescription (Rx). These applications were submitted in voluntary compliance with the goals of the FDA Center for Veterinary Medicine's (CVM's) Judicious Use Initiative as identified by guidance for industry #263, ''Recommendations for Sponsors of Medically Important Antimicrobial Drugs Approved for Use in Animals to Voluntarily Bring Under Veterinary Oversight All Products That Continue to be Available Over-the-Counter,'' June 11, 2021 (*https://www.fda.gov/media/130610/download*).

TABLE 2—SUPPLEMENTAL APPLICATIONS APPROVED DURING JANUARY, FEBRUARY, AND MARCH 2023 TO CHANGE THE MARKETING STATUS OF ANTIMICROBIAL ANIMAL DRUG PRODUCTS FROM OTC TO Rx

Approval date	File No.	Sponsor	Product name	21 CFR section
January 3, 2022	200–274	Zoetis Inc., 333 Portage St., Kalamazoo, MI 49007.	LINCOMIX (lincomycin hydrochloride) Injectable Solution.	522.1260
January 12, 2022	012–123	Bimeda Animal Health Ltd., 1B The Herbert Building, The Park, Carrickmines, Dublin 18, Ireland.	GALLIMYCIN 100 Injection (erythromycin) Injectable Solution.	522.820
January 12, 2022	130–952	Intervet, Inc., 2 Giralda Farms, Madison, NJ 07940.	GENTOCIN Pinkeye Spray (gentamicin) Topical Spray.	524.1044e
January 13, 2022	008–774	Huvepharma EEOD, 5th Floor, 3A Nikolay Haytov Str., 1113 Sofia, Bulgaria.	SULMET (sodium sulfamethazine) Injectable Solution.	522.2260
February 10, 2023	065–506	Bimeda Animal Health Ltd., 1B The Herbert Building, The Park, Carrickmines, Dublin 18, Ireland.	COMBI–PEN–48 (penicillin G benzathine and penicillin G procaine) Injectable Suspension.	522.1696a
February 14, 2023	055–018	Huvepharma EOOD, 5th Floor, 3A Nikolay Haytov Str., 1113 Sofia, Bulgaria.	Chlortetracycline (chlortetracycline hydrochloride) Tablets, 25 mg.	520.443
February 15, 2023	033–157	Do	SPECTAM Scour-Halt (spectinomycin) Oral Solution.	520.2123c
February 15, 2023	040–040	Do	SPECTAM (spectinomycin) Injectable Solution.	522.2120
February 24, 2023	065–010	Do	NOROCILLIN (penicillin G procaine) Injectable Suspension.	522.1696b
March 1, 2023	200–351	Do	Lincomycin Injectable, USP	522.1260
March 1, 2023	200–368	Do	Lincomycin Injectable, USP	522.1260
March 1, 2023	130–464	Intervet, Inc., 2 Giralda Farms, Madison, NJ 07940.	GARACIN Pig Pump (gentamicin) Oral Solution.	520.1044b

TABLE 2—SUPPLEMENTAL APPLICATIONS APPROVED DURING JANUARY, FEBRUARY, AND MARCH 2023 TO CHANGE THE MARKETING STATUS OF ANTIMICROBIAL ANIMAL DRUG PRODUCTS FROM OTC TO Rx—Continued

Approval date	File No.	Sponsor	Product name	21 CFR section
March 9, 2023	035–456	Bimeda Animal Health Ltd., 1B The Herbert Building, The Park, Carrickmines, Dublin 18, Ireland.	GALLIMYCIN–36 (erythromycin) Intramammary Solution.	526.820
March 13, 2023	200–315	Sparhawk Laboratories, Inc., 12340 Santa Fe Trail Dr., Lenexa, KS 66215.	LINCOMYCIN 300 (lincomycin hydrochloride) Injectable Solution.	522.1260
March 16, 2023	065–505	Bimeda Animal Health Ltd., 1B The Herbert Building, The Park, Carrickmines, Dublin 18, Ireland.	PRO–PEN–G (penicillin G procaine) Injectable Suspension.	522.1696b
March 20, 2023	200–127	Zoetis Inc., 333 Portage St., Kalamazoo, MI 49007.	PROSPEC (spectinomycin hydrochloride) Injectable Solution.	522.2120
March 25, 2023	040–181	Huvepharma EOOD, 5th Floor, 3A Nikolay Haytov Str., 1113 Sofia, Bulgaria.	VETSULID (sulfachlorpyridazine) Oral Suspension.	520.2200
March 28, 2023	065–081	HQ Specialty Pharma Corp., 120 Rte. 17 North, Suite 130, Paramus, NJ 07652.	MASTI–CLEAR (penicillin G procaine) Suspension and GO–DRY (penicillin G procaine) Suspension.	526.1696

II. Withdrawals of Approval

Elanco US Inc. (Elanco), 2500 Innovation Way, Greenfield, IN 46140 has requested that FDA withdraw approval of conditionally approved NADA 141–527 for BAYTRIL 100–CA1 (enrofloxacin) Injectable Solution. Pursuant to Elanco's request, approval of their application was withdrawn on March 31, 2023. As provided in the regulatory text of this document, the animal drug regulations in 21 CFR 516.812 are removed to reflect this action.

Boehringer Ingelheim Animal Health USA, Inc., 3239 Satellite Blvd., Duluth, GA 30096 has requested that FDA withdraw approval of the 49 applications listed in table 3 because the products are no longer manufactured or marketed. As provided in the regulatory text of this document, the animal drug regulations are amended where appropriate to reflect this action.

TABLE 3—APPLICATIONS FOR WHICH APPROVAL WAS VOLUNTARILY WITHDRAWN BY FDA

File No.	Product name	21 CFR cite
006–623	CAPARSOLATE (arsenamide sodium) Injectable Solution	Not codified
008–422	SELEEN (selenium disulfide) Topical Suspension	524.2101
010–424	NALLINE (nalorphine hydrochloride) Injectable Solution	522.1452
011–080	HYDELTRONE-TBA (prednisolone tertiary butylacetate) Injectable Suspension	522.1885
011–437	HYDELTRONE (neomycin sulfate and prednisolone sodium phosphate) Ointment	524.1484j
011–532	SULFABROM (sulfabromomethazine sodium) Bolus	520.2170
011–678	DIURIL (chlorothiazide) Tablets	520.420
012–734	DIURIL (chlorothiazide) Bolus	520.420
013–022	THIBENZOLE (thiabendazole) Sheep & Goat Wormer	520.2380c
013–407	EQUIZOLE (thiabendazole) Horse Wormer Top Dress	520.2380a
013–624	Triamcinolone Acetonide Tablets	520.2483
013–674	HYDROZIDE (hydrochlorothiazide) Injectable Solution	522.1150
013–954	THIBENZOLE (thiabendazole) 20% Swine Premix	558.600
014–350	OMNIZOLE (thiabendazole) Oral Liquid	520.2380b
015–123	TBZ (thiabendazole) Cattle Wormer Oral Liquid	520.2380b
015–875	TBZ 200 (thiabendazole) Medicated Feed Premix	558.600
030–103	THIBENZOLE (thiabendazole) Oral Liquid	520.2380b
032–702	PROM ACE (acepromazine maleate) Tablets	520.23
033–127	VETISULID (sulfachlorpyridazine) Bolus	520.2200
033–318	VETISULID (sulfachlorpyridazine) Injectable Solution	520.2200
033–319	VETISULID (sulfachlorpyridazine) Tablets	520.2200
034–114	EQUIZOLE (thiabendazole) Oral Liquid	520.2380b
034–879	DOPRAM-V (doxapram hydrochloride) Injectable Solution	522.775
035–631	THIBENZOLE (thiabendazole) Pig Wormer	520.2380b
037–410	EQUIZOLE A (thiabendazole and piperazine phosphate) Oral Liquid	520.2380e
043–141	THIBENZOLE 300 (thiabendazole) Medicated	558.600
044–654	EQUIZOLE (thiabendazole) Horse Wormer Pellets	520.2380a
046–146	VETALOG (triamcinolone acetonide) Cream	524.2483
047–333	EQUIZOLE A (thiabendazole and piperazine citrate) Oral Liquid	520.2380d
048–487	TBZ (thiabendazole) Wormer Paste 50%	520.2380b
049–461	TBZ (thiabendazole) Wormer Paste 43%	520.2380b
055–021	HETACIN K (hetacillin potassium) Capsules Vet	520.1130
055–022	HETACIN K (hetacillin potassium) Tablets	520.1130
055–048	HETACIN K (hetacillin potassium) Oral Liquid	520.1130
065–275	Penicillin VK (penicillin V potassium) Filmtab Tablets 250 mg	520.1696c
065–276	VEESYN (penicillin V potassium) Granules for Oral Solution	520.1696b
093–600	VOREN (dexamethasone-21-isonicotinate) Suspension	522.542

TABLE 3—APPLICATIONS FOR WHICH APPROVAL WAS VOLUNTARILY WITHDRAWN BY FDA—Continued

File No.	Product name	21 CFR cite
094–642	CAMVET (cambendazole) Suspension Horse Wormer	520.284a
095–642	OXY-TET (oxytetracycline hydrochloride) Injectable Solution	522.1662a
096–506	CAMVET (cambendazole) Horse Wormer Pellets	520.284b
096–731	CAMVET (cambendazole) Horse Wormer Paste 45%	520.284c
098–689	EQUIZOLE (thiabendazole) 50% Wormer Paste	520.2380b
099–388	VETALOG (triamcinolone acetonide) Oral Powder	520.2483
117–531	Acepromazine Maleate Injection	522.23
127–443	EQVALAN (ivermectin) Injectable Solution	522.1192
140–439	EQVALAN (ivermectin) Oral Liquid For Horses	522.1195
141–180	TORPEX (albuterol sulfate)	529.40
200–361	Acepromazine Maleate Injection	522.23
200–564	Ivermectin Paste 1.87%	520.1192

III. Technical Amendments

FDA is making the following amendments to improve the accuracy of the animal drug regulations.

- 21 CFR 520.48 is amended to reflect the sponsors of products containing altrenogest for use in horses and swine.
- 21 CFR 520.2380 is removed and 21 CFR 558.600 revised to characterize a free-choice block containing thiabendazole as a new animal drug for use in cattle feed.
- 21 CFR 522.1077 is amended to reflect indications for use of gonadorelin in cattle.
- 21 CFR 522.1222 is amended to reflect sponsors of approved applications for use of ketamine in cats and subhuman primates.
- 21 CFR 556.620 is removed because there are no longer any approved products containing sulfabromomethazine for use in food-producing animals.
- 21 CFR 556.730 is revised to reflect the removal of products containing thiabendazole for use in food-producing animals other than cattle.
- 21 CFR 558.311 is amended to reflect approved classes of pasture cattle for use of lasalocid medicated feeds.
- 21 CFR 558.455 is amended to reflect the approved conditions of use of medicated feeds containing oxytetracycline and neomycin in sheep.

IV. Legal Authority

This final rule is issued under section 512(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360b(i)), which requires **Federal Register** publication of ''notice[s] . . . effective as a regulation,'' of the conditions of use of approved new animal drugs. This rule sets forth technical amendments to the regulations to codify recent actions on approved new animal drug applications and corrections to improve the accuracy of the regulations, and as such does not impose any burden on regulated entities.

Although denominated a rule pursuant to the FD&C Act, this document does not meet the definition of ''rule'' in 5 U.S.C. 804(3)(A) because it is a ''rule of particular applicability.'' Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808. Likewise, this is not a rule subject to Executive Order 12866, which defines a rule as ''an agency statement of general applicability and future effect, which the agency intends to have the force and effect of law, that is designed to implement, interpret, or prescribe law or policy or to describe the procedure or practice requirements of an agency.''

List of Subjects

21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 516

Administrative practice and procedure, Animal drugs, Confidential business information, Reporting and recordkeeping requirements.

21 CFR Parts 520, 522, 524, 526, and 529

Animal drugs.

21 CFR Part 556

Animal drugs, Dairy products, Foods, Meat and meat products.

21 CFR Part 558

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 510, 516, 520, 522, 524, 526, 529, 556, and 558 are amended as follows:

PART 510—NEW ANIMAL DRUGS

■ 1. The authority citation for part 510 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

■ 2. In § 510.600:

■ a. In paragraph (c)(1), amend the table by adding an entry for ''Provetica LLC''; and

■ b. In paragraph (c)(2), amend the table by adding add an entry for ''086097''.

The additions read as follows:

§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

* * * * *

(c) * * *

(1) * * *

Firm name and address	Drug labeler code
* * * * * * *	
Provetica LLC, 8735 Rosehill Rd., Suite 300, Lenexa, KS 66215	086097
* * * * * * *	

(2) * * *

Drug labeler code	Firm name and address
* * * * * * *	
086097	Provetica LLC, 8735 Rosehill Rd., Suite 300, Lenexa, KS 66215.
* * * * * * *	

PART 516—NEW ANIMAL DRUGS FOR MINOR USE AND MINOR SPECIES

■ 3. The authority citation for part 516 continues to read as follows:

Authority: 21 U.S.C. 360ccc–1, 360ccc–2, 371.

§ 516.812 [Removed]

■ 4. Remove § 516.812.

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

■ 5. The authority citation for part 520 continues to read as follows:

Authority: 21 U.S.C. 360b.

■ 6. In § 520.48, revise paragraph (b) to read as follows:

§ 520.48 Altrenogest.

* * * * *

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter:

(1) Nos. 000061 and 051072 for use as in paragraph (d) of this section.

(2) No. 061133 for use as in paragraph (d)(1) of this section.

(3) No. 013744 for use as in paragraph (d)(2) of this section.

* * * * *

§§ 520.284, 520.284a, 520.284b, and 520.284c [Removed]

■ 7. Remove §§ 520.284, 520.284a, 520.284b, and 520.284c.

■ 8. In § 520.304, revise paragraphs (b)(1) and (2) to read as follows:

§ 520.304 Carprofen.

* * * * *

(b) * * *

(1) Nos. 017033, 054771, 055529, 062250, and 086101 for use of products described in paragraph (a)(1) and (2) of this section as in paragraph (c) of this section.

(2) Nos. 058198 and 086117 for use of product described in paragraph (a)(2) as in paragraph (c) of this section.

* * * * *

§§ 520.420 [Removed]

■ 9. Remove § 520.420.

■ 10. In § 520.443, amend paragraph (d)(2)(ii) by adding a sentence at the end of the paragraph to read as follows:

§ 520.443 Chlortetracycline tablets and boluses.

* * * * *

(d) * * *

(2) * * *

(ii) * * * Federal law restricts this drug to use by or on the order of a licensed veterinarian.

* * * * *

■ 11. In § 520.522, add paragraph (b)(4) and revise (d)(2)(ii) to read as follows:

§ 520.522 Cyclosporine.

* * * * *

(b) * * *

(4) No. 086097 for use of product described in paragraph (a)(2) as in paragraph (d) of this section.

* * * * *

(d) * * *

(2) * * *

(ii) *Indications for use.* For the control of feline allergic dermatitis as manifested by excoriations (including facial and neck), miliary dermatitis, eosinophilic plaques, and self-induced alopecia in cats at least 6 months of age and at least 3 lbs (1.4 kg) in body weight.

* * * * *

§ 520.812 [Amended]

■ 12. Amend § 520.812 by:

■ a. In paragraph (b)(2), removing ''No. 017033'' and in its place adding ''Nos. 017033 and 086117''; and

■ b. Removing paragraph (b)(4).

■ 13. In § 520.998, revise paragraph (c)(2)(i) to read as follows:

§ 520.998 Fluralaner.

* * * * *

(c) * * *

(2) * * *

(i) *Chewable tablets described in paragraph (a)(1) of this section.* Kills adult fleas; for the treatment and prevention of flea infestations (*Ctenocephalides felis*), and the treatment and control of tick infestations (*Ixodes scapularis* (black-legged tick), *Dermacentor variabilis* (American dog tick), *Rhipicephalus sanguineus* (brown dog tick), and *Haemaphysalis longicornis* (Asian longhorned tick)) for 12 weeks in dogs and puppies 6 months of age and older, and weighing 4.4 lbs or greater; and for the treatment and control of *Amblyomma americanum* (lone star tick) infestations for 8 weeks in dogs and puppies 6 months of age and older, and weighing 4.4 lbs or greater.

* * * * *

■ 14. Amend § 520.1044b by adding a sentence at the end of paragraph (d)(3) to read as follows:

§ 520.1044b [Amended]

* * * * *

(d) * * *

(3) * * * Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 520.1130 [Removed]

■ 15. Remove §§ 520.1130.

§ 520.1195 [Amended]

■ 16. In § 520.1195, in paragraph (b)(1), remove ''000010,''.

■ 17. In § 520.1310, revise paragraphs (a) and (b) to read as follows:

§ 520.1310 Marbofloxacin.

(a) *Specifications.* Each tablet or chewable tablet contains 25, 50, 100, or 200 milligrams (mg) marbofloxacin.

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter for use as in paragraph (d) of this section:

(1) Nos. 017033, 054771, and 086117 for use of tablets.

(2) No. 086101 for use of chewable tablets.

* * * * *

■ 18. In § 520.1315, revise paragraph (b) to read as follows:

§ 520.1315 Maropitant.

* * * * *

(b) *Sponsors.* See Nos. 054771 and 086117 in § 510.600(c) of this chapter.

* * * * *

§ 520.1696b [Removed]

■ 19. Remove § 520.1696b.

■ 20. In § 520.1696c, revise paragraph (b) to read as follows:

§ 520.1696c Penicillin V tablets.

* * * * *

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

* * * * *

§ 520.1870 [Amended]

■ 21. In § 520.1870, in paragraph (b)(2), remove ''No. 069043'' and in its place add ''Nos. 069043 and 086101''.

■ 22. In § 520.2200, revise paragraph (a)(2), remove paragraph (a)(3), revise paragraphs (d)(1)(i) and (d)(2)(i), and remove (d)(3) to read as follows:

§ 520.2200 Sulfachlorpyridazine.

(a) * * *

(2) Each milliliter (mL) of suspension contains 50 milligrams (mg) of sodium sulfachlorpyridazine.

* * * * *

(d) * * *

(1) * * *

(i) *Amount.* Administer 30 to 45 mg sulfachlorpyridazine powder per pound (/lb) of body weight per day in milk or milk replacer in divided doses twice daily for 1 to 5 days.

* * * * *

(2) * * *

(i) *Amount.* Administer 20 to 35 mg/lb body weight per day in divided doses twice daily for 1 to 5 days in drinking water or an oral suspension containing 50 mg per mL.

* * * * *

§§ 520.1696b, 520.2170, 520.2380, 520.2380a, 520.2380b, 520.2380c, 520.2380d and 520.2380e [Removed]

■ 23. Remove §§ 520.1696b, 520.2170, 520.2380, 520.2380a, 520.2380b, 520.2380c, 520.2380d and 520.2380e.

§ 520.2380f [Redesignated]

■ 24. Redesignate § 520.2380f as § 520.2382.

§ 520.2483 [Removed]

■ 25. Remove § 520.2483.

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

■ 26. The authority citation for part 522 continues to read as follows:

Authority: 21 U.S.C. 360b.

§ 522.536 [Amended]

■ 27. In § 522.536, in paragraph (b), remove ''Nos. 015914 and 052483'' and in its place add ''Nos. 015914, 052483, and 059399''.

§ 522.542 [Removed]

■ 28. Remove § 522.542.

§ 522.558 [Amended]

■ 29. In § 522.558, in paragraph (b)(1), remove ''Nos. 017033 and 059399'' and in its place add ''Nos. 017033, 059399, and 086117''.

§ 522.775 [Removed]

■ 30. Remove § 522.775.

■ 31. Amend § 522.820 by adding a sentence at the end of paragraph (d)(3)(iii) to read as follows:

§ 522.820 Erythromycin.

* * * * *

(d) * * *

(3) * * *

(iii) * * * Federal law restricts this drug to use by or on the order of a licensed veterinarian.

■ 32. In § 522.1077, revise paragraphs (b)(2), (d)(1)(iv), and (e)(1)(i) to read as follows:

§ 522.1077 Gonadorelin.

* * * * *

(b) * * *

(2) No. 068504 for use of the 100-µg/mL product described in paragraph (a)(2) as in paragraphs (d)(1)(i) and (iv) of this section.

* * * * *

(d) * * *

(1) * * *

(iv) Dinoprost injection for use as in paragraph (e)(1)(vi) of this section as provided by No. 054771 in § 510.600(c) of this chapter.

* * * * *

(e) * * *

(1) * * *

(i) For the treatment of ovarian follicular cysts in dairy cattle: Administer 86 µg gonadorelin (No. 000061), or 100 µg gonadorelin diacetate tetrahydrate (Nos. 000010 and 061133), or 100 µg gonadorelin (as gonadorelin acetate; No. 068504) by intramuscular or intravenous injection.

* * * * *

§ 522.1150 [Removed]

■ 33. Remove § 522.1150.

■ 34. In § 522.1192, remove and reserve paragraph (a)(1), and revise paragraphs (b)(1) and (2), remove and reserve paragraph (e)(1), and revise paragraph (e)(2)(i) to read as follows:

§ 522.1192 Ivermectin.

* * * * *

(b) * * *

(1) Nos. 000010, 016592, 055529, 058005, and 061133 for use of the product described in paragraph (a)(2) of this section as in paragraphs (e)(2) through (e)(5) of this section; and

(2) No. 000010 for use of the product described in paragraph (a)(3) of this section as in paragraphs (e)(3) and (e)(6) of this section.

* * * * *

(e) * * *

(2) * * *

(i) *Amount.* 200 micrograms per kilogram (µg/kg) of body weight by subcutaneous injection.

* * * * *

§ 522.1222 [Amended]

■ 35. In § 522.1222, revise paragraph (b) by adding, in numeric sequence, ''00010,''.

■ 36. In § 522.1450, revise paragraphs (a), (b), and (e) to read as follows:

§ 522.1450 Moxidectin solution.

(a) *Specifications.* Each milliliter (mL) of solution contains 10 milligrams (mg) moxidectin.

(b) *Sponsors.* See Nos. 055529 and 058198 in § 510.600(c) of this chapter.

* * * * *

(e) *Conditions of use in cattle—(1) Amount.* Administer by subcutaneous injection 1 mL for each 110 pounds (lb) (50 kilograms (kg)) body weight to provide 0.2 mg moxidectin/2.2 lb (0.2 mg/kg) body weight.

(2) *Indications for use.* Beef and nonlactating dairy cattle: For treatment and control of Gastrointestinal roundworms: *Ostertagia ostertagi* (adults, fourth-stage larvae, and inhibited larvae), *Haemonchus placei* (adults), *Trichostrongylus axei* (adults and fourth-stage larvae), *Trichostrongylus colubriformis* (adults and fourth-stage larvae), *Cooperia oncophora* (adults), *Cooperia pectinata* (adults), *Cooperia punctata* (adults and fourth-stage larvae), *Cooperia spatulata* (adults), *Cooperia surnabada* (adults

and fourth-stage larvae), *Nematodirus helvetianus* (adults), *Oesophagostomum radiatum* (adults and fourth-stage larvae), *Trichuris* spp. (adults); Lungworms: *Dictyocaulus viviparus* (adults and fourth-stage larvae); Cattle grubs: *Hypoderma bovis* and *Hypoderma lineatum;* Mites: *Psoroptes ovis* (*Psoroptes communis* var. *bovis*); Lice: *Linognathus vituli* and *Solenopotes capillatus.* For protection from reinfection with *Dictyocaulus viviparus* and *Oesophagostomum radiatum* for 42 days after treatment, with *Haemonchus placei* for 35 days after treatment, and with *Ostertagia ostertagi* and *Trichostrongylus axei* for 14 days after treatment.

(3) *Limitations.* Cattle must not be slaughtered for human consumption within 21 days of treatment. This drug product is not approved for use in female dairy cattle 20 months of age or older, including dry dairy cows. Use in these cattle may cause drug residues in milk and/or in calves born to these cows. A withdrawal period has not been established for preruminating calves. Do not use in calves to be processed for veal.

§ 522.1696b [Amended]

■ 37. In § 522.1696b, amend paragraph (d)(2)(iii)(C), by removing ''For Nos. 054771 and 055529:''.

§ 522.1885 [Removed]

■ 38. Remove § 522.1885.

■ 39. Amend § 522.2120 by adding a sentence at the end of paragraph (d)(1)(ii) to read follows:

§ 522.2120 Spectinomycin hydrochloride.

* * * * *

(d) * * *

(1) * * *

(ii) * * * Federal law restricts this drug to use by or on the order of a licensed veterinarian.

* * * * *

§ 522.2200 [Removed]

■ 40. Remove § 522.2200.

■ 41. In 522.2630, revise paragraph (b)(2) to read as follows:

§ 522.2630 Tulathromycin.

* * * * *

(b) * * *

(2) Nos. 013744, 051311, 054771, 058198, and 068504 for use of product described in paragraph (a)(2) as in paragraphs (d)(1)(i), (d)(1)(ii)(B), (d)(1)(iii)(B), and (d)(2) of this section.

* * * * *

PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

■ 42. The authority citation for part 524 continues to read as follows:

Authority: 21 U.S.C. 360b.

■ 43. In § 524.770, revise paragraph (b) to read as follows:

§ 524.770 Doramectin.

* * * * *

(b) *Sponsors.* See Nos. 051072 and 054771 in § 510.600(c) of this chapter.

* * * * *

■ 44. In § 524.814, revise paragraphs (b) and (e)(1) to read as follows:

§ 524.814 Eprinomectin.

* * * * *

(b) *Sponsors.* See Nos. 000010, 051072, and 055529 in § 510.600(c) of this chapter.

* * * * *

(e) * * *

(1) *Amount.* Apply 5 mg (1 mL) per 10 kilograms (kg) of body weight (500 micrograms/kg) topically along backbone from withers to tailhead.

* * * * *

§ 524.1044e [Amended]

■ 45. Amend § 524.1044e by adding a sentence at the end of paragraph (d)(3) to read as follows:

§ 524.1044e Gentamicin spray.

* * * * *

(d) * * *

(3) * * * Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 524.1146 [Amended]

■ 46. In § 524.1146, in paragraph (b)(3), remove ''Nos. 051072 and 058198'' and in its place add ''Nos. 051072, 055529, 058198, and 061651''.

§ 524.1484j [Removed]

■ 47. Remove § 524.1484j.

§ 524.2101 [Amended]

■ 48. In § 524.2101, in paragraph (b), remove ''000010, 000061,'' and in its place add ''000061''.

§ 524.2483 [Amended]

■ 49. In § 524.2483, in paragraph (b), remove ''Nos. 000010 and 054925'' and in its place add ''No. 054925''.

PART 526—INTRAMAMMARY DOSAGE FORM NEW ANIMAL DRUGS

■ 50. The authority citation for part 526 continues to read as follows:

Authority: 21 U.S.C. 360b.

■ 51. Amend § 526.1696 by adding a sentence at the end of paragraph (d)(3) and paragraph (e)(3) to read as follows:

§ 526.1696 Penicillin G procaine.

* * * * *

(d) * * *

(3) * * * For No. 042791: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(e)

(3) * * * For No. 042791: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

PART 529—CERTAIN OTHER DOSAGE FORM NEW ANIMAL DRUGS

■ 52. The authority citation for part 529 continues to read as follows:

Authority: 21 U.S.C. 360b.

§ 529.40 [Removed]

■ 53. Remove § 529.40.

PART 556—TOLERANCES FOR RESIDUES OF NEW ANIMAL DRUGS IN FOOD

■ 54. The authority citation for part 556 continues to read as follows:

Authority: 21 U.S.C. 342, 360b, 371.

§ 556.620 [Removed]

■ 55. Remove § 556.620.

■ 56. Revise § 556.730 to read as follows:

§ 556.730 Thiabendazole.

(a) [Reserved]

(b) *Tolerances.* The tolerances for thiabendazole are:

(1) *Cattle*—(i) Edible tissues (excluding milk): 0.1 ppm.

(ii) Milk: 0.05 ppm.

(2) [Reserved]

(c) *Related conditions of use.* See § 558.600.

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

■ 57. The authority citation for part 558 continues to read as follows:

Authority: 21 U.S.C. 354, 360b, 360ccc, 360ccc–1, 371.

■ 58. In § 558.311, revise paragraph (e)(3)(iii) to read as follows:

§ 558.311 Lasalocid.

* * * * *

(e) * * *

(3) * * *

Lasalocid amount	Indications for use	Limitations	Sponsor
* *	* *	* * *	*
(iii) Not less than 60 mg or more than 300 mg of lasalocid per head per day.	Pasture cattle (slaughter, stocker, feeder cattle, and beef replacement heifers): For increased rate of weight gain.	Feed continuously at a rate of not less than 60 mg or more than 300 mg of lasalocid per head per day when on pasture. The drug must be contained in at least 1 pound of feed. Daily intakes of lasalocid in excess of 200 mg/head/day have not been shown to be more effective than 200 mg/head/day.	054771
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■ 50. In § 558.455, revise paragraph (e)(5) to read as follows:

§ 558.455 Oxytetracycline and neomycin.

* * * * *

(e) * * *

(5) *Sheep.* It is used in feed as follows:

Oxytetracycline and neomycin sulfate amount	Indications for use	Limitations	Sponsors
(i) To provide 10 mg/lb of body weight daily.	Sheep: For treatment of bacterial enteritis caused by *Escherichia coli* and bacterial pneumonia caused by *Pasteurella multocida* susceptible to oxytetracycline; treatment and control of colibacillosis (bacterial enteritis) caused by *E. coli* susceptible to neomycin.	Feed continuously for 7 to 14 days. Treatment should continue 24 to 48 hours beyond remission of clinical signs of disease. Withdraw 5 days before slaughter.	066104 069254

(ii) [Reserved]

■ 59. Revise § 558.600 to read as follows:

§ 558.600 Thiabendazole.

(a) *Specifications.* Mineral protein block containing 3.3 percent thiabendazole.

(b) *Sponsor.* See No. 012286 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.730 of this chapter.

(d) *Special considerations.* See § 500.25 of this chapter.

(e) *Conditions of use in cattle*—(1) *Amount.* Provide free-choice to cattle on pasture or range accustomed to mineral protein block feeding for 3 days. Cattle should consume at a recommended level of 0.11 pound per 100 pounds of body weight per day. Animals maintained under conditions of constant worm exposure may require retreatment within 2 to 3 weeks.

(2) *Indications for use.* For control of infections of gastrointestinal roundworms (*Trichostrongylus, Haemonchus, Ostertagia,* and *Cooperia*).

(3) *Limitations.* Milk taken from animals during treatment and within 96 hours (8 milkings) after the latest treatment must not be used for food. Do not treat cattle within 3 days of slaughter.

Dated: April 26, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–09212 Filed 5–2–23; 8:45 am]

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 622

[Docket No. 230427–0115]

RIN 0648–BL89

Fisheries of the Caribbean, Gulf of Mexico, and South Atlantic; Reef Fish Resources of the Gulf of Mexico; Temporary Measures To Reduce Overfishing of Gag

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Final temporary rule.

SUMMARY: This final temporary rule implements interim measures to reduce overfishing of gag in Federal waters of the Gulf of Mexico (Gulf). This final temporary rule reduces the 2023 commercial and recreational sector harvest levels for gag and changes the 2023 recreational fishing season for gag in Federal waters of the Gulf. This temporary rule is effective for 180 days, but NMFS may extend the interim measures for a maximum of an additional 186 days. The purpose of this temporary rule is to reduce overfishing of gag while the long-term management measures are developed.

DATES: This final temporary rule is effective from May 3, 2023, until October 30, 2023.

ADDRESSES: An electronic copy of the environmental assessment (EA) supporting these interim measures may be obtained from the Southeast Regional Office website at *https://www.fisheries.noaa.gov/action/interim-action-reduce-overfishing-gag-gulf-mexico.* The EA includes a regulatory impact review and a Regulatory Flexibility Act (RFA) analysis.

FOR FURTHER INFORMATION CONTACT: Dan Luers, NMFS Southeast Regional Office, telephone: 727–824–5305, or email: *daniel.luers@noaa.gov.*

SUPPLEMENTARY INFORMATION: The reef fish fishery in the Gulf is managed under the Fishery Management Plan for the Reef Fish Resources of the Gulf of Mexico (FMP) and includes gag and 30 other managed reef fish species. The FMP was prepared by the Gulf of Mexico Fishery Management Council (Council) and is implemented by NMFS through regulations at 50 CFR part 622 under authority of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act).

On February 3, 2023, NMFS published a proposed temporary rule in the **Federal Register** and requested public comment (88 FR 7388). The proposed temporary rule and EA outline the rationale for the actions contained in this final temporary rule, and the EA is available from NMFS (see **ADDRESSES**

section). A summary of the management measures described in the EA and implemented by this temporary rule is provided below.

All weights described in this temporary rule are in gutted weight.

Gulf gag is harvested by the commercial and recreational sectors, with 39 percent of the total annual catch limit (ACL) allocated to the commercial sector and 61 percent allocated to the recreational sector. The gag stock was assessed in 2021 through the Southeast Data, Assessment, and Review (SEDAR) stock assessment process (SEDAR 72), and was determined to be overfished and undergoing overfishing. SEDAR 72 incorporated several modified data inputs from the previous gag stock assessment, including recreational catch and effort data generated by the Marine Recreational Information Program (MRIP) using the Fishing Effort Survey (FES; MRIP–FES). The MRIP–FES fully replaced the MRIP Coastal Household Telephone Survey (CHTS) in 2018. MRIP–FES generally estimates higher recreational effort, and thus higher recreational landings, than MRIP–CHTS. The recreational catch limits in this temporary rule are not directly comparable to the previous recreational catch limits because of the change from MRIP–CHTS to MRIP–FES to estimate recreational landings.

SEDAR 72 also accounted for observations of red tide mortality, since gag is vulnerable to red tide events and was negatively affected by these disturbances in 2005, 2014, 2018, and projected for 2021 directly within the stock assessment model. Lastly, modeling changes were made in SEDAR 72 to better quantify commercial discards by taking into account the potential misidentification between black grouper and gag, which are similar looking species, and to improve size estimates of gag retained by commercial and for-hire fishermen, and private anglers.

In November 2021, the Council's Scientific and Statistical Committee (SSC) reviewed SEDAR 72 and found it to be the best scientific information available for informing fisheries management. On January 26, 2022, NMFS notified the Council that gag was overfished and undergoing overfishing, and that measures to rebuild the stock and end overfishing must be implemented within 2 years, *i.e.,* by January 26, 2024. In response, the Council began work on Amendment 56 to the FMP. However, because the management measures in Amendment 56 are not expected to be effective until the 2024 fishing year, the Council requested that NMFS implement interim measures to reduce overfishing of gag during the 2023 fishing year. Specifically, the Council requested that NMFS implement reduced catch levels for gag using the current sector allocations of the total ACL, and that NMFS move the start of the gag recreational fishing season.

Management Measures Contained in This Final Temporary Rule

During the effectiveness of this temporary rule, the total ACL for gag is 661,901 lb (300,233 kg). This temporary rule also specifies the commercial and recreational sector ACLs and component commercial quotas using the existing sector allocations of the total ACL of 39 percent commercial and 61 percent recreational. The commercial ACL and commercial quota are 258,000 lb (117,027 kg) and 199,000 lb (90,265 kg), respectively. The recreational ACL is 403,759 lb (183,142 kg), and the recreational annual catch target (ACT) is 362,374 lb (164,370 kg).

The reduced catch limits requested by the Council are based on a rebuilding time that is equal to twice the time necessary to rebuild the stock if fishing mortality was reduced to zero, which is one of the rebuilding times considered in Amendment 56.

Although the Council requested a commercial ACL of 258,142 lb (117,091 kg) and commercial quota of 199,157 lb (90,336 kg) for 2023, the analyses conducted by NMFS supporting the implementation of interim measures use a commercial ACL and quota rounded to the nearest thousand pounds, as noted above. NMFS used the rounded numbers because they are consistent with the numerical format of the current gag commercial catch limits and the Council did not consider whether this practice should be continued for the purpose of the interim commercial catch limits. NMFS expects the Council to clearly articulate in Amendment 56 whether the commercial catch limits for gag should continue to be rounded to the nearest thousand pounds.

Because the commercial sector relies on the Individual Fishing Quota program for groupers and tilefishes (GT–IFQ program) that distributes commercial quota to shareholders for the entire fishing year, no change to the commercial fishing season would occur under this temporary rule. Further, the Council did not recommend interim modifications to the commercial sector's IFQ multi-use provision for gag and red grouper. Therefore, the gag and red grouper multi-use allocation will be available as specified in 50 CFR 622.22(a)(5).

In addition to the reduced gag catch limits, the Council requested that NMFS move the start of the gag recreational fishing season for the 2023 fishing year from June 1 to September 1. The Council also requested the season close on November 10, instead of remaining open through December 31, as it has in recent years. Therefore, the 2023 recreational fishing season will be open from September 1 through November 9, unless NMFS projects that the recreational ACL will be reached sooner and closes the recreational sector as required by the accountability measures (AM) specified in 50 CFR 622.41(r)(2).

The reduced recreational catch limits in this temporary rule will result in a shorter recreational season. However, the Council and NMFS expect that the change to the recreational season will mitigate the lower catch limits and will maximize the number of recreational fishing days for gag. If the opening date for the recreational season had remained June 1, 2023, NMFS projected that recreational landings of gag would reach the recreational ACL in only 16 days.

NMFS would implement the current AM of an in-season closure earlier if NMFS projects that recreational landings will meet or exceed the recreational ACL before the November 10 closure date.

The temporary reductions in the allowable harvest of gag will result in reduced allowable harvest for both the commercial and recreational sectors and a reduced recreational fishing season. The reduced harvest levels and shortened recreational fishing season will likely result in short-term adverse socio-economic effects. However, the temporary ACLs, commercial quota, and recreational ACT are expected to minimize future adverse socio-economic effects by potentially decreasing further reductions in the allowable harvest levels required to end overfishing of gag through Amendment 56. The temporary harvest levels in this rule will also provide biological benefits to the gag stock by reducing the past levels of fishing mortality.

Comments and Responses

NMFS received 24 comments during the public comment period on the proposed temporary rule. Most of the comments NMFS received were opposed to the interim measures for gag. NMFS acknowledges the comments in favor of the action in the proposed rule and agrees with them. Some comments were outside the scope of the proposed temporary rule, suggesting NMFS implement alternative management measures or apply restrictions to a specific fishery sector or component,

and those comments are not responded to in this final temporary rule. Comments that were opposed to or requested additional information about the actions contained in the proposed temporary rule are grouped as appropriate and summarized below, along with NMFS' responses.

Comment 1: The catch level reductions for gag are unnecessary because either the stock assessment is inaccurate or there is no shortage of gag in certain areas of the Gulf.

Response: NMFS disagrees that the reduction in the gag catch limits are unnecessary. The best scientific information available supports both the stock assessment results and the decision to reduce the catch limits through this temporary rule. The most recent stock assessment for Gulf gag (SEDAR 72) was completed in 2021 and determined that the stock is undergoing overfishing and is overfished. The assessment included a multi-day data review workshop and several webinars, and was reviewed by the Council's SSC, which concluded that SEDAR 72 was based on the best scientific information available. Although NMFS recognizes that the abundance of gag varies across locations in the Gulf, gag is managed as a single stock in the Gulf, and the stock assessment, which used Gulf-wide data, concluded that the overall abundance has declined precipitously since the previous gag stock assessment was completed in 2016. This conclusion is supported by the inability of both the commercial and recreation sectors to harvest their allotted quotas of gag. In the last 5 years covered by SEDAR 72 (2015–2019), the combined commercial and recreational harvest only exceeded 50 percent of the gag stock ACL once (2016).

Comment 2: The recreational season for gag should be open from October through December because that is when gag move closer to shore.

Response: The Council recommended a recreational season opening on September 1 because public comments from stakeholders supported the longest season possible. The season starting September 1 is scheduled for a maximum of 70 days, closing on November 10, while the alternative start dates considered for the recreational season resulted in shorter season estimates. NMFS estimated that a June 1 start date would last only 16 days; an October 1 start date is estimated to last 55 days; and a November 1 start date is estimated to last 29 days. Thus, even if an October 1 start date for the recreational season was implemented, NMFS projected the season would only last until late November. In addition, shorter seasons are more likely to result in ''derby-like'' fishing, where greater effort and greater numbers of fish are harvested in a shorter period, and fishermen may decide go out in more dangerous conditions.

Comment 3: NMFS should reduce the recreational bag limit from two fish to one fish instead of reducing the season length. Alternatively, NMFS should reduce bag limit to one fish and reduce the recreational season length.

Response: The Council did not consider an action to change the existing bag limit for gag, nor recommend that NMFS reduce the gag two-fish bag limit through this temporary rule. Additional analysis is necessary to determine the combined impacts of reducing the bag limit and shortening the open season. The Council has indicated that it may explore a bag limit reduction in the future, which would provide the opportunity to complete this additional analysis and evaluate whether a reduction in bag limit combined with the change to the open season would achieve the desired reduction in harvest.

Comment 4: Although the commercial quota and recreational ACT are decreased by 79 percent, the recreational season length in number of days is only reduced by 61 percent. The percentage reduction in recreational fishing days should be the same as the reduction in the recreational ACT.

Response: This temporary rule shortens the recreational season for gag from 214 days (June 1 through December 31) to 70 days (September 1 through November 9), which is approximately a 67 percent reduction. In addition, consistent with the current accountability measures, this temporary rule limits recreational harvest to the recreational ACL also set in this rule, not the recreational ACT. The recreational ACL will be reduced from 1,903,000 lb (863,186 kg) to 403,759 lb (183,142 kg). However, as explained above, these catch limits are not directly comparable because of the change from MRIP–CHTS to MRIP–FES to estimate recreational landings. Further, NMFS would not expect the reduction in the ACL to directly correspond to the reduction in the season length because recreational fishing effort and catch rates for gag change during a fishing year, so the time of year when fishing occurs is important in projecting how quickly the catch limit will be reached. This temporary rule will change the start date for the gag recreational season from June 1 to September 1. Because the recreational harvest of gag in total pounds is historically much lower in September and October than in June, NMFS projects that it will take longer to catch the decreased ACL than it would if the season were to open on June 1.

Comment 5: The proposed recreational season of September 1 through November 9 is problematic for three reasons. First, the catch rates of gag in June, July, and August are low and a recreational closure during this time will not have a significant reduction on recreational harvest. Second, gag are commonly caught while targeting red snapper and a closure for gag from June through August, when red snapper harvest is generally at its peak, will most likely cause a significant number of gag discards in deep water. Therefore, the gag season should be open concurrent with the red snapper season to reduce bycatch of gag during that time, and then close the gag season late in the year, such as, an open season from June 1 through September 30. Separating the fishing seasons for gag and red snapper seems more likely to maximize bycatch, not minimize it to the extent practicable as required by National Standard 9. Last, the recreational season of September 1 through November 9 will heavily favor commercial fishermen instead of recreational fishermen due to the less favorable weather conditions at that time of year.

Response: NMFS has determined that the change in the recreational open season implemented through this temporary rule will reduce gag bycatch and bycatch mortality, to the maximum extent practicable, consistent with the requirements of National Standard 9. The Council considered multiple factors in recommending the preferred alternative for the start date of the gag recreational season, including the season length projections, economic concerns, especially associated with the for-hire sector, and the potential changes in bycatch. The Council determined that it is important to provide recreational fishermen and for-hire businesses the longest season possible to harvest the recreational ACL. A season starting September 1 (the longest projected season length of the alternatives considered) is scheduled to be open for 70 days, while a season beginning June 1 (the shortest projected season) is projected to last 16 days. Although gag catch rates, *i.e.,* catch per unit effort, may be lower during June through August, concurrent with most of the Gulf States recreational seasons for red snapper and with the Federal red snapper for-hire season, than in some months later in the year (*e.g.,* November), the total pounds of gag harvested during this season is higher

than any other time in the year due to the higher number of anglers that harvest gag. This is because of the larger number of recreational fishermen targeting reef fish, and also likely due to relatively favorable fishing weather and the open red snapper season. In addition, a June 1 start date would have the greatest adverse economic effects on the for-hire component because during the limited 16-day season fishermen on for-hire vessels would have to take single trips to harvest both red snapper and gag, instead of having a different season to schedule trips for the two species. Thus, a June 1 season is expected to result in a decreased number of trips and decreased revenue for the for-hire component.

With respect to bycatch, opening the recreational season on June 1 would require recreational fishermen to discard all gag caught after the short 16-day season concludes. Although the September 1 opening may result in discards during the few weeks that the season would have been open in early June, it is also expected to eliminate targeted harvest of gag from June 1 through August 31. Many experienced fishermen have explained during public meetings that gag can be avoided when targeting other species, including red snapper. Thus, although there are uncertainties with regard to the extent of bycatch given each of the season opening dates, NMFS expects the September 1 season opening to reduce gag mortality during the peak of the red snapper recreational season, reduce overall gag mortality, and also provide economic and social benefits to the recreational sector.

NMFS does not believe the recreational season in this temporary rule will favor commercial fishermen over recreational fishermen. Because there are separate commercial and recreational catch limits, harvest by the commercial sector will not impact the recreational season. This longer recreational season will provide the greatest flexibility to recreational fishermen to avoid periods of poor weather and harvest gag, compared to the other shorter seasons that the Council considered. Further, in at least some areas, gag move closer to shore in the fall as the water cools, which may allow for safer access by anglers when compared to areas farther offshore where gag occur in the summer. The cooler, shallower water may also reduce release mortality for those gag that are caught but cannot be kept.

Comment 6: The initial regulatory flexibility analysis (IRFA) for the proposed temporary rule is faulty because it does not account for effects on commercial crew members.

Response: Analyses conducted to satisfy the requirements of the RFA only consider the effects of a rule on entities subject to the regulation (*i.e.,* entities to which the rule will directly apply) rather than entities indirectly affected by the regulation. Because the commercial quota for gag is allocated to businesses that possess shares for gag in the GT–IFQ program, crew members on commercial fishing vessels who do not also possess such shares would be indirectly rather than directly affected by the temporary rule. Therefore, consideration of effects on individual crew members is outside the scope of the IRFA analysis.

Comment 7: The temporary rule will adversely affect consumers who purchase gag by raising prices or they will not be able to purchase the fish.

Response: NMFS agrees that the reduction in the commercial quota proposed by this temporary rule would be expected to temporarily increase the ex-vessel price of gag, which would likely be passed on to consumers and result in a decrease in consumer surplus, *i.e.,* economic value to consumers. Specifically, Table 4.1.3.2 in the environmental assessment indicates that the ex-vessel price of gag is expected to increase by $1.44 per lb, which in turn is expected to reduce consumer surplus by $497,585, over the maximum effective period of the temporary rule, 366 days. These economic losses for consumers cannot be avoided because NMFS has determined that the commercial quota reduction in this temporary rule is necessary to reduce overfishing of gag while a rebuilding plan is being developed.

Comment 8: The gag commercial quota reduction will cause extreme hardship to commercial fishermen and their families, their communities, and the seafood supply chain, and could have been avoided or at least mitigated had the Council and NMFS acted sooner. The reduction in the recreational catch limits will cause for-hire vessels to go out of businesses or greatly affect their ability to make a living, and may cause effort to shift to other species.

Response: NMFS recognizes that the temporary rule may cause economic hardships for commercial and recreational for-hire stakeholders and communities reliant on gag. However, not reducing harvest would be expected to result in further declines to the gag population and greater economic hardships in the longer term. Regarding the timeliness of this action, the Council and NMFS use the SEDAR process to assess the abundance and health of populations of several managed stocks. The gag stock has been assessed frequently since 2006, with some assessments indicating the population was overfished and overfishing was occurring, and other assessments indicating the population was healthy. Prior to SEDAR 72, the next most recent stock assessment (SEDAR 33 Update, 2016) indicated the gag population was healthy. Thus, the Council and NMFS did not have sufficient information to support reducing catch levels prior to the Council receiving the results of SEDAR 72 at its September 2021 meeting. Stock assessments take several years to complete, so the data from the stock assessment may be several years old before a final rule can be implemented, and thus a population status may change before the Council and NMFS receive the results.

Comment 9: The temporary rule is unlikely to achieve its purpose due to unconstrained and inaccurate estimates of recreational discards. The temporary rule does not adequately track or account for dead discards of gag by the recreational sector. It is unclear if NMFS' analysis takes into account the potential for increased directed fishing for gag during the new open fishing season, which could increase catch rates beyond what was historically observed during that period of time and thus fail to control overall fishing mortality. The analysis concludes that overall gag mortality is expected to decrease, but the basis for that conclusion is not explained. It does not appear that the temporary rule or the accompanying analysis quantifies the numbers of gag expected to be caught and discarded dead as bycatch by recreational anglers during the closed or open seasons, or the potential for increased directed fishing pressure during the proposed 70-day fishing season. Without those figures, the public has no way to assess the actual impact on ''overall gag mortality.''

Response: The purpose of this temporary rule is to reduce overfishing of gag during the 2023 fishing year while the Council and NMFS work to implement permanent measures to end overfishing and rebuild the stock. As explained in the response to *Comment 5,* NMFS recognizes that shifting the recreational season may change fishing pressure during the fall months and the magnitude of gag discards during the red snapper season. However, NMFS does not agree that it is necessary to quantify expected discards to conclude that the reduction in the commercial and recreational catch limits will

achieve the purpose of reducing overfishing during this interim period. As explained in the environmental assessment supporting this rule, the average total gag commercial and recreational landings between 2017 and 2021 was over 3 million lb (1,360,777 kg). This temporary rule is expected to constrain total harvest in 2023 to 661,901 lb (300,233 kg) and, therefore, regardless of any uncertainty related discard mortality, reduce overfishing compared to the status quo catch limits and recent landings. Further, the Council considered uncertainty in the catch rates when recommending the September 1 to November 10 recreational season. This 70-day season is more conservative than NMFS' current estimate for the season length based on previous years of fishing effort during September through December, which suggests that it would take 80 to 96 days to harvest the revised gag recreational ACL. The shorter 70-day season accounts for changes in effort that may occur due to the new season timeframe, and provide a buffer in case recreational landings are higher than estimated. Also, NMFS will use all available data, including final 2022 recreational data, which are not yet available, to determine whether the season should be reduced further. If the data indicate a recreational closure for gag is necessary to avoid exceeding its recreational ACL prior to November 10, NMFS will close the season.

Comment 10: The voluntary data collection from private recreational anglers that occurs through MRIP–FES is delayed by months after landings occur and before they are available for use by management. NMFS does not explain how it will obtain sufficient information from the recreational sector about what is caught during the proposed open season in time to actually shorten that season.

Response: NMFS will use the best data available to project the duration of the recreational season. The recreational season implemented by this final temporary rule will be a maximum of 70 days and is based on a conservative estimate that is expected to result in landings less than the new recreational ACL for gag. NMFS will continue to run projections that include newly available recreational landings, such as the final 2022 recreational landings of gag, which are not included in the current projection. If the updated projections indicate that recreational landings will reach the recreational ACL before November 10, NMFS will shorten the season.

Future Action

NMFS has determined that this temporary rule is necessary to reduce overfishing of gag. NMFS considered all public comments received within the scope of the proposed temporary rule in the determination of whether to proceed with a final temporary rule and whether any revisions to the final temporary rule were appropriate. This final temporary rule is effective for 180 days after the date of publication in the **Federal Register**, as authorized by section 305(c) of the Magnuson-Stevens Act. The temporary rule could be extended for up to an additional 186 days if NMFS publishes a temporary rule extension in the **Federal Register**, because the public has had an opportunity to comment on the proposed temporary rule, and the Council is actively preparing an FMP amendment to address overfishing on a permanent basis.

Classification

This action is issued pursuant to section 305(c) of the Magnuson-Stevens Act, 16 U.S.C. 1855(c). The NMFS Assistant Administrator has determined that this temporary rule is consistent with the Magnuson-Stevens Act and other applicable law.

This temporary rule has been determined to be not significant for purposes of Executive Order 12866.

The Magnuson-Stevens Act provides the legal basis for this temporary rule. No duplicative, overlapping, or conflicting Federal rules have been identified. In addition, no new reporting and record-keeping requirements are introduced by this temporary rule. This temporary rule contains no information collection requirements under the Paperwork Reduction Act of 1995.

NMFS prepared a final regulatory flexibility analysis (FRFA) for this temporary rule. The FRFA incorporates the IRFA, a summary of the significant issues raised by the public comments in response to the IRFA, NMFS' responses to those comments, and a summary of the analyses completed to support the action. NMFS' responses to public comments regarding the IRFA and the Executive Order 12866 analysis are in the **SUPPLEMENTARY INFORMATION** section of the preamble under the Comments and Responses heading. A copy of the full analysis is available from NMFS (see **ADDRESSES**). A summary of the FRFA follows.

The objective of this temporary rule is to use the best scientific information available to reduce overfishing of gag while a rebuilding plan is developed, consistent with the authority under the Magnuson-Stevens Act. All monetary estimates in the following analysis are in 2019 dollars.

This temporary rule will revise the stock ACL, sector ACLs, commercial quota, and recreational ACT for gag based on the ''TMin*2'' rebuilding scenario, which is twice the minimum time for the stock to rebuild with zero fishing mortality and is an alternative under consideration in Amendment 56. This temporary rule retains the existing sector allocations of the stock ACL of 39 percent to the commercial sector and 61 percent to the recreational sector, but will reduce the stock ACL, commercial ACL, recreational ACL, commercial quota and recreational ACT to 661,901 lb (300,233 kg), 258,000 lb (117,027 kg), 403,759 lb (183,142 kg), 199,000 lb (90,265 kg), and 362,374 lb (164,370 kg), respectively. The recreational portion of the revised stock ACL, the recreational ACL, and the recreational ACT are based on MRIP–FES data. This temporary rule will also change the recreational season start date from June 1 to September 1, and close the season on November 10 unless NMFS projects the recreational ACL to be met sooner. As a result, this temporary rule is expected to regulate commercial fishing businesses that possess shares of gag in the GT–IFQ program and for-hire fishing businesses that target gag.

The gag commercial quota is allocated annually based on the percentage of gag shares in each IFQ account. For example, if an account possesses 1 percent of the gag shares and the commercial quota is 1 million lb (0.45 million kg), then that account would receive 10,000 lb (4,536 kg) of commercial gag quota. Although it is common for a single IFQ account with gag shares to be held by a single business, some businesses have multiple IFQ accounts with gag shares. As of July 8, 2021, 506 IFQ accounts held gag shares. These accounts and gag shares were owned by 455 businesses. Thus, NMFS assumes this temporary rule would regulate 455 commercial fishing businesses.

A valid charter vessel/headboat permit for Gulf reef fish is required to legally harvest gag on a recreational for-hire fishing trip. NMFS does not possess complete ownership data regarding businesses that hold a charter vessel/headboat permit for Gulf reef fish, and thus potentially harvest gag. Therefore, it is not currently feasible to accurately determine affiliations between vessels and the businesses that own them. As a result, for purposes of this analysis, NMFS assumes each for-hire vessel is independently owned by a single business, which NMFS expects to result in an overestimate of the actual number

of for-hire fishing businesses regulated by this temporary rule.

NMFS also does not have data indicating how many for-hire vessels actually harvest gag in a given year. However, in 2020, there were 1,289 vessels with valid charter vessel/headboat permits for Gulf reef fish. Further, gag is only targeted and almost entirely harvested in waters off the west coast of Florida. Of the 1,289 federally permitted vessels, 803 were homeported in Florida. Of these permitted vessels, 62 are primarily used for commercial fishing rather than for-hire fishing purposes, and thus are not considered for-hire fishing businesses. In addition, 46 of these permitted vessels are considered headboats, which are considered for-hire fishing businesses. However, headboats take a relatively large, diverse set of anglers to harvest a diverse range of species on a trip, and therefore do not typically target a particular species exclusively. Therefore, NMFS assumes that no headboat trips would be canceled, and thus no headboats would be directly affected as a result of this regulatory action. However, charter vessels often target gag. Of the 803 vessels with a valid charter vessel/headboat permit for Gulf reef fish that are homeported in Florida, 695 vessels are charter vessels. A recent study reported that 76 percent of charter vessels with a valid charter vessel/headboat permit in the Gulf were active in 2017, *i.e.,* 24 percent were not fishing. A charter vessel would only be directly affected by this temporary rule if it used to go fishing. Given this information, NMFS' best estimate of the number of charter vessels that are likely to harvest gag in a given year is 528, and thus this temporary rule is estimated to regulate 528 for-hire fishing businesses.

For RFA purposes, NMFS has established a small business size standard for businesses, including their affiliates, whose primary industry is commercial fishing (50 CFR 200.2). A business primarily involved in the commercial fishing industry is classified as a small business if it is independently owned and operated, is not dominant in its field of operation (including its affiliates), and its combined annual receipts (revenue) are not in excess of $11 million for all of its affiliated operations worldwide. NMFS does not collect revenue data specific to commercial fishing businesses that have IFQ accounts; rather, revenue data are collected for commercial fishing vessels in general. It is not possible to assign revenues earned by commercial fishing vessels back to specific IFQ accounts and the businesses that possess them because quota is often transferred across many IFQ accounts before it is used by the business on a vessel for harvesting purposes, and specific units of quota cannot be tracked. However, from 2016 through 2020, the maximum annual gross revenue earned by a single vessel during this time was about $1.73 million in 2016. The average gross revenue per vessel was about $108,000 in that year. By 2020, the maximum and average gross revenue per vessel had decreased to about $730,000 and $79,700, respectively. Based on this information, all commercial fishing businesses regulated by this temporary rule are determined to be small entities for the purpose of this analysis.

For other industries, the Small Business Administration has established size standards for all major industry sectors in the U.S., including for-hire businesses (North American Industry Classification System code 487210). A business primarily involved in for-hire fishing is classified as a small business if it is independently owned and operated, is not dominant in its field of operation (including its affiliates), and has annual receipts (revenue) not in excess of $12.5 million for all its affiliated operations worldwide. The maximum annual gross revenue for a single headboat in the Gulf was about $1.38 million in 2017. On average, annual gross revenue for headboats in the Gulf is about three times greater than annual gross revenue for charter vessels, reflecting the fact that businesses that own charter vessels are typically smaller than businesses that own headboats. Based on this information, all for-hire fishing businesses regulated by this temporary rule are determined to be small businesses for the purpose of this analysis.

If implemented, NMFS expects this temporary rule to regulate 455 of the 536 businesses with IFQ accounts, or approximately 85 percent of those commercial fishing businesses. Further, NMFS expects this temporary rule would regulate 528 of the 1,227 for-hire fishing businesses with valid charter vessel/headboat permits for Gulf reef fish, or approximately 43 percent of those for-hire fishing businesses. NMFS has determined that, for the purpose of this analysis, all regulated commercial and for-hire fishing businesses are small entities. Based on this information, NMFS expects the temporary rule to affect a substantial number of small entities.

Because revenue and cost data are not collected for the commercial fishing businesses that are expected to be regulated by this temporary rule, direct estimates of their economic profits are not available. However, economic theory suggests that annual allocation (quota) prices should reflect expected annual economic profits, which allows economic profits to be estimated indirectly. Further, the 455 businesses with gag shares also own shares in the other IFQ share categories and thus are expected to earn profits from their ownership of these shares as well, *i.e.,* red snapper, red grouper, shallow-water grouper, deep-water grouper, and tilefish.

However, economic profits will only be realized if the allocated quota is used for harvesting purposes. For example, practically all of the commercial red snapper quota has been used for harvesting in recent years, and so NMFS assumes that all of that quota will be harvested in the foreseeable future. Important management changes have occurred for red grouper, which partly resulted in 96 percent of the commercial quota being harvested in 2021. Thus, this analysis also assumes that all of the red grouper quota will be harvested in the future as well. However, based on 2017–2021 data, only 82 percent of the deep-water grouper quota, 38 percent of the shallow-water grouper quota, and 73 percent of the tilefish quota have been harvested, and that is expected to continue in the foreseeable future. For gag, the quota utilization rate from 2017–2021 was approximately 52 percent. Given these quota utilization rates in combination with average annual allocation prices from 2017–2021 and annual commercial quotas in 2021, the total expected economic profits for businesses with gag shares are estimated to be at least $29.4 million at the present time. This estimate does not account for any economic profits that may accrue to businesses with gag shares that also own commercial fishing vessels that harvest non-IFQ species. Such profits are likely to be small because harvest of IFQ species accounts for around 84 percent of commercial IFQ vessels' annual revenue and economic profits from the harvest of non-IFQ species tend to be smaller than those from IFQ species. Given that there are 455 businesses with gag shares, the average annual expected economic profit per commercial fishing business is at least $64,620.

However, most of these economic profits (82 percent) are the result of owning red snapper shares. Only approximately $502,930 (or 1.7 percent) of their expected economic profits is due to the ownership of gag shares. This temporary rule is only expected to affect economic profits from the ownership of gag shares, specifically because of the action that reduces the gag commercial

ACL from 1.217 million lb (0.552 million kg) to 258,000 lb (117,027 kg) and the gag commercial quota from 939,000 lb (426,000 kg) to 199,000 lb (90,265 kg). Average annual commercial landings of gag from 2017–2021 were 492,401 lb (223,349 kg). Because average annual landings exceed the commercial quota, NMFS assumes all of the commercial quota will be harvested in the future. Further, the expected reduction in annual commercial landings is 293,401 lb (133,084 kg). The reduction in commercial landings is expected to increase the average ex-vessel price of gag from $6.10 per lb to $7.54 per lb, thereby partially offsetting the adverse effects of the expected landings reduction. Thus, the expected reduction in annual ex-vessel revenue for gag is approximately $1.5 million, over the maximum effective period of the temporary rule, 366 days. Given an average annual allocation price of $1.03 per lb for gag from 2017–2021, the expected reduction in commercial landings of gag is expected to reduce economic profits to these commercial fishing businesses by about $302,200, or by approximately $660 per commercial fishing business. Thus, economic profit is expected to be reduced by no more than 1 percent on average per commercial fishing business.

Based on the most recent information available, average annual profit is $27,948 per charter vessel. The action that revises the stock ACL changes the gag recreational ACL from 1.903 million lb (0.86 million kg) in MRIP–CHTS units to 403,759 lb (183,142 kg) in MRIP–FES units. The terms ''MRIP–CHTS units'' and ''MRIP–FES units'' signify that although the current and recreational ACLs are expressed in pounds, they are in different scales and not directly comparable. However, average recreational landings from 2017–2021 were approximately 2.538 million lb (1.151 million kg) in MRIP–FES units. Given that average recreational landings have been considerably greater than the recreational ACL, all of the recreational ACL is expected to be harvested in the future. The recreational ACL reduction would be expected to reduce the recreational season length from 214 days to 16 days, which in turn is expected to reduce the number of trips targeting gag on charter vessels by 26,542 angler trips. Net Cash Flow per Angler Trip (CFpA) is the best available estimate of economic profit per angler trip by charter vessels. CFpA on charter vessels is estimated to be $149 per angler trip. Thus, NMFS expects the estimated reduction in charter vessel economic profits from this action to be $3.955 million. The reduction in charter vessel economic profits is estimated to be $7,490 per vessel, or almost 27 percent on average per for-hire fishing business.

The action that changes the recreational season would increase the number of target trips for gag by charter vessels during this period over the number of target trips in previous years by 2,159 trips, thereby partially mitigating the reduction in target trips due to the recreational ACL reduction. Assuming the CFpA on charter vessels is $149 per angler trip, this action is expected to increase economic profits for charter vessels by $321,733, or by $609 per charter vessel. Thus, economic profits are expected to be increased by around 2.2 percent on average per for-hire fishing business.

Based on the above, the total reduction in economic profits for charter vessels from this temporary rule is expected to be about $3.634 million, or approximately $6,882 per charter vessel. Thus, economic profits are expected to be reduced by approximately 24.6 percent on average per for-hire fishing business.

Three alternatives, including the status quo, were considered for the action to revise the gag stock ACL, commercial ACL, recreational ACL, commercial quota, and recreational ACT of 3.12 million lb (1.415 million kg), 1.217 million lb (0.552 million kg), 1.903 million lb (0.863 million kg), 939,000 lb (426,000 kg), and 1.708 million lb (0.775 million kg) based on MRIP–CHTS data. The action in this temporary rule will revise the same catch levels for gag to 661,901 lb (300,233 kg), 258,000 lb (117,027 kg), 403,759 lb (183,142 kg), 199,000 lb (90,265 kg), and 362,374 lb (164,370 kg), respectively, based on the TMin*2 rebuilding scenario and MRIP–FES data. Similar to the action in this temporary rule, the status quo alternative would have retained the current allocation of the stock ACL of 39 percent to the commercial sector and 61 percent to the recreational sector. But, it also would have maintained current the stock ACL, commercial ACL, recreational ACL, commercial quota, and recreational ACT stated earlier based on MRIP–CHTS data. The status quo alternative was not selected because it would not reduce overfishing of gag while a rebuilding plan is being developed, contrary to the purpose of this temporary rule.

A second alternative would have decreased the allocation percentage of the gag stock ACL to the commercial sector from 39 percent to 20.5 percent and increased the allocation percentage to the recreational sector from 61 percent to 79.5 percent. Further, based on the TMin*2 rebuilding scenario and MRIP–FES data, this alternative would have revised the gag stock ACL, commercial ACL, recreational ACL, commercial quota, and recreational ACT from 3.12 million lb (1.415 million kg), 1.217 million lb (0.552 million kg), 1.903 million lb (0.863 million kg), 939,000 lb (426,000 kg), and 1.708 million lb (0.775 million kg) based on MRIP–CHTS data to 611,578 lb (277,407 kg), 125,000 lb (56,699 kg), 486,204 lb (220,538 kg), 98,000 lb (44,452 kg), and 436,368 lb (197,933 kg). This alternative would have reduced overfishing while a rebuilding plan is being developed. However, because this temporary rule and an extension cannot in combination be in effect for more than 366 days, this alternative was not selected because the Council advised NMFS that it would prefer to address sector allocations for gag on a longer-term basis through an amendment to the FMP.

A third alternative would have decreased the allocation percentage of the gag stock ACL to the commercial sector from 39 percent to 18 percent and increased the allocation percentage to the recreational sector from 61 percent to 82 percent. Further, based on the TMin*2 rebuilding scenario and MRIP–FES data, this alternative would have revised the gag stock ACL, commercial ACL, recreational ACL, commercial quota and recreational ACT from 3.12 million lb (1.42 million kg), 1.217 million lb (0.55 million kg), 1.903 million lb (0.86 million kg), 939,000 lb (426,000 kg), and 1.708 million lb (0.78 million kg) based on MRIP–CHTS data to 605,165 lb (274,745 kg), 109,000 lb (49,486 kg), 496,235 lb (225,291 kg), 84,000 lb (38,136 kg), and 445,370 lb (202,198 kg). Similar to the second alternative, this alternative would have reduced overfishing while a rebuilding plan is being developed. However, because this temporary rule and an extension cannot be in effect for more than 366 days, this alternative was not selected because the Council advised NMFS that it would prefer to address sector allocations for gag on a longer-term basis through an amendment to the FMP.

Three alternatives, including the status quo, were considered for the action to change the recreational start date from June 1 to September 1, and close the season on November 10, unless NMFS projects the recreational ACL will be met sooner. The status quo alternative would have maintained the recreational season start date of June 1, which was expected to result in a recreational season length of only 16

days compared to 70 days under the action in this temporary rule. This alternative was not selected as it would not mitigate the adverse effects from the recreational ACL reduction and thereby would have resulted in greater adverse effects on small for-hire fishing businesses.

The second alternative would have changed the recreational season start date from June 1 to October 1, which would have resulted in a recreational season length of 55 days compared to 70 days under the action in this temporary rule. Although the second alternative would have mitigated some of the adverse effects from the recreational ACL reduction, this alternative was not selected because, given the shorter season length compared to the action, it would not allow for-hire fishing businesses as much flexibility in planning target trips for gag, which is particularly desirable during hurricane season, which occurs from June 1 through November 30 each year. Further, unlike the action in this temporary rule, this alternative does not have a fixed closure date, which would increase the probability of exceeding the recreational ACL relative to the action in this temporary rule.

The third alternative would have changed the recreational season start date from June 1 to November 1, which would have resulted in a recreational season length of 29 days compared to 70 days under the action in this temporary rule. Although the third alternative would have mitigated some of the adverse effects from the recreational ACL reduction, this alternative was not selected because it would not have mitigated those adverse effects as much as the action, thereby causing relatively greater adverse effects on small for-hire fishing businesses. Further, given the shorter season length compared to the action in this temporary rule, it would not allow for-hire fishing businesses as much flexibility in planning target trips for gag, which is particularly desirable during hurricane season. Also, similar to the second alternative, this alternative does not have a fixed closure date, which would increase the probability of exceeding the recreational ACL relative to the action in this temporary rule.

Section 212 of the Small Business Regulatory Enforcement Fairness Act of 1996 states that, for each rule or group of related rules for which an agency is required to prepare a FRFA, the agency shall publish one or more guides to assist small entities in complying with the rule, and shall designate such publications as ''small entity compliance guides.'' The agency shall explain the actions a small entity is required to take to comply with a rule or group of rules. As part of this rulemaking process, NMFS prepared a fishery bulletin that also serves as the small entity compliance guide. NMFS will send the fishery bulletin to all interested parties. A copy of this final temporary rule is available from NMFS (*see* **ADDRESSES**), and the small entity compliance guide is available on the NMFS website at *https://www.fisheries.noaa.gov/rules-and-announcements/bulletins.*

There is good cause under authority contained in 5 U.S.C. 553(d)(3) to waive the 30-day delay in effectiveness so that this final temporary rule can be effective by June 1, 2023. On December 13, 2022, NMFS published a temporary rule to withhold a portion of the commercial allocation of gag for the 2023 fishing year in anticipation of the reduction in the commercial quota in this final temporary rule (87 FR 76125). If this final temporary rule is not effective by June 1, 2023, the regulations at 50 CFR 622.22(a)(4) require NMFS to distribute the previously withheld commercial allocation, which would be contrary to the purpose of this rule to reduce overfishing for the 2023 fishing year. In addition, the current recreational fishing season opens on June 1. Therefore, this final temporary rule must be effective by that date to constrain recreational harvest to the reduced recreational catch limit while providing the maximum number of fishing days. NMFS was unable to publish this final temporary rule sooner because NMFS determined that it was important to solicit public comments on the interim measures, which substantially reduce the allowable harvest of gag for the 2023 fishing year, and it took time to complete the analyses supporting the proposed temporary rule and to respond to the comments received.

List of Subjects in 50 CFR Part 622

Fisheries, Fishing, Gag, Gulf of Mexico.

Dated: April 27, 2023.

Samuel D. Rauch, III,

Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

For the reasons set out in the preamble, NMFS amends 50 CFR part 622 as follows:

PART 622—FISHERIES OF THE CARIBBEAN, GULF OF MEXICO, AND SOUTH ATLANTIC

■ 1. The authority citation for part 622 continues to read as follows:

Authority: 16 U.S.C. 1801 *et seq.*

■ 2. In § 622.34:
■ a. Suspend paragraph (e); and
■ b. Add paragraph (i).
The addition reads as follows:

§ 622.34 Seasonal and area closures designed to protect Gulf reef fish.

* * * * *

(i) *Seasonal closure of the recreational sector for gag.* The recreational harvest of gag in or from the Gulf EEZ is closed from January 1 through August 31 and from November 10 through December 31. During the closure, the bag and possession limits for gag harvested in or from the Gulf EEZ are zero.

■ 3. In § 622.39:
■ a. Suspend paragraph (a)(1)(iii)(B); and
■ b. Add paragraph (a)(1)(iii)(D).
The addition reads as follows:

§ 622.39 Quotas.

* * * * *

(a) * * *
(1) * * *
(iii) * * *

(D) *Gag.* Shallow-water groupers (SWG) have a separate quota for gag, among the other species described in the introductory text of paragraph (a)(1)(iii) of this section, and as specified in this paragraph (a)(1)(iii)(D). This quota is specified in gutted weight, that is, eviscerated but otherwise whole. The commercial quota for gag is 199,000 lb (90,265 kg).

* * * * *

■ 4. In § 622.41:
■ a. Suspend paragraph (d); and
■ b. Add paragraph (r).
The addition reads as follows:

§ 622.41 Annual catch limits (ACLs), annual catch targets (ACTs), and accountability measures (AMs).

* * * * *

(r) *Gag*—(1) *Commercial sector.* The IFQ program for groupers and tilefishes in the Gulf of Mexico serves as the accountability measure for commercial gag. The commercial ACL in gutted weight is 258,000 lb (117,027 kg).

(2) *Recreational sector.* (i) Without regard to overfished status, if gag recreational landings, as estimated by the SRD, reach or are projected to reach the applicable ACLs specified in paragraph (r)(2)(iv) of this section, the AA will file a notification with the Office of the Federal Register, to close the recreational sector for the remainder of the fishing year. On and after the effective date of such a notification, the bag and possession limits of gag in or from the Gulf EEZ are zero. These bag and possession limits apply in the Gulf

on a vessel for which a valid Federal charter vessel/headboat permit for Gulf reef fish has been issued, without regard to where such species were harvested, *i.e.,* in State or Federal waters.

(ii) Without regard to overfished status, and in addition to the measures specified in paragraph (r)(2)(i) of this section, if gag recreational landings, as estimated by the SRD, exceed the applicable ACLs specified in paragraph (r)(2)(iv) of this section, the AA will file a notification with the Office of the Federal Register to maintain the gag ACT, specified in paragraph (r)(2)(iv) of this section, for that following fishing year at the level of the prior year's ACT, unless the best scientific information available determines that maintaining the prior year's ACT is unnecessary. In addition, the notification will reduce the length of the recreational gag fishing season the following fishing year by the amount necessary to ensure gag recreational landings do not exceed the recreational ACT in the following fishing year.

(iii) If gag are overfished, based on the most recent status of U.S. Fisheries Report to Congress, and gag recreational landings, as estimated by the SRD, exceed the applicable ACL specified in paragraph (r)(2)(iv) of this section, the following measures will apply. In addition to the measures specified in paragraphs (r)(2)(i) and (ii) of this section, the AA will file a notification with the Office of the Federal Register, at or near the beginning of the following fishing year to reduce the ACL for that following year by the amount of the ACL overage in the prior fishing year, and reduce the ACT, as determined in paragraph (r)(2)(ii) of this section, by the amount of the ACL overage in the prior fishing year, unless the best scientific information available determines that a greater, lesser, or no overage adjustment is necessary.

(iv) The recreational ACL in gutted weight is 403,759 lb (183,142 kg). The recreational ACT in gutted weight is 362,374 lb (164,370 kg).

[FR Doc. 2023–09336 Filed 5–2–23; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 648

[Docket No. 230427–0114]

RTID 0648–XC715

Fisheries of the Northeastern United States; Atlantic Spiny Dogfish Fishery; 2023 Specifications

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Final rule.

SUMMARY: NMFS issues final specifications for the 2023 Atlantic spiny dogfish fishery, as recommended by the Mid-Atlantic and New England Fishery Management Councils. This action is necessary to establish allowable harvest levels for the spiny dogfish fishery to prevent overfishing while enabling optimum yield, using the best scientific information available.

DATES: Effective on May 1, 2023.

ADDRESSES: The Mid-Atlantic Fishery Management Council prepared an environmental assessment (EA) for these specifications that describes the action, other considered alternatives, and analyses of the impacts of all alternatives. Copies of the specifications document, including the EA, are available on request from Dr. Christopher M. Moore, Executive Director, Mid-Atlantic Fishery Management Council, Suite 201, 800 North State Street, Dover, DE 19901. These documents are also accessible via the internet at *https://www.mafmc.org/action-archive.*

FOR FURTHER INFORMATION CONTACT: Cynthia Ferrio, Fishery Policy Analyst, (978) 281–9180.

SUPPLEMENTARY INFORMATION:

Background

The Mid-Atlantic and New England Fishery Management Councils jointly manage the Atlantic Spiny Dogfish Fishery Management Plan (FMP), with the Mid-Atlantic Council acting as the administrative lead. Additionally, the Atlantic States Marine Fisheries Commission manages the spiny dogfish fishery in state waters from Maine to North Carolina through an interstate fishery management plan. The Federal FMP requires the specification of an acceptable biological catch (ABC), annual catch limit (ACL), annual catch target (ACT), total allowable landings (TAL), and a coastwide commercial quota. These limits and other related management measures may be set for up to 5 fishing years at a time, with each fishing year running from May 1 through April 30. This action implements Atlantic spiny dogfish specifications for fishing year 2023, as recommended by the Councils and Commission.

In response to declining trends in stock biomass and productivity shown in a 2022 data update, the Mid-Atlantic Council's Scientific and Statistical Committee (SSC) recommended a 2023 ABC of 7,788 mt, a 55-percent decrease from fishing year 2022. Preliminary indications from the December 2022 Atlantic spiny dogfish research track assessment support the SSC's recommendations. Both the Mid-Atlantic and New England Councils accepted the SSC's recommended ABC, and recommended the subsequent catch limits in accordance with the specifications process, including a coast-wide commercial quota of 5,449 mt; a 59-percent decrease from fishing year 2022. Neither Council recommended any changes to other management measures, such as trip limits.

The proposed rule for this action published in the **Federal Register** on March 9, 2023 (88 FR 14590), and comments were accepted through March 24, 2023. NMFS received 18 comments from the public, and no changes were made to the final rule because of those comments (see Comments and Responses for additional detail). Additional background information regarding the development of these specifications was provided in the proposed rule and is not repeated here.

Final Specifications

This action implements the Councils' recommendations for 2023 Atlantic spiny dogfish specifications (Table 1), which are consistent with the Mid-Atlantic SSC's recommendations and the best available science. These final specifications decrease the ABC by 55 percent from fishing year 2022 and coastwide commercial quota by 59 percent, based on declining trends in stock biomass and productivity. This action makes no changes to the 7,500-lb (3,402-kg) trip limit.

TABLE 1—FINAL SPINY DOGFISH FISHERY SPECIFICATIONS FOR FISHING YEAR 2023

	Million lb	Metric tons
ABC	17.17	7,788
ACL = ACT	17.09	7,751
TAL	12.48	5,663

TABLE 1—FINAL SPINY DOGFISH FISHERY SPECIFICATIONS FOR FISHING YEAR 2023—Continued

	Million lb	Metric tons
Commercial Quota	12.01	5,449

The reduction in commercial quota is not expected to substantially change overall fishing activity, or result in catch overages or revenue losses in the spiny dogfish fishery. In recent years, the spiny dogfish quotas have not constrained landings in the fishery, and even with a 59-percent decrease the 2023 commercial quota will still be higher than the total annual landings in fishing year 2021. There is a 2023 management track stock assessment for Atlantic spiny dogfish that is expected to inform development of the next set of specifications for fishing year 2024.

Comments and Responses

The public comment period for the proposed rule ended on March 24, 2023, and NMFS received 18 comments from the public. No changes were made to the final rule as a result of these comments.

Comment 1: Twelve comments did not support the proposed decrease in 2023 commercial quota. Six of these comments simply opposed this action, and expressed reservations about the data used to determine that the stock is declining, because many fishing vessels regularly encounter high numbers of dogfish. They also mentioned that dogfish should continue to be fished, because they are a predator of more valuable fish. Four of these commenters were also specifically concerned about the effect that the reduction in quota may have on the few remaining processors that accept spiny dogfish, and that the industry itself (and not the stock) is at risk. Two of these comments also mentioned that managers should focus on the potential negative effects of wind farm development, because it could be affecting the dogfish stock more than fishing pressure.

Response: These specifications are based on the best available science, and impacts to industry or from offshore wind were discussed throughout the development of this action and analyzed in the EA for this action. As noted in the proposed rule and this final rule, although these specifications substantially reduce the annual quota, there are no substantial impacts expected to fishing behavior overall as a result of this reduction.

Comment 2: One commenter suggested that fishing behavior is impacted more by weather and market price than by quotas, so we should not compare quotas to annual landings.

Response: NMFS recognizes that there are other factors that may impact fishing behavior more than annual quotas, but is adjusting measures within and in accordance with the FMP, as appropriate, to prevent overfishing of the spiny dogfish stock.

Comment 3: Another commenter recommended reducing trip limits instead of the coastwide quota to better address fishing pressure on the stock.

Response: NMFS is adjusting the quota as described in the FMP specifications process based on the reduced ABC recommended by the Mid-Atlantic SSC to prevent overfishing of the stock. There has also been no substantial impact on fishing effort resulting from the trip limit increase in fishing year 2022.

Comment 4: Three comments were in support of this action as proposed, noting the need to protect the declining stock and acknowledging that the economic impacts of the quota reduction are expected to be minimal due to the comparatively low annual landings in recent years.

Response: NMFS agrees and is implementing the 2023 specifications as proposed.

Comment 5: One comment expressed concern about the overfishing of spiny dogfish, while also opposing this action in its entirety. However, no explanation or rationale was provided for the opposition to this action.

Response: The specifications in this final rule were developed and proposed to prevent overfishing on the spiny dogfish stock. NMFS is unable to respond further to this comment, as no specific reasons were given for the opposition to this action.

Changes From the Proposed Rule

There are no changes from the proposed rule.

Classification

Pursuant to section 304(b)(3) of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act), the NMFS Assistant Administrator, Greater Atlantic Region, has determined that these final specifications are necessary for the conservation and management of the Atlantic spiny dogfish fishery, and that they are consistent with the Atlantic Spiny Dogfish FMP, the Magnuson-Stevens Act, and other applicable law.

The need to implement these measures in a timely manner to ensure that these final specifications are in place for the start of the 2023 spiny dogfish fishing year constitutes good cause under the authority contained in 5 U.S.C. 553(d)(3) to waive the 30-day delay in the effective date of this action. The 2023 fishing year begins on May 1, 2023. A delay in the date of effectiveness beyond May 1 would be contrary to the public interest as it could create confusion in the spiny dogfish industry around current quotas, and with state agencies as they prepare their annual management measures. Furthermore, regulated parties do not require any additional time to come into compliance with this rule, and thus, a 30-day delay before the final rule becomes effective does not provide any benefit. Unlike actions that require an adjustment period, spiny dogfish fishing vessels will not have to purchase new equipment or otherwise expend time or money to comply with these management measures. Rather, complying with this final rule simply means adhering to the new catch limits set for the 2023 fishing year. Fishery stakeholders have also been involved in the development of this action and are anticipating this rule. For these reasons, there is good cause not to delay this final rule's effectiveness, consistent with 5 U.S.C. 553(d)(3), and to implement this action on May 1, 2023, for the start of the 2023 fishing year.

This final rule is not subject to review under Executive Order 12866 because the action contains no implementing regulations.

The Chief Counsel for Regulation of the Department of Commerce certified to the Chief Counsel for Advocacy of the Small Business Administration at the proposed rule stage that this action would not have a significant economic impact on a substantial number of small entities. The factual basis for the certification was published in the proposed rule and is not repeated here. No comments were received regarding this certification, and the initial certification remains unchanged. As a result, a final regulatory flexibility analysis is not required and none was prepared.

This final rule does not duplicate, conflict, or overlap with any existing Federal rules.

This action contains no information collection requirements under the Paperwork Reduction Act of 1995.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: April 27, 2023.

Samuel D. Rauch, III,

Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

[FR Doc. 2023–09391 Filed 5–1–23; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[Docket No. 230224–0053; RTID 0648–XC942]

Fisheries of the Exclusive Economic Zone off Alaska; Pacific Cod by Vessels Using Jig Gear in the Central Regulatory Area of the Gulf of Alaska

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Temporary rule; closure.

SUMMARY: NMFS is prohibiting directed fishing for Pacific cod by vessels using jig gear in the Central Regulatory Area of the Gulf of Alaska (GOA). This action is necessary to prevent exceeding the A season allowance of the 2023 total allowable catch of Pacific cod by vessels using jig gear in the Central Regulatory Area of the GOA.

DATES: Effective 1200 hours, Alaska local time (A.l.t.), April 28, 2023, through 1200 hours, A.l.t., June 10, 2023.

FOR FURTHER INFORMATION CONTACT: Obren Davis, 907–586–7241.

SUPPLEMENTARY INFORMATION: NMFS manages the groundfish fishery in the GOA exclusive economic zone according to the Fishery Management Plan for Groundfish of the Gulf of Alaska (FMP) prepared by the North Pacific Fishery Management Council under authority of the Magnuson-Stevens Fishery Conservation and Management Act. Regulations governing fishing by U.S. vessels in accordance with the FMP appear at subpart H of 50 CFR part 600 and 50 CFR part 679.

The A season allowance of the 2023 Pacific cod total allowable catch (TAC) apportioned to vessels using jig gear in the Central Regulatory Area of the GOA is 67 metric tons (mt) as established by the final 2023 and 2024 harvest specifications for groundfish in the GOA (88 FR 13238, March 2, 2023).

In accordance with § 679.20(d)(1)(i), the Regional Administrator has determined that the A season allowance of the 2023 Pacific cod TAC apportioned to vessels using jig gear in the Central Regulatory Area of the GOA will soon be reached. Therefore, the Regional Administrator is establishing a directed fishing allowance of 62 mt and is setting aside the remaining 5 mt as bycatch to support other anticipated groundfish fisheries. In accordance with § 679.20(d)(1)(iii), the Regional Administrator finds that this directed fishing allowance has been reached. Consequently, NMFS is prohibiting directed fishing for Pacific cod by vessels using jig gear in the Central Regulatory Area of the GOA.

While this closure is effective, the maximum retainable amounts at § 679.20(e) and (f) apply at any time during a trip.

Classification

NMFS issues this action pursuant to section 305(d) of the Magnuson-Stevens Act. This action is required by 50 CFR part 679, which was issued pursuant to section 304(b), and is exempt from review under Executive Order 12866.

Pursuant to 5 U.S.C. 553(b)(B), there is good cause to waive prior notice and an opportunity for public comment on this action, as notice and comment would be impracticable and contrary to the public interest, as it would prevent NMFS from responding to the most recent fisheries data in a timely fashion, and would delay the closure of Pacific cod by vessels using jig gear in the Central Regulatory Area of the GOA. NMFS was unable to publish a notice providing time for public comment because the most recent, relevant data only became available as of April 27, 2023.

The Assistant Administrator for Fisheries, NOAA also finds good cause to waive the 30-day delay in the effective date of this action under 5 U.S.C. 553(d)(3). This finding is based upon the reasons provided above for waiver of prior notice and opportunity for public comment.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: April 28, 2023.

Jennifer M. Wallace,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2023–09367 Filed 4–28–23; 4:15 pm]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register
Vol. 88, No. 85
Wednesday, May 3, 2023

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

NUCLEAR REGULATORY COMMISSION

10 CFR Part 50

[NRC–2018–0291]

RIN 3150–AK23

American Society of Mechanical Engineers Code Cases and Update Frequency; Extension of Comment Period

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule; extension of comment period.

SUMMARY: On March 6, 2023, the U.S. Nuclear Regulatory Commission (NRC) solicited comments on proposed amendments to its regulations to incorporate by reference proposed revisions to three regulatory guides, which would approve new, revised, and reaffirmed code cases published by the American Society of Mechanical Engineers. In addition, the rulemaking proposed to extend the time periods required for licensees to update their codes of record. The public comment period was originally scheduled to close on May 5, 2023. The NRC has decided to extend the public comment period by an additional 42 days to June 16, 2023, to allow more time for members of the public to develop and submit their comments.

DATES: The due date of comments requested in the document published on March 6, 2023 (88 FR 13717) is extended. Comments should be filed no later than June 16, 2023. Comments received after this date will be considered, if it is practical to do so, but the Commission is able to ensure consideration only for comments received on or before this date.

ADDRESSES: You may submit comments by any of the following methods (unless the document published on March 6, 2023, describes a different method for submitting comments on a specific subject); however, the NRC encourages electronic comment submission through the Federal rulemaking website:

- *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2018–0291. Address questions about NRC dockets to Dawn Forder; telephone: 301–415–3407; email: *Dawn.Forder@nrc.gov.* For technical questions contact the individuals listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *Email comments to: Rulemaking.Comments@nrc.gov.* If you do not receive an automatic email reply confirming receipt, then contact us at 301–415–1677.
- *Fax comments to:* Secretary, U.S. Nuclear Regulatory Commission at 301–415–1101.
- *Mail comments to:* Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, ATTN: Rulemakings and Adjudications Staff.
- *Hand deliver comments to:* 11555 Rockville Pike, Rockville, Maryland 20852, between 7:30 a.m. and 4:15 p.m. eastern time, Federal workdays; telephone: 301–415–1677.

For additional direction on obtaining information and submitting comments, see ''Obtaining Information and Submitting Comments'' in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Soly I. Soto Lugo, Office of Nuclear Material and Safeguards, telephone: 301–415–7528, email: *Soly.Sotolugo@nrc.gov* and Bruce Lin, Office of Nuclear Regulatory Research, telephone: 301–415–2446, email: *Bruce.Lin@nrc.gov.* Both are staff of the U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2018–0291 when contacting the NRC about the availability of information for this action. You may obtain publicly available information related to this action by any of the following methods:

- *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2018–0291.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *PDR.Resource@nrc.gov.* The ADAMS accession number for each document referenced (if it is available in ADAMS) is provided the first time that it is mentioned in this document.
- *NRC's PDR:* You may examine and purchase copies of public documents, by appointment, at the NRC's PDR, Room P1 B35, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852. To make an appointment to visit the PDR, please send an email to *PDR.Resource@nrc.gov* or call 1–800–397–4209 or 301–415–4737, between 8 a.m. and 4 p.m. eastern time (ET), Monday through Friday, except Federal holidays.

B. Submitting Comments

The NRC encourages electronic comment submission through the Federal rulemaking website (*https://www.regulations.gov*). Please include Docket ID NRC–2018–0291 in your comment submission.

The NRC cautions you not to include identifying or contact information that you do not want to be publicly disclosed in your comment submission. The NRC will post all comment submissions at *https://www.regulations.gov* as well as enter the comment submissions into ADAMS. The NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. Discussion

On March 6, 2023, the NRC solicited comments on proposed amendments to

its regulations to incorporate by reference proposed revisions to three regulatory guides, which would approve new, revised, and reaffirmed code cases published by the American Society of Mechanical Engineers. In addition, the NRC requested comments on its proposal to extend the time periods required for licensees to update their codes of record. The public comment period was originally scheduled to close on May 5, 2023.

On April 19, 2023, the NRC received two public comments (ADAMS Accession Nos. ML23109A141 and ML23109A142) requesting that the comment period for the proposed rule be extended by an additional 1 to 2 months. The requesters expressed that American Society of Mechanical Engineers (ASME) Code Committee meetings are scheduled for May 2023, and that these ASME meetings would be beneficial to allow discussions of the proposed rule before submission of any further public comments.

The NRC seeks to ensure that the public has a reasonable opportunity to provide the NRC with comments on this proposed action. The NRC acknowledges that discussions at the ASME Code Committee meetings may assist in the development of comments. The NRC has decided to extend the public comment period on this document until June 16, 2023, to allow more time for members of the public to submit their comments.

The NRC may post materials related to this document, including public comments, on the Federal rulemaking website at *https://www.regulations.gov* under Docket ID NRC–2018–0291. In addition, the Federal rulemaking website allows members of the public to receive alerts when changes or additions occur in a docket folder. To subscribe: (1) navigate to the docket folder (NRC–2018–0291); (2) click the ''Subscribe'' link; and (3) enter an email address and click on the ''Subscribe'' link.

Dated: April 26, 2023.

For the Nuclear Regulatory Commission.

Andrea D. Veil,

Director, Office of Nuclear Reactor Regulation.

[FR Doc. 2023–09218 Filed 5–2–23; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

10 CFR Parts 50 and 52

[NRC–2023–0054]

Draft Regulatory Guide: Quality Assurance Program Criteria (Design and Construction)

AGENCY: Nuclear Regulatory Commission.

ACTION: Draft guide; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is issuing for public comment a draft regulatory guide (DG), DG–1403, ''Quality Assurance Program Criteria (Design and Construction).'' This DG is proposed Revision 6 of Regulatory Guide (RG) 1.28 of the same name. The proposed revision endorses Nuclear Energy Institute (NEI) 14–05A, ''Guidelines for the Use of Accreditation in Lieu of Commercial Grade Surveys for Procurement of Laboratory Calibration and Test Services,'' Revision 1, issued November 2020, as an acceptable approach for licensees and suppliers subject to the quality assurance (QA) requirements of NRC regulations. Also in this proposed revision, the NRC staff endorses the Part I and Part II requirements included in NQA–1–2017, NQA–1–2019, and NQA–1–2022 for the implementation of a QA program during the design and construction phases of nuclear power plants and fuel reprocessing plants.

DATES: Submit comments by June 2, 2023. Comments received after this date will be considered if it is practical to do so, but the NRC is able to ensure consideration only for comments received on or before this date.

ADDRESSES: You may submit comments by any of the following methods; however, the NRC encourages electronic comment submission through the Federal rulemaking website:

- *Federal Rulemaking website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2023–0054. Address questions about Docket IDs in *Regulations.gov* to Stacy Schumann; telephone: 301–415–0624; email: *Stacy.Schumann@nrc.gov.* For technical questions, contact the individuals listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *Mail comments to:* Office of Administration, Mail Stop: TWFN–7–A06, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, ATTN: Program Management, Announcements and Editing Staff.

For additional direction on obtaining information and submitting comments, see ''Obtaining Information and Submitting Comments'' in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Andrea Keim, Office of Nuclear Reactor Regulation, telephone: 301–415–1671; email: *Andrea.Keim@nrc.gov,* or James Steckel, Office of Nuclear Regulatory Research, telephone: 301 415–1026; email: *James.Steckel@nrc.gov.* Both are staff members of the U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2023–0054 when contacting the NRC about the availability of information regarding this action. You may obtain publicly available information related to this action, by any of the following methods:

- *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2023–0054.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, at 301–415–4737, or by email to *PDR.Resource@nrc.gov.* The ADAMS accession number for each document referenced (if it is available in ADAMS) is provided the first time that it is mentioned in this document.
- *NRC's PDR:* You may examine and purchase copies of public documents, by appointment, at the NRC's PDR, Room P1 B35, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852. To make an appointment to visit the PDR, please send an email to *PDR.Resource@nrc.gov* or call 1–800–397–4209 or 301–415–4737, between 8 a.m. and 4 p.m. eastern time (ET), Monday through Friday, except Federal holidays.

B. Submitting Comments

The NRC encourages electronic comment submission through the Federal rulemaking website (*https://www.regulations.gov*). Please include Docket ID NRC–2023–0054 in your comment submission.

The NRC cautions you not to include identifying or contact information that you do not want to be publicly

disclosed in your comment submission. The NRC will post all comment submissions at *https://www.regulations.gov* as well as enters the comment submissions into ADAMS. The NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment submissions into ADAMS.

II. Additional Information

The NRC is issuing for public comment a DG in the NRC's ''Regulatory Guide'' series. This series was developed to describe methods that are acceptable to the NRC staff for implementing specific parts of the agency's regulations, to explain techniques that the staff uses in evaluating specific issues or postulated events, and to describe information that the staff needs in its review of applications for permits and licenses.

The DG, entitled, ''Quality Assurance Program Criteria (Design and Construction)'' is temporarily identified by its task number, DG–1403 (ADAMS Accession No. ML22304A054).

This DG is proposed Revision 6 of RG 1.28, ''Quality Assurance Program Criteria (Design and Construction).'' The proposed DG describes methods and procedures that the NRC staff considers acceptable for use in complying with the agency's regulations regarding the QA program criteria for the design and construction phases of nuclear power plants and fuel reprocessing plants. It provides an adequate basis for complying with the requirements of appendix B to part 50 of title 10 of the *Code of Federal Regulations* (10 CFR), subject to certain exceptions and clarifications of NQA–1–2017, NQA–1–2019, and NQA–1–2022 identified in proposed Revision 6 of RG 1.28. DG–1403, endorses, with some clarifications and exceptions, three versions of the American Society of Mechanical Engineers (ASME) NQA–1 standard: NQA–1–2017, NQA–1–2019, and NQA–1–2022. The previous version of RG 1.28 (Revision 5) approved the use of NQA–1b–2011 Addenda to ASME NQA–1–2008, NQA–1–2012, and NQA–1–2015, with certain clarifications and regulatory positions. The staff determined that the NQA–1–2017, NQA–1–2019, and NQA–1–2022 versions provide the most current guidance for QA, and the NRC staff endorses the Part I and Part II requirements included in NQA–1–2017, NQA–1–2019, and NQA–1–2022 for the implementation of a QA program during the design and construction phases of nuclear power plants and fuel reprocessing plants. These Parts provide an adequate basis for complying with the requirements of appendix B to 10 CFR part 50, subject to certain exceptions and clarifications of NQA–1–2017, NQA–1–2019, and NQA–1–2022 identified in DG–1403. This DG also endorses NEI 14–05A, ''Guidelines for the Use of Accreditation in Lieu of Commercial Grade Surveys for Procurement of Laboratory Calibration and Test Services,'' Revision 1, issued November 2020, as an acceptable approach for licensees and suppliers subject to the QA requirements of appendix B to 10 CFR part 50.

The staff is also issuing for public comment a draft regulatory analysis (ADAMS Accession No. ML22304A055). The staff developed a regulatory analysis to assess the value of issuing or revising a regulatory guide as well as alternative courses of action.

As noted in the **Federal Register** on December 9, 2022 (87 FR 75671), this document is being published in the ''Proposed Rules'' section of the **Federal Register** to comply with publication requirements under 1 CFR chapter I.

III. Backfitting, Forward Fitting, and Issue Finality

DG–1403, if finalized, would revise RG 1.28, and provide NRC staff endorsement of the Part I and Part II requirements. This revision would apply to both production and utilization nuclear facilities. Issuance of DG–1403, if finalized, would not constitute backfitting as defined in 10 CFR 50.109, ''Backfitting,'' and as described in NRC Management Directive (MD) 8.4, ''Management of Backfitting, Forward Fitting, Issue Finality, and Information Requests''; constitute forward fitting as that term is defined and described in MD 8.4; or affect the issue finality of any approval issued under 10 CFR part 52.

IV. Submitting Suggestions for Improvement of Regulatory Guides

A member of the public may, at any time, submit suggestions to the NRC for improvement of existing RGs or for the development of new RGs. Suggestions can be submitted on the NRC's public website at *https://www.nrc.gov/reading-rm/doc-collections/reg-guides/contactus.html.* Suggestions will be considered in future updates and enhancements to the ''Regulatory Guide'' series.

Dated: April 26, 2023.

For the Nuclear Regulatory Commission.

Meraj Rahimi,

Chief, Regulatory Guide and Programs Management Branch, Division of Engineering, Office of Nuclear Regulatory Research.

[FR Doc. 2023–09160 Filed 5–2–23; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

10 CFR Parts 50 and 52

[NRC–2023–0089]

Draft Regulatory Guide: Guidelines for Lightning Protection for Production and Utilization Facilities

AGENCY: Nuclear Regulatory Commission

ACTION: Draft guide; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is issuing for public comment a draft regulatory guide (DG), DG–1409, ''Guidelines for Lightning Protection for Production and Utilization Facilities.'' This DG is the proposed Revision 1 of Regulatory Guide (RG) 1.204, ''Guidelines for Lightning Protection of Nuclear Power Plants.'' DG–1409 describes an approach that is acceptable to the staff of the NRC to meet regulatory requirements for adequate lightning protection of safety-related systems, structures, and components (SSCs). This DG endorses, with clarifications, the methods described in Institute of Electrical and Electronics Engineers (IEEE) Standard (Std.) 665–1995, ''IEEE Standard for Generating Station Grounding''; IEEE Std. 666–2007, ''IEEE Design Guide for Electrical Power Service Systems for Generating Stations''; IEEE Std. 1050–2004, ''IEEE Guide for Instrumentation and Control Equipment Grounding in Generating Stations''; and IEEE Std. C62.23–2017, ''IEEE Application Guide for Surge Protection of Electric Generating Plants.''

DATES: Submit comments by June 2, 2023. Comments received after this date will be considered if it is practical to do so, but the NRC is able to ensure consideration only for comments received on or before this date.

ADDRESSES: You may submit comments by any of the following methods; however, the NRC encourages electronic

comment submission through the Federal rulemaking website:

• *Federal rulemaking website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2023–0089. Address questions about Docket IDs in *Regulations.gov* to Stacy Schumann; telephone: 301–415–0624; email: *Stacy.Schumann@nrc.gov.* For technical questions, contact the individuals listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

• *Mail comments to:* Office of Administration, Mail Stop: TWFN–7–A60M, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, ATTN: Program Management, Announcements and Editing Staff.

For additional direction on obtaining information and submitting comments, see ''Obtaining Information and Submitting Comments'' in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: James Steckel, telephone: 301–415–1026; email: *James.Steckel@nrc.gov;* and Roy Hardin, telephone: 301–415–2181; email: *Roy.Hardin@nrc.gov.* Both are staff of the Office of Nuclear Regulatory Research at the U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2023–0089, when contacting the NRC about the availability of information for this action. You may obtain publicly available information related to this action by any of the following methods:

• *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2023–0089.

• *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *PDR.Resource@nrc.gov.* DG–1409, ''Guidelines for Lightning Protection for Production and Utilization Facilities,'' is available in ADAMS under Accession No. ML22208A232.

• *NRC's PDR:* You may examine and purchase copies of public documents, by appointment, at the NRC's PDR, Room P1 B35, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852. To make an appointment to visit the PDR, please send an email to *PDR.Resource@nrc.gov* or call 1–800–397–4209 or 301–415–4737, between 8 a.m. and 4 p.m. eastern time (ET), Monday through Friday, except Federal holidays.

B. Submitting Comments

The NRC encourages electronic comment submission through the Federal rulemaking website (*https://www.regulations.gov*). Please include Docket ID NRC–2023–0089 in your comment submission.

The NRC cautions you not to include identifying or contact information that you do not want to be publicly disclosed in your comment submission. The NRC will post all comment submissions at *https://www.regulations.gov* as well as enter the comment submissions into ADAMS. The NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. Additional Information

The NRC is issuing for public comment a DG in the NRC's ''Regulatory Guide'' series. This series was developed to describe methods that are acceptable to the NRC staff for implementing specific parts of the agency's regulations, to explain techniques that the staff uses in evaluating specific issues or postulated events, and to describe information that the staff needs in its review of applications for permits and licenses.

The DG, entitled ''Guidelines for Lightning Protection for Production and Utilization Facilities,'' is temporarily identified by its task number, DG–1409.

DG–1409 is proposed Revision 1 of RG 1.204. This proposed revision endorses, with clarifications, the methods described in Institute of Electrical and Electronics Engineers (IEEE) Standard (Std.) 665–1995, ''IEEE Standard for Generating Station Grounding''; IEEE Std. 666–2007, ''IEEE Design Guide for Electrical Power Service Systems for Generating Stations''; IEEE Std. 1050–2004, ''IEEE Guide for Instrumentation and Control Equipment Grounding in Generating Stations''; and IEEE Std. C62.23–2017, ''IEEE Application Guide for Surge Protection of Electric Generating Plants'' as acceptable methods for demonstrating compliance with the applicable NRC regulations for adequate lightning protection of safety-related systems, structures, and components.

The staff is also issuing for public comment a draft regulatory analysis (ADAMS Accession No. ML22208A234). The staff developed a regulatory analysis to assess the value of issuing or revising a regulatory guide as well as alternative courses of action.

As noted in the **Federal Register** on December 9, 2022 (87 FR 75671), this document is being published in the ''Proposed Rules'' section of the **Federal Register** to comply with publication requirements under 1 CFR chapter I.

III. Backfitting, Forward Fitting, and Issue Finality

Issuance of DG–1409, if finalized, would not constitute backfitting as that term is defined in section 50.109 of title 10 of the *Code of Federal Regulations* (10 CFR), ''Backfitting,'' and as described in NRC Management Directive (MD) 8.4, ''Management of Backfitting, Forward Fitting, Issue Finality, and Information Requests''; affect issue finality of any approval issued under 10 CFR part 52, ''Licenses, Certificates, and Approvals for Nuclear Power Plants''; or constitute forward fitting as defined in MD 8.4, because, as explained in this DG, applicants and licensees would not be required to comply with the positions set forth in this DG.

IV. Submitting Suggestions for Improvement of Regulatory Guides

A member of the public may, at any time, submit suggestions to the NRC for improvement of existing RGs or for the development of new RGs. Suggestions can be submitted on the NRC's public website at *https://www.nrc.gov/reading-rm/doc-collections/reg-guides/contactus.html.* Suggestions will be considered in future updates and enhancements to the ''Regulatory Guide'' series.

Dated: April 28, 2023.

For the Nuclear Regulatory Commission.

Meraj Rahimi,

Chief, Regulatory Guide and Programs Management Branch, Division of Engineering, Office of Nuclear Regulatory Research.

[FR Doc. 2023–09390 Filed 5–2–23; 8:45 am]

BILLING CODE 7590–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2023–0163; Project Identifier AD–2022–01380–T]

RIN 2120–AA64

Airworthiness Directives; The Boeing Company Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to supersede Airworthiness Directive (AD) 2022–02–16, which applies to all The Boeing Company Model 787–8, 787–9, and 787–10 airplanes. AD 2022–02–16 requires revising the limitations and operating procedures sections of the existing airplane flight manual (AFM) to incorporate limitations prohibiting certain landings and the use of certain minimum equipment list (MEL) items, and to incorporate operating procedures for calculating landing distances, when in the presence of 5G C-Band interference as identified by Notices to Air Missions (NOTAMs). Since the FAA issued AD 2022–02–16, the FAA determined that additional limitations are needed due to the continued deployment of new 5G C-Band base stations whose signals are expected to cover most of the contiguous United States at transmission frequencies between 3.7–3.98 GHz. This proposed AD would require revising the limitations section of the existing AFM to incorporate limitations prohibiting certain landings and the use of certain MEL items, and would retain the operating procedures from AD 2022–02–16 for calculating landing distances, due to the presence of 5G C-Band interference. The FAA is proposing this AD to address the unsafe condition on these products.

DATES: The FAA must receive comments on this proposed AD by May 23, 2023.

ADDRESSES: You may send comments, using the procedures found in 14 CFR 11.43 and 11.45, by any of the following methods:

- *Federal eRulemaking Portal:* Go to *regulations.gov*. Follow the instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.
- *Hand Delivery:* Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

AD Docket: You may examine the AD docket at *regulations.gov* under Docket No. FAA–2023–0163; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this NPRM, any comments received, and other information. The street address for Docket Operations is listed above.

FOR FURTHER INFORMATION CONTACT: Brett Portwood, Continued Operational Safety Technical Advisor, COS Program Management Section, Operational Safety Branch, FAA, 3960 Paramount Boulevard, Lakewood, CA 90712–4137; phone: 817–222–5390; email: *operationalsafety@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under **ADDRESSES**. Include ''Docket No. FAA–2023–0163; Project Identifier AD–2022–01380–T'' at the beginning of your comments. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend the proposal because of those comments.

Except for Confidential Business Information (CBI) as described in the following paragraph, and other information as described in 14 CFR 11.35, the FAA will post all comments received, without change, to *regulations.gov*, including any personal information you provide. The agency will also post a report summarizing each substantive verbal contact received about this proposed AD.

Confidential Business Information

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this NPRM contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this NPRM, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as ''PROPIN.'' The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this NPRM. Submissions containing CBI should be sent to Brett Portwood, Continued Operational Safety Technical Advisor, COS Program Management Section, Operational Safety Branch, FAA, 3960 Paramount Boulevard, Lakewood, CA 90712–4137; phone: 817–222–5390; email: *operationalsafety@faa.gov.* Any commentary that the FAA receives that is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Background

The FAA issued AD 2021–23–12, Amendment 39–21810 (86 FR 69984, December 9, 2021) (AD 2021–23–12), for all transport and commuter category airplanes equipped with a radio altimeter. AD 2021–23–12 was prompted by a determination that radio altimeters cannot be relied upon to perform their intended function if they experience interference from wireless broadband operations in the 3.7–3.98 GHz frequency band (5G C-Band). AD 2021–23–12 requires revising the limitations section of the existing AFM to incorporate limitations prohibiting certain operations requiring radio altimeter data when in the presence of 5G C-Band interference as identified by NOTAMs. The agency issued AD 2021–23–12 because radio altimeter anomalies that are undetected by the automation or pilot, particularly close to the ground (*e.g.,* landing flare), could lead to loss of continued safe flight and landing.

The FAA subsequently identified an additional hazard presented by 5G C-Band interference on The Boeing Company Model 787–8, 787–9, and 787–10 airplanes and issued AD 2022–02–16, Amendment 39–21913 (87 FR 2692, January 19, 2022) (AD 2022–02–16). AD 2022–02–16 was prompted by a determination that, during landings, as a result of 5G C-Band interference, certain airplane systems may not properly transition from AIR to GROUND mode when landing on certain runways, resulting in degraded deceleration performance and longer landing distance than normal due to the effect on thrust reverser deployment, speedbrake deployment, and increased idle thrust. AD 2022–02–16 mandates procedures for operators to account for this longer landing distance, for all runway conditions, when in the presence of 5G C-Band interference as identified by NOTAM. AD 2022–02–16 prohibits operators from dispatching or releasing airplanes to affected airports when certain braking and anti-skid functions on the airplane are inoperable.

It also prohibits operators from dispatching or releasing airplanes to, or landing on, runways with condition codes 1 (ice) and 0 (wet ice, water on top of compacted snow, dry snow, or wet snow over ice). The agency issued AD 2022–02–16 to address degraded deceleration performance and longer landing distance, which could lead to a runway excursion.

Actions Since AD 2022–02–16 Was Issued

Since issuing AD 2022–02–16, the FAA determined that additional limitations are needed due to the continued deployment of new 5G C-Band base stations whose signals are expected to cover most of the contiguous United States at transmission frequencies between 3.7–3.98 GHz. Therefore, the FAA issued an NPRM, Docket No. FAA–2022–1647 (88 FR 1520, January 11, 2023) (the NPRM), proposing to supersede AD 2021–23–12. In the NPRM, the FAA proposed to retain most of the operational prohibitions required by AD 2021–23–12 until June 30, 2023; on or before June 30, 2023, operators would be required to revise their existing AFM to prohibit these operations unless the airplane has a radio altimeter meeting proposed minimum performance levels (a defined power spectral density (PSD) curve as well as a defined aggregate spurious emission level) and is operating at a 5G C-Band mitigated airport (5G CMA). In the NPRM, the FAA also proposed to require all airplanes operating under 14 CFR part 121 to have a radio altimeter meeting the proposed minimum performance standards by February 1, 2024.

Since the NPRM was published, the FAA has determined that a PSD curve is a more appropriate method to define performance than a single fixed emission level. The proposed PSD curve more accurately reflects differences in radio altimeter susceptibility to interfering emissions at different altitude levels. The FAA plans to issue guidance on how to show compliance with both the fundamental PSD curve and spurious PSD curve, including the data to be submitted, for the FAA to approve the method used.

AD 2022–02–16 relies on the FAA's use of NOTAMs to identify 5G C-band interference at certain airports in the U.S. airspace. As explained in more detail in the NPRM, those NOTAMs are no longer the best means of communicating the location of the 5G C-Band environment. Therefore, this proposed AD would retain the AFM limitations required by AD 2022–02–16 until June 30, 2023. On or before June 30, 2023, this proposed AD would require operators to replace the limitations with limitations prohibiting the same operations, except the prohibitions would not be tied to NOTAMs but instead would depend on whether the airplane is operated at a 5G CMA as identified by an FAA Domestic Notice. Because the 5G C-Band Interference operating procedure required by AD 2022–02–16 does not reference NOTAMs, this proposed AD would retain that operating procedure requirement with no change.

FAA's Determination

The FAA is issuing this NPRM after determining that the unsafe condition described previously is likely to exist or develop on other products of the same type design.

Proposed AD Requirements in This NPRM

This proposed AD would retain the AFM revisions required by AD 2022–02–16 until June 30, 2023. On or before June 30, 2023, this proposed AD would require replacing those AFM revisions with limitations prohibiting the same landings and use of certain MEL items at all airports for non-radio altimeter tolerant airplanes. For radio altimeter tolerant airplanes, the prohibited operations would be allowed at 5G CMAs as identified in an FAA Domestic Notice. The minimum performance levels in this proposed AD for determining whether an airplane is radio altimeter tolerant are the same minimum performance levels proposed in the NPRM, except the FAA has replaced the proposed fixed emission level with a proposed PSD curve emission threshold that more accurately reflects differences in radio altimeter susceptibility to interfering emissions at different altitude levels.

Paragraph (k)(3) of this proposed AD specifies that AMOCs approved for AD 2021–23–12 providing relief for specific radio altimeter installations would be approved as AMOCs for the requirements specified in paragraph (h) of this proposed AD until June 30, 2023. After June 30, 2023, operators with AMOCs approved for AD 2021–23–12 would be required to incorporate the 5G C-Band Interference operating procedure specified in paragraph (h)(2) of this proposed AD. The new AFM limitations, which would be required by paragraph (i) or (j) of this proposed AD, specify that operators must comply with this 5G C-Band Interference operating procedure.

Interim Action

The FAA considers that this AD, if adopted as proposed, would be an interim action. Once the Technical Standard Order (TSO) standard for radio altimeters is established, which will follow the existing international technical consensus on the establishment of the minimum operational performance standards (MOPS), the FAA anticipates that the MOPS will be incorporated into the TSO. The FAA also anticipates that aircraft incorporating equipment approved under the new Radio Altimeter TSO will be able to operate in both 5G CMAs and non-5G CMAs with no 5G C-Band-related AFM limitations. Once a new radio altimeter TSO is developed, approved, and available, the FAA might consider additional rulemaking.

Costs of Compliance

The cost information below describes the costs to change the AFM. Although this proposed AD would largely maintain the AFM limitations currently required by AD 2022–02–16, the FAA acknowledges that this proposed AD may also impose costs on some aircraft operators from having to change their conduct to comply with the amended AFM. However, the FAA lacks the data necessary to quantify the costs associated with aircraft operators changing their conduct. The FAA is seeking public comment on these costs so the agency can more fully account for the impact of this regulatory action.

The FAA estimates that this AD, if adopted as proposed, would affect 145 airplanes of U.S. registry.[1] The FAA estimates the following costs to comply with this proposed AD:

[1] This is the number of Boeing Model 787–8, 787–9, and 787–10 airplanes on the FAA's registry as of December 1, 2022.

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
AFM revision (retained action from AD 2022–02–16).	1 work-hour × $85 per hour[2] = $85	$0	$85	$12,325
New AFM revision (new proposed action)	1 work-hour × $85 per hour = $85	0	85	[3] 12,325

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the Agency's authority.

The FAA is issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701: General requirements. Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

The FAA has determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that the proposed regulation:

(1) Is not a ''significant regulatory action'' under Executive Order 12866,

(2) Would not affect intrastate aviation in Alaska, and

(3) Would not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA proposes to amend 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by:

■ a. Removing Airworthiness Directive (AD) 2022–02–16, Amendment 39–21913 (87 FR 2692, January 19, 2022), and

■ b. Adding the following new AD:

The Boeing Company Airplanes: Docket No. FAA–2023–0163; Project Identifier AD–2022–01380–T.

(a) Comments Due Date

The FAA must receive comments on this airworthiness directive (AD) by May 23, 2023.

(b) Affected ADs

This AD replaces AD 2022–02–16, Amendment 39–21913 (87 FR 2692, January 19, 2022) (AD 2022–02–16).

(c) Applicability

This AD applies to all The Boeing Company Model 787–8, 787–9, and 787–10 airplanes, certificated in any category.

(d) Subject

Air Transport Association (ATA) of America Code 34, Navigation.

(e) Unsafe Condition

This AD was prompted by a determination that radio altimeters cannot be relied upon to perform their intended function if they experience interference from wireless broadband operations in the 3.7–3.98 GHz frequency band (5G C-Band), and a determination that, during landings, as a result of this interference, certain airplane systems may not properly transition from AIR to GROUND mode when landing on certain runways, resulting in a longer landing distance than normal due to the effect on thrust reverser deployment, speedbrake deployment, and increased idle thrust. The FAA is issuing this AD to address degraded deceleration performance and longer landing distance, which could lead to a runway excursion.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Definitions

(1) For purposes of this AD, a ''5G C-Band mitigated airport'' (5G CMA) is an airport at which the telecommunications companies have agreed to voluntarily limit their 5G deployment at the request of the FAA, as identified by an FAA Domestic Notice.

(2) For purposes of this AD, a ''radio altimeter tolerant airplane'' is one for which the radio altimeter, as installed, demonstrates the tolerances specified in paragraphs (g)(2)(i) and (ii) of this AD, using a method approved by the FAA.

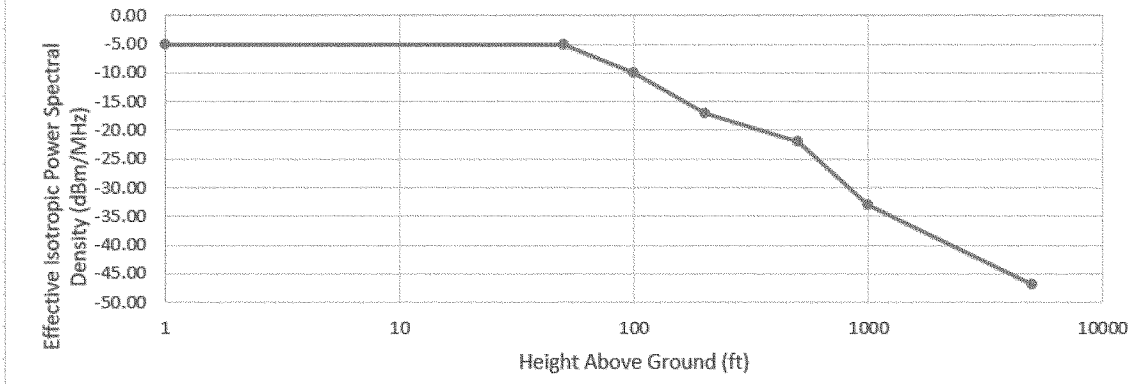
(i) Tolerance to radio altimeter interference, for the fundamental emissions (3.7–3.98 GHz), at or above the power spectral density (PSD) curve threshold specified in figure 1 to paragraph (g)(2)(i) of this AD.

BILLING CODE 4910–13–P

Figure 1 to paragraph (g)(2)(i)—*Fundamental Effective Isotropic PSD at Outside Interface of Aircraft Antenna*

[2] The labor rate of $85 per hour is the average wage rate for an aviation mechanic.

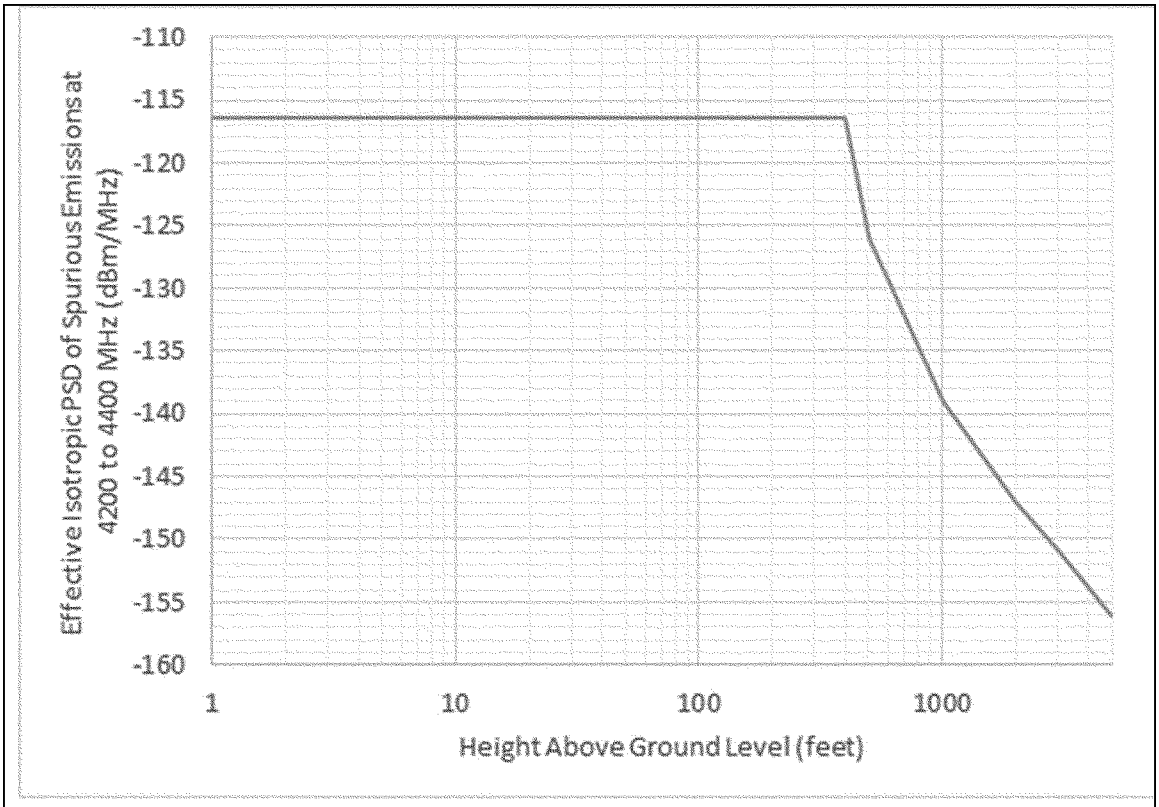
[3] The estimated cost for this revision would not constitute a significant economic impact (even for small entities) because $85 is a minimal cost compared to the regular costs of maintaining and operating a Model 787–8, 787–9, or 787–10 transport category airplane.



Height above ground (ft)	Effective Isotropic PSD (dBm/MHz)
Aircraft on the ground	-5
50	-5
100	-10
200	-17
500	-22
1000	-33
5000	-47

Figure 2 to paragraph (g)(2)(ii)—*Spurious Effective Isotropic PSD at Outside Interface of Aircraft Antenna*

(ii) Tolerance to radio altimeter interference, for the spurious emissions (4.2–4.4 GHz), at or above the PSD curve threshold specified in figure 2 to paragraph (g)(2)(ii) of this AD.



Aircraft Altitude (ft AGL)	Effective Isotropic PSD (dBm/MHz)
1	-116.50
400	-116.50
500	-126.00
1000	-139.00
2000	-147.00
3000	-151.00
5000	-156.00

Figure 3 to paragraph (g)(4)—*Runway Condition Codes*

(3) For purposes of this AD, a ''non-radio altimeter tolerant airplane'' is one for which the radio altimeter, as installed, does not demonstrate the tolerances specified in paragraphs (g)(2)(i) and (ii) of this AD.

(4) Runway condition codes are defined in figure 3 to paragraph (g)(4) of this AD.

Runway Condition Code	Runway Condition Description	Reported Braking Action
6	Dry	Dry
5	Wet (smooth, grooved, or porous friction course (PFC)) or frost 3 mm (0.12 inch) or less of: water, slush, dry snow, or wet snow	Good
4	Compacted snow at or below -15°C (5°F) outside air temperature (OAT)	Good to medium
3	Wet (slippery), dry snow, or wet snow (any depth) over compacted snow Greater than 3 mm (0.12 inch) of: dry snow or wet snow Compacted snow at OAT warmer than -15°C (5°F)	Medium
2	Greater than 3 mm (0.12 inch) of: water or slush	Medium to poor
1	Ice	Poor
0	Wet ice, water on top of compacted snow, dry snow, or wet snow over ice	Nil

(h) Retained Airplane Flight Manual (AFM) Revision

This paragraph restates the requirements of paragraph (h) of AD 2022–02–16.

(1) Within 2 days after January 19, 2022 (the effective date of AD 2022–02–16): Revise the Limitations Section of the existing AFM to include the information specified in figure 4 to paragraph (h)(1) of this AD. This may be done by inserting a copy of figure 4 to paragraph (h)(1) of this AD into the existing AFM.

Figure 4 to paragraph (h)(1)—*AFM Limitations Revisions*

(Required by AD 2022-02-16)

Radio Altimeter 5G C-Band Interference, Landing Distance

The following limitations are required if dispatching or releasing to or landing on runways in U.S. airspace in the presence of 5G C-Band wireless broadband interference as identified by NOTAM (NOTAMs will be issued to state the specific airports or approaches where the radio altimeter is unreliable due to the presence of 5G C-Band wireless broadband interference).

Minimum Equipment List (MEL)

Dispatch or release with any of the following MEL items is prohibited:

- 32-42-02 – Antiskid Control Systems
- 32-45-01 – Wheel Brake Systems
- 32-45-01-01 – Wheel Brake Systems, Electric Brake Actuator Systems

Landing Operations on Runways with Condition Code 1 or 0

Dispatch or releasing to or landing on runways with a runway condition code of 1 or 0 is prohibited.

Landing Distance Calculations for Runway Condition Codes 6 through 2

Operators must follow the 5G C-Band Interference Landing Distance Procedure contained in the Operating Procedures Section of this AFM.

(2) Within 2 days after January 19, 2022 (the effective date of AD 2022–02–16): Revise the Operating Procedures Section of the existing AFM to include the information specified in figure 5 to paragraph (h)(2) of this AD. This may be done by inserting a

copy of figure 5 to paragraph (h)(2) of this AD into the existing AFM.

Figure 5 to paragraph (h)(2)—*AFM Operating Procedures Revision*

(Required by AD 2022-02-16)

5G C-Band Interference Landing Distance

When dispatching or releasing to or landing on runways with a runway condition code of 6 through 2:

- Dispatch or Release:
  - No additional landing distance calculations are required for runway condition codes 6 and 5.
  - For runway condition codes 4 through 2, use Table 1 through 6, as applicable, to determine the unfactored landing distance, applying all adjustments. Multiply the resulting unfactored landing distance by 1.15 to obtain the minimum required landing distance.

Table 1:

787-10 / TRENT 1000

	Landing Distances and Adjustments (Feet)								
	Reference Distance	Weight Adjustment	Altitude Adjustment	Wind Adjustment per 10 Knots	Slope Adjustment per 1%	Temperature Adjustment per 10°C	Approach Speed Adjustment	Reverse Thrust Adjustment	
Runway Condition Code	440,000 LB Landing Weight	Per 10,000 LB Above / Below 440,000 LB	Per 1,000 ft	Head / Tail Wind	Down / Up Hill	Above / Below ISA	per 5 KTS above VREF	One Reverser	No Reverser
6	5640	110 / -90	160	-240 / 790	90 / -80	150 / -150	230	0	0
5	7680	170 / -150	330	-430 / 1570	250 / -210	280 / -270	390	0	0
4	8450	170 / -150	340	-450 / 1610	330 / -270	280 / -280	390	0	0
3	9180	170 / -150	340	-470 / 1680	440 / -340	290 / -280	390	0	0
2	12180	280 / -250	560	-770 / 2850	970 / -690	480 / -460	540	0	0

Table 2:

787-10 / GEnx

	Landing Distances and Adjustments (Feet)								
	Reference Distance	Weight Adjustment	Altitude Adjustment	Wind Adjustment per 10 Knots	Slope Adjustment per 1%	Temperature Adjustment per 10°C	Approach Speed Adjustment	Reverse Thrust Adjustment	
Runway Condition Code	440,000 LB Landing Weight	Per 10,000 LB Above / Below 440,000 LB	Per 1,000 ft	Head / Tail Wind	Down / Up Hill	Above / Below ISA	per 5 KTS above VREF	One Reverser	No Reverser
6	5670	110 / -90	170	-240 / 800	90 / -80	150 / -150	230	0	0
5	7760	160 / -150	350	-440 / 1590	260 / -220	280 / -280	400	0	0
4	8550	160 / -150	350	-450 / 1640	340 / -280	290 / -280	400	0	0
3	9300	170 / -150	360	-480 / 1710	450 / -350	290 / -290	400	0	0
2	12400	280 / -250	610	-790 / 2930	1010 / -710	480 / -470	540	0	0

Table 3:

787-9 / TRENT 1000

	Landing Distances and Adjustments (Feet)								
	Reference Distance	Weight Adjustment	Altitude Adjustment	Wind Adjustment per 10 Knots	Slope Adjustment per 1%	Temperature Adjustment per 10°C	Approach Speed Adjustment	Reverse Thrust Adjustment	
Runway Condition Code	420,000 LB Landing Weight	Per 10,000 LB Above / Below 420,000 LB	Per 1,000 ft	Head / Tail Wind	Down / Up Hill	Above / Below ISA	per 5 KTS above VREF	One Reverser	No Reverser
6	5470	100 / -90	160	-240 / 780	80 / -80	150 / -150	230	0	0
5	7500	160 / -150	330	-430 / 1550	250 / -210	280 / -270	390	0	0
4	8280	160 / -150	330	-440 / 1600	330 / -270	280 / -270	390	0	0
3	9010	170 / -160	340	-470 / 1670	430 / -340	290 / -280	390	0	0
2	11740	270 / -260	540	-750 / 2780	910 / -650	460 / -440	530	0	0

Table 4:

787-9 / GEnx

	Landing Distances and Adjustments (Feet)								
	Reference Distance	Weight Adjustment	Altitude Adjustment	Wind Adjustment per 10 Knots	Slope Adjustment per 1%	Temperature Adjustment per 10°C	Approach Speed Adjustment	Reverse Thrust Adjustment	
Runway Condition Code	420,000 LB Landing Weight	Per 10,000 LB Above / Below 420,000 LB	Per 1,000 ft	Head / Tail Wind	Down / Up Hill	Above / Below ISA	per 5 KTS above VREF	One Reverser	No Reverser
6	5500	100 / -90	170	-240 / 790	90 / -80	150 / -150	230	0	0
5	7580	160 / -150	340	-430 / 1580	250 / -210	280 / -280	390	0	0
4	8380	160 / -150	350	-450 / 1630	340 / -280	280 / -280	390	0	0
3	9130	170 / -150	360	-480 / 1700	450 / -350	290 / -280	390	0	0
2	11960	270 / -260	590	-770 / 2860	940 / -670	460 / -460	530	0	0

Table 5:

787-8 / TRENT 1000

	Landing Distances and Adjustments (Feet)								
	Reference Distance	Weight Adjustment	Altitude Adjustment	Wind Adjustment per 10 Knots	Slope Adjustment per 1%	Temperature Adjustment per 10°C	Approach Speed Adjustment	Reverse Thrust Adjustment	
Runway Condition Code	380,000 LB Landing Weight	Per 10,000 LB Above / Below 380,000 LB	Per 1,000 ft	Head / Tail Wind	Down / Up Hill	Above / Below ISA	per 5 KTS above VREF	One Reverser	No Reverser
6	5050	110 / -80	150	-230 / 750	80 / -70	130 / -130	220	0	0
5	6990	180 / -140	310	-410 / 1510	230 / -190	260 / -250	370	0	0
4	7410	140 / -130	250	-370 / 1270	280 / -230	210 / -210	310	0	0
3	8370	170 / -150	290	-440 / 1500	410 / -320	250 / -250	340	0	0
2	10800	290 / -240	520	-720 / 2680	820 / -590	430 / -420	510	0	0

Table 6:

787-8 / GEnx

	Landing Distances and Adjustments (Feet)								
	Reference Distance	Weight Adjustment	Altitude Adjustment	Wind Adjustment per 10 Knots	Slope Adjustment per 1%	Temperature Adjustment per 10°C	Approach Speed Adjustment	Reverse Thrust Adjustment	
Runway Condition Code	380,000 LB Landing Weight	Per 10,000 LB Above / Below 380,000 LB	Per 1,000 ft	Head / Tail Wind	Down / Up Hill	Above / Below ISA	per 5 KTS above VREF	One Reverser	No Reverser
6	5100	110 / -80	160	-230 / 760	80 / -70	130 / -140	220	0	0
5	7100	180 / -140	330	-420 / 1550	240 / -200	260 / -250	380	0	0
4	7530	140 / -120	260	-380 / 1290	290 / -240	210 / -220	310	0	0
3	8530	180 / -140	300	-450 / 1530	430 / -330	250 / -250	340	0	0
2	11090	290 / -240	560	-740 / 2790	880 / -620	430 / -430	510	0	0

Reference distance is based on Max Manual Braking, sea level, standard day, no wind or slope, and no reverse thrust.
Reference distance includes a distance from threshold to touchdown associated with flare time of 7 seconds.
Distances are based on HYD PRESS L+R failure distances which conservatively approximate the effects of 5G interference.
Actual (unfactored) distances are shown.
Note: per procedure, Max Manual Braking is not required for normal operations and is to be used only in the event that significant 5G interference effects occur.

- En route:
  - Plan to use Flaps 30 and V_{REF30} (with appropriate wind additives) for landing.
  - For runway condition codes 6 to 2, compute time of arrival (en route) landing distance using Table 1 through 6, as applicable, applying all adjustments. Multiply the resulting unfactored landing distance by 1.15 to obtain the minimum required landing distance at the destination. This approximates a minimum required landing distance resulting from 5G C-Band interference.
  - Determine desired AUTOBRAKE setting by using the normal configuration landing distance information from an approved source. Maximum manual braking may not be required.

- During approach and landing:
  - Monitor radio altimeter for anomalies.
  - Normal use of autothrottles is allowed. Monitor performance of autopilot and autothrottle. If the autopilot or autothrottle is not performing as expected, disconnect both the autopilot and autothrottle and apply manual inputs to ensure proper control of flight path.
  - If the autothrottle does not reduce the thrust to IDLE at 25 feet, manually reduce the thrust to idle, hold the thrust levers in the idle position and disconnect the autothrottle to prevent autothrottle from advancing the thrust levers after touchdown.
    Caution: If the autothrottle advances the thrust levers after landing, the speedbrakes will stow and the autobrake will disarm. It will not be possible to raise the reverse thrust levers to deploy the thrust reversers until the thrust levers are at idle.
  - Manual deployment of the speedbrakes may be required.
  - If the thrust reversers do not deploy, immediately ensure the speedbrakes are extended, apply manual braking and modulate as required for the existing runway conditions.
    Note: In some conditions, maximum manual braking may be required throughout the entire landing roll.

(i) New Requirement: AFM Revision for Non-Radio Altimeter Tolerant Airplanes

For non-radio altimeter tolerant airplanes, do the actions specified in paragraphs (i)(1) and (2) of this AD.

(1) On or before June 30, 2023, revise the Limitations Section of the existing AFM to include the information specified in figure 6 to paragraph (i) of this AD. This may be done by inserting a copy of figure 6 to paragraph (i) of this AD into the existing AFM. Incorporating the AFM revision required by this paragraph terminates the AFM revision required by paragraph (h)(1) of this AD.

(2) Before further flight after incorporating the limitations specified in figure 6 to paragraph (i) of this AD, remove the AFM revision required by paragraph (h)(1) of this AD.

Figure 6 to paragraph (i)—*AFM Revision for Non-Radio Altimeter Tolerant Airplanes*

(Required by AD 20-**-**-**)**

Radio Altimeter 5G C-Band Interference, Landing Distance

Due to the presence of 5G C-Band wireless broadband interference, when dispatching or releasing to or landing on runways in the contiguous U.S. airspace, the following limitations are required.

Minimum Equipment List (MEL)

Dispatch or release with any of the following MEL items is prohibited:

- 32-42-02 – Antiskid Control Systems
- 32-45-01 – Wheel Brake Systems
- 32-45-01-01 – Wheel Brake Systems, Electric Brake Actuator Systems

Landing Operations on Runways with Condition Code 1 or 0

Dispatch or releasing to or landing on runways with a runway condition code of 1 or 0 is prohibited.

Landing Distance Calculations for Runway Condition Codes 6 through 2

Operators must follow the 5G C-Band Interference Landing Distance Procedure contained in the Operating Procedures Section of this AFM.

(j) New Requirement: AFM Revision for Radio Altimeter Tolerant Airplanes

For radio altimeter tolerant airplanes, do the actions specified in paragraphs (j)(1) and (2) of this AD.

(1) On or before June 30, 2023, revise the Limitations Section of the existing AFM to include the information specified in figure 7 to paragraph (j) of this AD. This may be done by inserting a copy of figure 7 to paragraph (j) of this AD into the existing AFM. Incorporating the AFM revision required by this paragraph terminates the AFM revision required by paragraph (h)(1) of this AD.

(2) Before further flight after incorporating the limitations specified in figure 7 to paragraph (j) of this AD, remove the AFM revision required by paragraph (h)(1) of this AD.

Figure 7 to paragraph (j)—*AFM Revision for Radio Altimeter Tolerant Airplanes*

(Required by AD 20-**-**-**)**

Radio Altimeter 5G C-Band Interference, Landing Distance

Due to the presence of 5G C-Band wireless broadband interference, when dispatching or releasing to or landing on runways in the contiguous U.S. airspace, the following limitations are required unless operating at a 5G C-Band mitigated airport as identified in an FAA *Domestic Notice*.

Minimum Equipment List (MEL)

Dispatch or release with any of the following MEL items is prohibited:

- 32-42-02 – Antiskid Control Systems
- 32-45-01 – Wheel Brake Systems
- 32-45-01-01 – Wheel Brake Systems, Electric Brake Actuator Systems

Landing Operations on Runways with Condition Code 1 or 0

Dispatch or releasing to or landing on runways with a runway condition code of 1 or 0 is prohibited.

Landing Distance Calculations for Runway Condition Codes 6 through 2

Operators must follow the 5G C-Band Interference Landing Distance Procedure contained in the Operating Procedures Section of this AFM.

(k) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Operational Safety Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or responsible Flight Standards Office, as appropriate. If sending information directly to the manager of the Operational Safety Branch, send it to the attention of the person identified in paragraph (m) of this AD. Information may be emailed to: *AMOC@faa.gov*.

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the responsible Flight Standards Office.

(3) AMOCs approved for AD 2021–23–12, Amendment 39–21810 (86 FR 69984, December 9, 2021) providing relief for specific radio altimeter installations are approved as AMOCs for the requirements specified in paragraph (h) of this AD until June 30, 2023.

(l) Related Information

For more information about this AD, contact Brett Portwood, Continued Operational Safety Technical Advisor, COS Program Management Section, Operational Safety Branch, FAA, 3960 Paramount Boulevard, Lakewood, CA 90712–4137; phone: 817–222–5390; email: *operationalsafety@faa.gov*.

(m) Material Incorporated by Reference

None.

Issued on April 28, 2023.

Michael Linegang,

Acting Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2023–09432 Filed 5–1–23; 4:15 pm]

BILLING CODE 4910–13–C

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2023–0921; Project Identifier AD–2022–01430–T]

RIN 2120–AA64

Airworthiness Directives; The Boeing Company Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to supersede Airworthiness Directive (AD) 2022–05–04, which applies to all The Boeing Company Model 737–100, –200, –200C, –300, –400, –500, –600, –700, –700C, –800, –900, and –900ER series airplanes, except for Model 737–200 and –200C series airplanes equipped with a certain flight control system. AD 2022–05–04 requires revising the limitations and operating procedures sections of the existing airplane flight manual (AFM) to incorporate specific operating procedures for instrument landing system (ILS) approaches, speedbrake deployment, go-arounds, and missed approaches, when in the presence of 5G C-Band interference as identified by Notices to Air Missions (NOTAMs). Since the FAA issued AD 2022–05–04, the FAA determined that additional limitations are needed due to the continued deployment of new 5G C-Band base stations whose signals are expected to cover most of the contiguous United States at transmission frequencies between 3.7–3.98 GHz. This proposed AD would require revising the limitations and operating procedures sections of the

existing AFM to incorporate specific operating procedures for ILS approaches, speedbrake deployment, go-arounds, and missed approaches, due to the presence of 5G C-Band interference. The FAA is proposing this AD to address the unsafe condition on these products.

DATES: The FAA must receive comments on this proposed AD by May 23, 2023.

ADDRESSES: You may send comments, using the procedures found in 14 CFR 11.43 and 11.45, by any of the following methods:

- *Federal eRulemaking Portal:* Go to *regulations.gov*. Follow the instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.
- *Hand Delivery:* Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

AD Docket: You may examine the AD docket at *regulations.gov* under Docket No. FAA–2023–0921; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this NPRM, any comments received, and other information. The street address for Docket Operations is listed above.

FOR FURTHER INFORMATION CONTACT: Brett Portwood, Continued Operational Safety Technical Advisor, COS Program Management Section, Operational Safety Branch, FAA, 3960 Paramount Boulevard, Lakewood, CA 90712–4137; phone: 817–222–5390; email: *operationalsafety@faa.gov*.

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under **ADDRESSES**. Include ''Docket No. FAA–2023–0921; Project Identifier AD–2022–01430–T'' at the beginning of your comments. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend the proposal because of those comments.

Except for Confidential Business Information (CBI) as described in the following paragraph, and other information as described in 14 CFR 11.35, the FAA will post all comments received, without change, to regulations.gov, including any personal information you provide. The agency will also post a report summarizing each substantive verbal contact received about this proposed AD.

Confidential Business Information

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this NPRM contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this NPRM, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as ''PROPIN.'' The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this NPRM. Submissions containing CBI should be sent to Brett Portwood, Continued Operational Safety Technical Advisor, COS Program Management Section, Operational Safety Branch, FAA, 3960 Paramount Boulevard, Lakewood, CA 90712–4137; phone: 817–222–5390; email: *operationalsafety@faa.gov*. Any commentary that the FAA receives that is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Background

The FAA issued AD 2021–23–12, Amendment 39–21810 (86 FR 69984, December 9, 2021) (AD 2021–23–12), for all transport and commuter category airplanes equipped with a radio altimeter. AD 2021–23–12 was prompted by a determination that radio altimeters cannot be relied upon to perform their intended function if they experience interference from wireless broadband operations in the 3.7–3.98 GHz frequency band (5G C-Band). AD 2021–23–12 requires revising the limitations section of the existing AFM to incorporate limitations prohibiting certain operations requiring radio altimeter data when in the presence of 5G C-Band interference as identified by NOTAMs. The agency issued AD 2021–23–12 because radio altimeter anomalies that are undetected by the automation or pilot, particularly close to the ground (*e.g.,* landing flare), could lead to loss of continued safe flight and landing.

The FAA subsequently identified an additional hazard presented by 5G C-Band interference on The Boeing Company Model 737–100, –200, –200C, –300, –400, –500, –600, –700, –700C, –800, –900, and –900ER series airplanes, except for Model 737–200 and –200C series airplanes equipped with a certain flight control system, and issued AD 2022–05–04, Amendment 39–21955 (87 FR 10299, February 24, 2022) (AD 2022–05–04). AD 2022–05–04 was prompted by a determination that, during approach, landings, and go-arounds, as a result of 5G C-Band interference, certain airplane systems may not properly function, resulting in increased flightcrew workload while on approach with the flight director, autothrottle, or autopilot engaged. AD 2022–05–04 requires revising the limitations and operating procedures sections of the existing AFM to incorporate specific operating procedures for ILS approaches, speedbrake deployment, go-arounds, and missed approaches, when in the presence of 5G C-Band interference as identified by NOTAMs. The agency issued AD 2022–05–04 to address 5G C-Band interference that could result in increased flightcrew workload and could lead to reduced ability of the flightcrew to maintain safe flight and landing of the airplane.

Actions Since AD 2022–05–04 Was Issued

Since issuing AD 2022–05–04, the FAA determined that additional limitations are needed due to the continued deployment of new 5G C-Band base stations whose signals are expected to cover most of the contiguous United States at transmission frequencies between 3.7–3.98 GHz. Therefore, the FAA issued an NPRM, Docket No. FAA–2022–1647 (88 FR 1520, January 11, 2023) (the NPRM), proposing to supersede AD 2021–23–12. In the NPRM, the FAA proposed to retain most of the operational prohibitions required by AD 2021–23–12 until June 30, 2023; on or before June 30, 2023, operators would be required to revise their existing AFM to prohibit these operations unless the airplane has a radio altimeter meeting proposed minimum performance levels (a defined power spectral density (PSD) curve as well as a defined aggregate spurious emission level) and is operating at a 5G C-Band mitigated airport (5G CMA). In the NPRM, the FAA also proposed to require all airplanes operating under 14 CFR part 121 to have a radio altimeter meeting the proposed minimum performance standards by February 1, 2024.

Since the NPRM was published, the FAA has determined that a PSD curve is a more appropriate method to define

performance than a single fixed emission level. The proposed PSD curve more accurately reflects differences in radio altimeter susceptibility to interfering emissions at different altitude levels. The FAA plans to issue guidance on how to show compliance with both the fundamental PSD curve and spurious PSD curve, including the data to be submitted, for the FAA to approve the method used.

2022–05–04 relies on the FAA's use of NOTAMs to identify 5G C-band interference at certain airports in the U.S. airspace. As explained in more detail in the NPRM, those NOTAMs are no longer the best means of communicating the location of the 5G C-Band environment. Therefore, this proposed AD would retain the AFM limitations and operating procedures required by AD 2022–05–04 until June 30, 2023. On or before June 30, 2023, this proposed AD would require operators to replace the limitations with limitations prohibiting the same operations, except the prohibitions would not be tied to NOTAMs but instead would depend on whether the airplane is operated at a 5G CMA as identified by an FAA Domestic Notice. Because the 5G C-Band Interference operating procedure required by AD 2022–05–04 references AD 2021–23–12 for certain prohibited ILS approaches, this proposed AD would require operators to replace the procedure with an operating procedure containing the same information, except it would list the specific prohibited ILS approaches.

FAA's Determination

The FAA is issuing this NPRM after determining that the unsafe condition described previously is likely to exist or develop on other products of the same type design.

Proposed AD Requirements in This NPRM

This proposed AD would retain the AFM revisions required by AD 2022–05–04 until June 30, 2023. On or before June 30, 2023, this proposed AD would require replacing those AFM revisions with limitations requiring the same procedures for dispatch or release to airports, and approach, landing, and go-around on runways, at all airports for non-radio altimeter tolerant airplanes. For radio altimeter tolerant airplanes, the procedures would not be required at 5G CMAs as identified in an FAA Domestic Notice. The minimum performance levels in this proposed AD for determining whether an airplane is radio altimeter tolerant are the same minimum performance levels proposed in the NPRM, except the FAA has replaced the proposed fixed emission level with a proposed PSD curve emission threshold that more accurately reflects differences in radio altimeter susceptibility to interfering emissions at different altitude levels.

Paragraph (l)(3) of this proposed AD specifies that AMOCs approved for AD 2021–23–12 providing relief for specific radio altimeter installations would be approved as AMOCs for the requirements specified in paragraph (h) of this proposed AD until June 30, 2023.

Interim Action

The FAA considers that this AD, if adopted as proposed, would be an interim action. Once the Technical Standard Order (TSO) standard for radio altimeters is established, which will follow the existing international technical consensus on the establishment of the minimum operational performance standards (MOPS), the FAA anticipates that the MOPS will be incorporated into the TSO. The FAA also anticipates that aircraft incorporating equipment approved under the new Radio Altimeter TSO will be able to operate in both 5G CMAs and non-5G CMAs with no 5G C-Band-related AFM limitations. Once a new radio altimeter TSO is developed, approved, and available, the FAA might consider additional rulemaking.

Costs of Compliance

The cost information below describes the costs to change the AFM. Although this proposed AD would largely maintain the AFM limitations currently required by AD 2022–05–04, the FAA acknowledges that this proposed AD may also impose costs on some aircraft operators from having to change their conduct to comply with the amended AFM. However, the FAA lacks the data necessary to quantify the costs associated with aircraft operators changing their conduct. The FAA is seeking public comment on these costs so the agency can more fully account for the impact of this regulatory action.

The FAA estimates that this AD, if adopted as proposed, would affect 2,328 airplanes of U.S. registry.[1] The FAA estimates the following costs to comply with this proposed AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
AFM revision (retained actions from AD 2022–05–04).	1 work-hour × $85 per hour[2] = $85	$0	$85	$197,880
New AFM revisions (new proposed action)	1 work-hour × $85 per hour = $85	0	85	[3] 197,880

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the Agency's authority.

The FAA is issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701: General requirements. Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

[1] This is the number of affected Boeing Model 737–100, –200, –200C, –300, –400, –500, –600, –700, –700C, –800, –900, and –900ER series airplanes on the FAA's registry as of December 1, 2022.

[2] The labor rate of $85 per hour is the average wage rate for an aviation mechanic.

[3] The estimated cost for this revision would not constitute a significant economic impact (even for small entities) because $85 is a minimal cost compared to the regular costs of maintaining and operating a Model 737–100, –200, –200C, –300, –400, –500, –600, –700, –700C, –800, –900, or –900ER transport category airplane.

Regulatory Findings

The FAA has determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that the proposed regulation:

(1) Is not a ''significant regulatory action'' under Executive Order 12866,

(2) Would not affect intrastate aviation in Alaska, and

(3) Would not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA proposes to amend 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by:

■ a. Removing Airworthiness Directive (AD) 2022–05–04, Amendment 39–21955 (87 FR 10299, February 24, 2022), and

■ b. Adding the following new AD:

The Boeing Company Airplanes: Docket No. FAA–2023–0921; Project Identifier AD–2022–01430–T.

(a) Comments Due Date

The FAA must receive comments on this airworthiness directive (AD) by May 23, 2023.

(b) Affected ADs

This AD replaces AD 2022–05–04, Amendment 39–21955 (87 FR 10299, February 24, 2022) (AD 2022–05–04).

(c) Applicability

This AD applies to all The Boeing Company 737–100, –200, –200C, –300, –400, –500, –600, –700, –700C, –800, –900, and –900ER series airplanes, certificated in any category, except for Model 737–200 and –200C series airplanes equipped with an SP–77 flight control system.

(d) Subject

Air Transport Association (ATA) of America Code 34, Navigation.

(e) Unsafe Condition

This AD was prompted by a determination that radio altimeters cannot be relied upon to perform their intended function if they experience interference from wireless broadband operations in the 3.7–3.98 GHz frequency band (5G C-Band), and a determination that, during approach, landings, and go-arounds, as a result of this interference, certain airplane systems may not properly function, resulting in increased flightcrew workload while on approach with the flight director, autothrottle, or autopilot engaged. The FAA is issuing this AD to address 5G C-Band interference that could result in increased flightcrew workload and could lead to reduced ability of the flightcrew to maintain safe flight and landing of the airplane.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

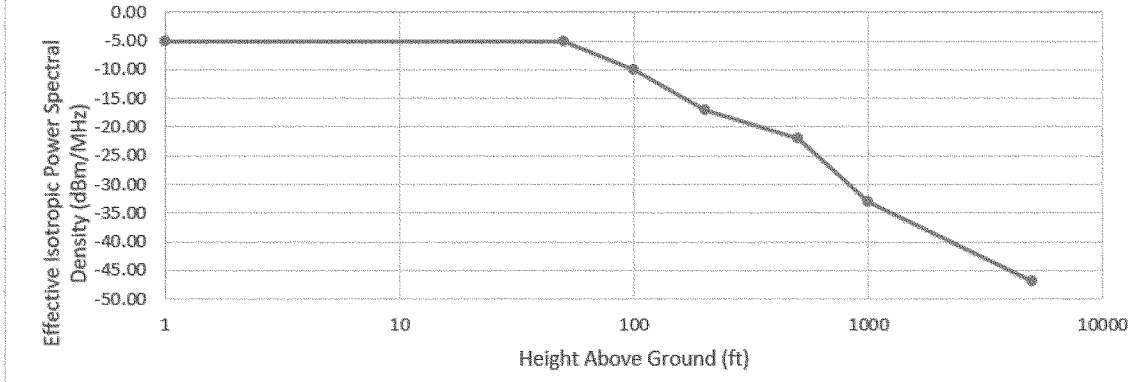
(g) Definitions

(1) For purposes of this AD, a ''5G C-Band mitigated airport'' (5G CMA) is an airport at which the telecommunications companies have agreed to voluntarily limit their 5G deployment at the request of the FAA, as identified by an FAA Domestic Notice.

(2) For purposes of this AD, a ''radio altimeter tolerant airplane'' is one for which the radio altimeter, as installed, demonstrates the tolerances specified in paragraphs (g)(2)(i) and (ii) of this AD, using a method approved by the FAA.

(i) Tolerance to radio altimeter interference, for the fundamental emissions (3.7–3.98 GHz), at or above the power spectral density (PSD) curve threshold specified in figure 1 to paragraph (g)(2)(i) of this AD.

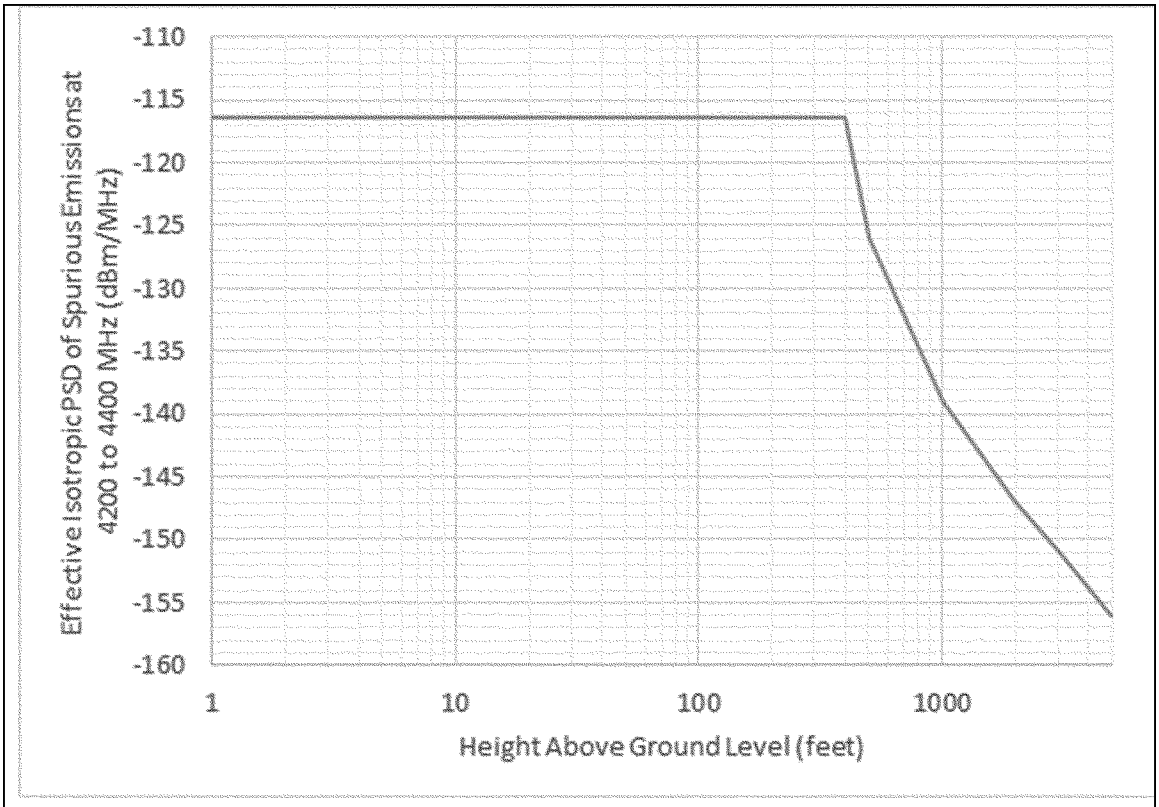
Figure 1 to paragraph (g)(2)(i)—*Fundamental Effective Isotropic PSD at Outside Interface of Aircraft Antenna*



Height above ground (ft)	Effective Isotropic PSD (dBm/MHz)
Aircraft on the ground	-5
50	-5
100	-10
200	-17
500	-22
1000	-33
5000	-47

Figure 2 to paragraph (g)(2)(ii)—*Spurious Effective Isotropic PSD at Outside Interface of Aircraft Antenna*

(ii) Tolerance to radio altimeter interference, for the spurious emissions (4.2–4.4 GHz), at or above the PSD curve threshold specified in figure 2 to paragraph (g)(2)(ii) of this AD.



Aircraft Altitude (ft AGL)	Effective Isotropic PSD (dBm/MHz)
1	-116.50
400	-116.50
500	-126.00
1000	-139.00
2000	-147.00
3000	-151.00
5000	-156.00

(3) For purposes of this AD, a ''non-radio altimeter tolerant airplane'' is one for which the radio altimeter, as installed, does not demonstrate the tolerances specified in paragraphs (g)(2)(i) and (ii) of this AD.

(h) Retained Airplane Flight Manual (AFM) Revision

This paragraph restates the requirements of paragraph (g) of AD 2022–05–04.

(1) Within 2 days after February 24, 2022 (the effective date of AD 2022–05–04): Revise the Limitations Section of the existing AFM to include the information specified in figure 3 to paragraph (h)(1) of this AD. This may be done by inserting a copy of figure 3 to paragraph (h)(1) of this AD into the existing AFM.

Figure 3 to paragraph (h)(1)—*AFM Limitations Revisions*

(Required by AD 2022-05-04)

Radio Altimeter 5G C-Band Interference, Approach, Landing, and Go-Around
The following limitations are required for dispatch or release to airports, and approach, landing, and go-around on runways, in U.S. airspace in the presence of 5G C-Band wireless broadband interference as identified by NOTAM (NOTAMs will be issued to state the specific airports or approaches where the radio altimeter is unreliable due to the presence of 5G C-Band wireless broadband interference).

Approach, Landing, and Go-Around
Operators must use the Radio Altimeter 5G C-Band Interference, Approach, Landing, and Go-Around procedure contained in the Operating Procedures Section of this AFM.

(2) Within 2 days after February 24, 2022 (the effective date of AD 2022–05–04): Revise the Operating Procedures Section of the existing AFM to include the information specified in figure 4 to paragraph (h)(2) of this AD or figure 5 to paragraph (h)(2) of this AD, as applicable. This may be done by inserting a copy of figure 4 to paragraph (h)(2) or figure 5 to paragraph (h)(2) of this AD, as applicable, into the Operating Procedures Section of the existing AFM.

Figure 4 to paragraph (h)(2)—*AFM Operating Procedures Revision for Model 737–100, –200, –200C, –300, –400, and –500 series airplanes*

(Required by AD 2022-05-04)

Radio Altimeter 5G C-Band Interference, Approach, Landing, and Go-Around

ILS Approaches
For ILS approaches not prohibited by AD 2021-23-12, during any ILS approach with autopilot engaged or flight director ON, execute a go-around for any of the following conditions, unless the runway environment is in sight and a manual, visual landing can be accomplished:

- If the flight directors automatically retract from view, or
- If the pitch guidance indicates FLARE mode prematurely, or
- If the autothrottle retards to IDLE prematurely.

During Go-Around and Missed Approach
If go-around is required, ensure thrust is increased to go-around power. Do not use flight director, autopilot, or autothrottles until reaching a safe altitude. TOGA mode may not be available. Autopilot may not be available. Monitor pitch and roll modes for engagement.

Figure 5 to paragraph (h)(2)—*AFM Operating Procedures Revision for Model 737–600, –700, –700C, –800, –900, and –900ER series airplanes*

(Required by AD 2022-05-04)

Radio Altimeter 5G C-Band Interference, Approach, Landing, and Go-Around

ILS Approaches
For ILS approaches not prohibited by AD 2021-23-12, during any ILS (and GLS if installed) approach with autopilot engaged or flight director ON, execute a go-around for any of the following conditions, unless the runway environment is in sight and a manual, visual landing can be accomplished:

- If the flight directors automatically retract from view, or
- If the pitch guidance indicates FLARE mode prematurely, or
- If the autothrottle retards to IDLE prematurely.

Landing
Adjust operational (time of arrival) landing distance for manual speedbrakes. Automatic speedbrake deployment may not occur after touchdown.

During Go-Around and Missed Approach
If go-around is required, ensure thrust is increased to go-around power. Do not use flight director, autopilot, or autothrottles until reaching a safe altitude. TOGA mode may not be available. Autopilot may not be available. Monitor pitch and roll modes for engagement.

(i) New Requirement: AFM Limitations Revision for Non-Radio Altimeter Tolerant Airplanes

For non-radio altimeter tolerant airplanes, do the actions specified in paragraphs (i)(1) and (2) of this AD.

(1) On or before June 30, 2023, revise the Limitations Section of the existing AFM to include the information specified in figure 6 to paragraph (i) of this AD. This may be done by inserting a copy of figure 6 to paragraph (i) of this AD into the existing AFM. Incorporating the AFM revision required by this paragraph terminates the AFM revision required by paragraph (h)(1) of this AD.

(2) Before further flight after incorporating the limitations specified in figure 6 to paragraph (i) of this AD, remove the AFM revision required by paragraph (h)(1) of this AD.

Figure 6 to paragraph (i)—*AFM Limitations Revision for Non-Radio Altimeter Tolerant Airplanes*

(Required by AD 20-**-**)**

Radio Altimeter 5G C-Band Interference, Approach, Landing, and Go-Around
Due to the presence of 5G C-Band wireless broadband interference, the following limitations are required for dispatch or release to airports, and approach, landing, and go-around on runways, in the contiguous U.S. airspace.

Approach, Landing, and Go-Around
Operators must use the Radio Altimeter 5G C-Band Interference, Approach, Landing, and Go-Around procedure contained in the Operating Procedures Section of this AFM.

(j) New Requirement: AFM Limitations Revision for Radio Altimeter Tolerant Airplanes

For radio altimeter tolerant airplanes, do the actions specified in paragraphs (j)(1) and (2) of this AD.

(1) On or before June 30, 2023, revise the Limitations Section of the existing AFM to include the information specified in figure 7 to paragraph (j) of this AD. This may be done by inserting a copy of figure 7 to paragraph (j) of this AD into the existing AFM. Incorporating the AFM revision required by this paragraph terminates the AFM revision required by paragraph (h)(1) of this AD.

(2) Before further flight after incorporating the limitations specified in figure 7 to paragraph (j) of this AD, remove the AFM revision required by paragraph (h)(1) of this AD.

Figure 7 to paragraph (j)—*AFM Limitations Revision for Radio Altimeter Tolerant Airplanes*

(Required by AD 20-**-**-**)**

Radio Altimeter 5G C-Band Interference, Approach, Landing, and Go-Around
Due to the presence of 5G C-Band wireless broadband interference, the following limitations are required for dispatch or release to airports, and approach, landing, and go-around on runways, in the contiguous U.S. airspace unless operating at a 5G C-Band mitigated airport as identified in an FAA *Domestic Notice*.

Approach, Landing, and Go-Around
Operators must use the Radio Altimeter 5G C-Band Interference, Approach, Landing, and Go-Around procedure contained in the Operating Procedures Section of this AFM.

(k) New Requirement: AFM Operating Procedures Revision

For all airplanes, do the actions specified in paragraphs (k)(1) and (2) of this AD.

(1) On or before June 30, 2023, revise the Operating Procedures Section of the existing AFM to include the information specified in figure 8 to paragraph (k) of this AD or figure 9 to paragraph (k) of this AD, as applicable. This may be done by inserting a copy of figure 8 to paragraph (k) of this AD or figure 9 to paragraph (k) of this AD, as applicable, into the Operating Procedures Section of the existing AFM. Incorporating the AFM revision required by this paragraph terminates the AFM revision required by paragraph (h)(2) of this AD.

(2) Before further flight after incorporating the operating procedures specified in figure 8 to paragraph (k) of this AD or figure 9 to paragraph (k) of this AD, remove the AFM revision required by paragraph (h)(2) of this AD.

Figure 8 to paragraph (k)—*AFM Operating Procedures Revision for Model 737–100, –200, –200C, –300, –400, and –500 series airplanes*

(Required by AD 20-**-**-**)**

Radio Altimeter 5G C-Band Interference, Approach, Landing, and Go-Around

ILS Approaches
For ILS approaches other than SA CAT I, SA CAT II, CAT II, and CAT III, during any ILS approach with autopilot engaged or flight director ON, execute a go-around for any of the following conditions, unless the runway environment is in sight and a manual, visual landing can be accomplished:

- If the flight directors automatically retract from view, or
- If the pitch guidance indicates FLARE mode prematurely, or
- If the autothrottle retards to IDLE prematurely.

During Go-Around and Missed Approach
If go-around is required, ensure thrust is increased to go-around power. Do not use flight director, autopilot, or autothrottles until reaching a safe altitude. TOGA mode may not be available. Autopilot may not be available. Monitor pitch and roll modes for engagement.

Figure 9 to paragraph (k)—*AFM Operating Procedures Revision for Model 737–600, –700, –700C, –800, –900, and –900ER series airplanes*

(Required by AD 20-**-**-**)**

Radio Altimeter 5G C-Band Interference, Approach, Landing, and Go-Around

ILS Approaches

For ILS approaches other than SA CAT I, SA CAT II, CAT II, and CAT III, during any ILS (and GLS if installed) approach with autopilot engaged or flight director ON, execute a go-around for any of the following conditions, unless the runway environment is in sight and a manual, visual landing can be accomplished:

- If the flight directors automatically retract from view, or
- If the pitch guidance indicates FLARE mode prematurely, or
- If the autothrottle retards to IDLE prematurely.

Landing

Adjust operational (time of arrival) landing distance for manual speedbrakes. Automatic speedbrake deployment may not occur after touchdown.

During Go-Around and Missed Approach

If go-around is required, ensure thrust is increased to go-around power. Do not use flight director, autopilot, or autothrottles until reaching a safe altitude. TOGA mode may not be available. Autopilot may not be available. Monitor pitch and roll modes for engagement.

(l) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Operational Safety Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or responsible Flight Standards Office, as appropriate. If sending information directly to the manager of the Operational Safety Branch, send it to the attention of the person identified in paragraph (m) of this AD. Information may be emailed to: *AMOC@faa.gov*.

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the responsible Flight Standards Office.

(3) AMOCs approved for AD 2021–23–12, Amendment 39–21810 (86 FR 69984, December 9, 2021) providing relief for specific radio altimeter installations are approved as AMOCs for the requirements specified in paragraph (h) of this AD until June 30, 2023.

(m) Related Information

For more information about this AD, contact Brett Portwood, Continued Operational Safety Technical Advisor, COS Program Management Section, Operational Safety Branch, FAA, 3960 Paramount Boulevard, Lakewood, CA 90712–4137; phone: 817–222–5390; email: *operationalsafety@faa.gov*.

(m) Material Incorporated by Reference

None.

Issued on April 28, 2023.

Michael Linegang,

Acting Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2023–09436 Filed 5–1–23; 4:15 pm]

BILLING CODE 4910–13–C

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2023–0922; Project Identifier AD–2022–01431–T]

RIN 2120–AA64

Airworthiness Directives; The Boeing Company Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to supersede Airworthiness Directive (AD) 2022–06–16, which applies to all The Boeing Company Model 747–100, 747–100B, 747–100B SUD, 747–200B, 747–200C, 747–200F, 747–300, 747–400, 747–400D, and 747–400F series airplanes. AD 2022–06–16 requires revising the limitations and operating procedures sections of the existing airplane flight manual (AFM) to incorporate specific operating procedures for takeoff, instrument landing system (ILS) approaches, non-precision approaches, and go around and missed approaches, when in the presence of 5G C-Band interference as identified by Notices to Air Missions (NOTAMs). Since the FAA issued AD 2022–06–16, the FAA determined that additional limitations are needed due to the continued deployment of new 5G C-Band base stations whose signals are expected to cover most of the contiguous United States at transmission frequencies between 3.7–3.98 GHz. This proposed AD would require revising the limitations section of the existing AFM to incorporate limitations requiring specific operating procedures, and would retain the operating procedures for takeoff, ILS approaches, non-precision approaches, and go around and missed approaches from AD 2022–06–16, due to the presence of 5G C-Band interference. The FAA is proposing this AD to address the unsafe condition on these products.

DATES: The FAA must receive comments on this proposed AD by May 23, 2023.

ADDRESSES: You may send comments, using the procedures found in 14 CFR 11.43 and 11.45, by any of the following methods:

- *Federal eRulemaking Portal:* Go to *regulations.gov.* Follow the instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.
- *Hand Delivery:* Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

AD Docket: You may examine the AD docket at *regulations.gov* under Docket No. FAA–2023–0922; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this NPRM, any comments received, and other information. The street address for Docket Operations is listed above.

FOR FURTHER INFORMATION CONTACT: Brett Portwood, Continued Operational Safety Technical Advisor, COS Program Management Section, Operational Safety Branch, FAA, 3960 Paramount Boulevard, Lakewood, CA 90712–4137; phone: 817–222–5390; email: *operationalsafety@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under **ADDRESSES**. Include ''Docket No. FAA–2023–0922; Project Identifier AD–2022–01431–T'' at the beginning of your comments. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend the proposal because of those comments.

Except for Confidential Business Information (CBI) as described in the following paragraph, and other information as described in 14 CFR 11.35, the FAA will post all comments received, without change, to *regulations.gov*, including any personal information you provide. The agency will also post a report summarizing each substantive verbal contact received about this proposed AD.

Confidential Business Information

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this NPRM contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this NPRM, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as ''PROPIN.'' The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this NPRM. Submissions containing CBI should be sent to Brett Portwood, Continued Operational Safety Technical Advisor, COS Program Management Section, Operational Safety Branch, FAA, 3960 Paramount Boulevard, Lakewood, CA 90712–4137; phone: 817–222–5390; email: *operationalsafety@faa.gov.* Any commentary that the FAA receives that is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Background

The FAA issued AD 2021–23–12, Amendment 39–21810 (86 FR 69984, December 9, 2021) (AD 2021–23–12), for all transport and commuter category airplanes equipped with a radio altimeter. AD 2021–23–12 was prompted by a determination that radio altimeters cannot be relied upon to perform their intended function if they experience interference from wireless broadband operations in the 3.7–3.98 GHz frequency band (5G C-Band). AD 2021–23–12 requires revising the limitations section of the existing AFM to incorporate limitations prohibiting certain operations requiring radio altimeter data when in the presence of 5G C-Band interference as identified by NOTAMs. The agency issued AD 2021–23–12 because radio altimeter anomalies that are undetected by the automation or pilot, particularly close to the ground (*e.g.,* landing flare), could lead to loss of continued safe flight and landing.

The FAA subsequently identified an additional hazard presented by 5G C-Band interference on The Boeing Company Model 747–100, 747–100B, 747–100B SUD, 747–200B, 747–200C, 747–200F, 747–300, 747–400, 747–400D, and 747–400F series airplanes and issued AD 2022–06–16, Amendment 39–21982 (87 FR 14780, March 16, 2022) (AD 2022–06–16). AD 2022–06–16 was prompted by a determination that, during takeoff, approach, landings, and go-arounds, as a result of 5G C-Band interference, certain airplane systems may not properly function, resulting in increased flightcrew workload while on approach with the flight director, autothrottle, or autopilot engaged. AD 2022–06–16 requires revising the limitations and operating procedures sections of the existing AFM to incorporate specific operating procedures for takeoff, ILS approaches, non-precision approaches, and go around and missed approaches, when in the presence of 5G C-Band interference as identified by Notices to Air Missions (NOTAMs). The agency issued AD 2022–06–16 to address 5G C-Band interference that could result in increased flightcrew workload and could lead to reduced ability of the flightcrew to maintain safe flight and landing of the airplane.

Actions Since AD 2022–06–16 Was Issued

Since issuing AD 2022–06–16, the FAA determined that additional limitations are needed due to the continued deployment of new 5G C-Band base stations whose signals are expected to cover most of the contiguous United States at transmission frequencies between 3.7–3.98 GHz. Therefore, the FAA issued an NPRM, Docket No. FAA–2022–1647 (88 FR 1520, January 11, 2023) (the NPRM), proposing to supersede AD 2021–23–12. In the NPRM, the FAA proposed to retain most of the operational prohibitions required by AD 2021–23–12 until June 30, 2023; on or before June 30, 2023, operators would be required to revise their existing AFM to prohibit these operations unless the airplane has a radio altimeter meeting proposed minimum performance levels (a defined power spectral density (PSD) curve as well as a defined aggregate spurious emission level) and is operating at a 5G C-Band mitigated airport (5G CMA). In the NPRM, the FAA also proposed to require all airplanes operating under 14 CFR part 121 to have a radio altimeter meeting the proposed minimum performance standards by February 1, 2024.

Since the NPRM was published, the FAA has determined that a PSD curve is a more appropriate method to define performance than a single fixed emission level. The proposed PSD curve more accurately reflects differences in radio altimeter susceptibility to interfering emissions at different altitude levels. The FAA plans to issue guidance on how to show compliance with both the fundamental PSD curve and spurious PSD curve, including the data to be submitted, for the FAA to approve the method used.

AD 2022–06–16 relies on the FAA's use of NOTAMs to identify 5G C-band interference at certain airports in the U.S. airspace. As explained in more detail in the NPRM, those NOTAMs are no longer the best means of communicating the location of the 5G C-Band environment. Therefore, this proposed AD would retain the AFM limitations required by AD 2022–06–16 until June 30, 2023. On or before June 30, 2023, this proposed AD would require operators to replace the limitations with limitations prohibiting the same operations, except the prohibitions would not be tied to NOTAMs but instead would depend on whether the airplane is operated at a 5G CMA as identified by an FAA Domestic Notice. Because the 5G C-Band Interference operating procedure required by AD 2022–06–16 does not reference NOTAMs, this proposed AD would retain that operating procedure requirement with no change.

FAA's Determination

The FAA is issuing this NPRM after determining that the unsafe condition described previously is likely to exist or develop on other products of the same type design.

Proposed AD Requirements in This NPRM

This proposed AD would retain the AFM revisions required by AD 2022–06–16, until June 30, 2023. On or before June 30, 2023, this proposed AD would require replacing those AFM revisions with limitations requiring the same procedures for dispatch or release to airports, and takeoff, approach, landing, and go-around on runways at all airports for non-radio altimeter tolerant airplanes. For radio altimeter tolerant airplanes, the procedures would not be required at 5G CMAs as identified in an FAA Domestic Notice. The minimum performance levels in this proposed AD for determining whether an airplane is radio altimeter tolerant are the same minimum performance levels proposed in the NPRM, except the FAA has replaced the proposed fixed emission level with a proposed PSD curve emission threshold that more accurately reflects differences in radio altimeter susceptibility to interfering emissions at different altitude levels.

Paragraph (k)(3) of this proposed AD specifies that AMOCs approved for AD 2021–23–12 providing relief for specific radio altimeter installations would be approved as AMOCs for the requirements specified in paragraph (h) of this proposed AD until June 30, 2023. After June 30, 2023, operators with AMOCs approved for AD 2021–23–12 would be required to incorporate the 5G C-Band Interference operating procedure specified in paragraph (h)(2) of this proposed AD. The new AFM limitations, which would be required by paragraph (i) or (j) of this proposed AD, specify that operators must comply with this 5G C-Band Interference operating procedure.

Interim Action

The FAA considers that this AD, if adopted as proposed, would be an interim action. Once the Technical Standard Order (TSO) standard for radio altimeters is established, which will follow the existing international technical consensus on the establishment of the minimum operational performance standards (MOPS), the FAA anticipates that the MOPS will be incorporated into the TSO. The FAA also anticipates that aircraft incorporating equipment approved under the new Radio Altimeter TSO will be able to operate in both 5G CMAs and non-5G CMAs with no 5G C-Band-related AFM limitations. Once a new radio altimeter TSO is developed, approved, and available, the FAA might consider additional rulemaking.

Costs of Compliance

The cost information below describes the costs to change the AFM. Although this proposed AD would largely maintain the AFM limitations currently required by AD 2022–06–16, the FAA acknowledges that this proposed AD may also impose costs on some aircraft operators from having to change their conduct to comply with the amended AFM. However, the FAA lacks the data necessary to quantify the costs associated with aircraft operators changing their conduct. The FAA is seeking public comment on these costs so the agency can more fully account for the impact of this regulatory action.

The FAA estimates that this AD, if adopted as proposed, would affect 137 airplanes of U.S. registry.[1] The FAA estimates the following costs to comply with this proposed AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
AFM revision (retained actions from AD 2022–02–16).	1 work-hour × $85 per hour[2] = $85	$0	$85	$11,645
New AFM revisions (new proposed action)	1 work-hour × $85 per hour = $85	0	85	[3] 11,645

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the Agency's authority.

The FAA is issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701: General requirements. Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

The FAA has determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or

[1] This is the number of Boeing Model 747–100, 747–100B, 747–100B SUD, 747–200B, 747–200C, 747–200F, 747–300, 747–400, 747–400D, and 747–400F series airplanes on the FAA's registry as of December 1, 2022.

[2] The labor rate of $85 per hour is the average wage rate for an aviation mechanic.

[3] The estimated cost for this revision would not constitute a significant economic impact (even for small entities) because $85 is a minimal cost compared to the regular costs of maintaining and operating a Model 747–100, 747–100B, 747–100B SUD, 747–200B, 747–200C, 747–200F, 747–300, 747–400, 747–400D, or 747–400F transport category airplane.

on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that the proposed regulation:

(1) Is not a ''significant regulatory action'' under Executive Order 12866,

(2) Would not affect intrastate aviation in Alaska, and

(3) Would not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA proposes to amend 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by:

■ a. Removing Airworthiness Directive (AD) 2022–06–16, Amendment 39–21982 (87 FR 14780, March 16, 2022), and

■ b. Adding the following new AD:

The Boeing Company Airplanes: Docket No. FAA–2023–0922; Project Identifier AD–2022–01431–T.

(a) Comments Due Date

The FAA must receive comments on this airworthiness directive (AD) by May 23, 2023.

(b) Affected ADs

This AD replaces AD 2022–06–16, Amendment 39–21982 (87 FR 14780, March 16, 2022) (AD 2022–06–16).

(c) Applicability

This AD applies to all The Boeing Company Model 747–100, 747–100B, 747–100B SUD, 747–200B, 747–200C, 747–200F, 747–300, 747–400, 747–400D, and 747–400F series airplanes, certificated in any category.

(d) Subject

Air Transport Association (ATA) of America Code 34, Navigation.

(e) Unsafe Condition

This AD was prompted by a determination that radio altimeters cannot be relied upon to perform their intended function if they experience interference from wireless broadband operations in the 3.7–3.98 GHz frequency band (5G C-Band), and a determination that during takeoff, approach, landings, and go-arounds, as a result of this interference, certain airplane systems may not properly function, resulting in increased flightcrew workload while on approach with the flight director, autothrottle, or autopilot engaged. The FAA is issuing this AD to address 5G C-Band interference that could result in increased flightcrew workload and could lead to reduced ability of the flightcrew to maintain safe flight and landing of the airplane.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Definitions

(1) For purposes of this AD, a ''5G C-Band mitigated airport'' (5G CMA) is an airport at which the telecommunications companies have agreed to voluntarily limit their 5G deployment at the request of the FAA, as identified by an FAA Domestic Notice.

(2) For purposes of this AD, a ''radio altimeter tolerant airplane'' is one for which the radio altimeter, as installed, demonstrates the tolerances specified in paragraphs (g)(2)(i) and (ii) of this AD, using a method approved by the FAA.

(i) Tolerance to radio altimeter interference, for the fundamental emissions (3.7–3.98 GHz), at or above the power spectral density (PSD) curve threshold specified in figure 1 to paragraph (g)(2)(i) of this AD.

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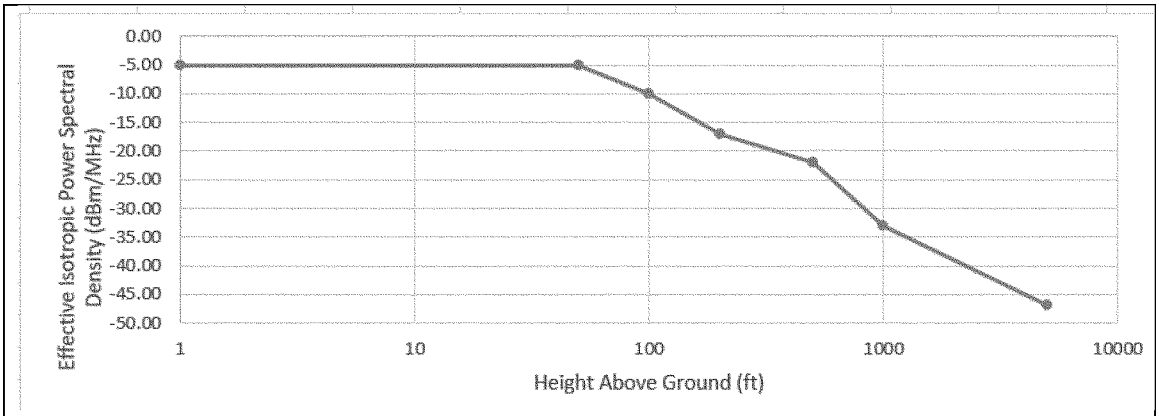
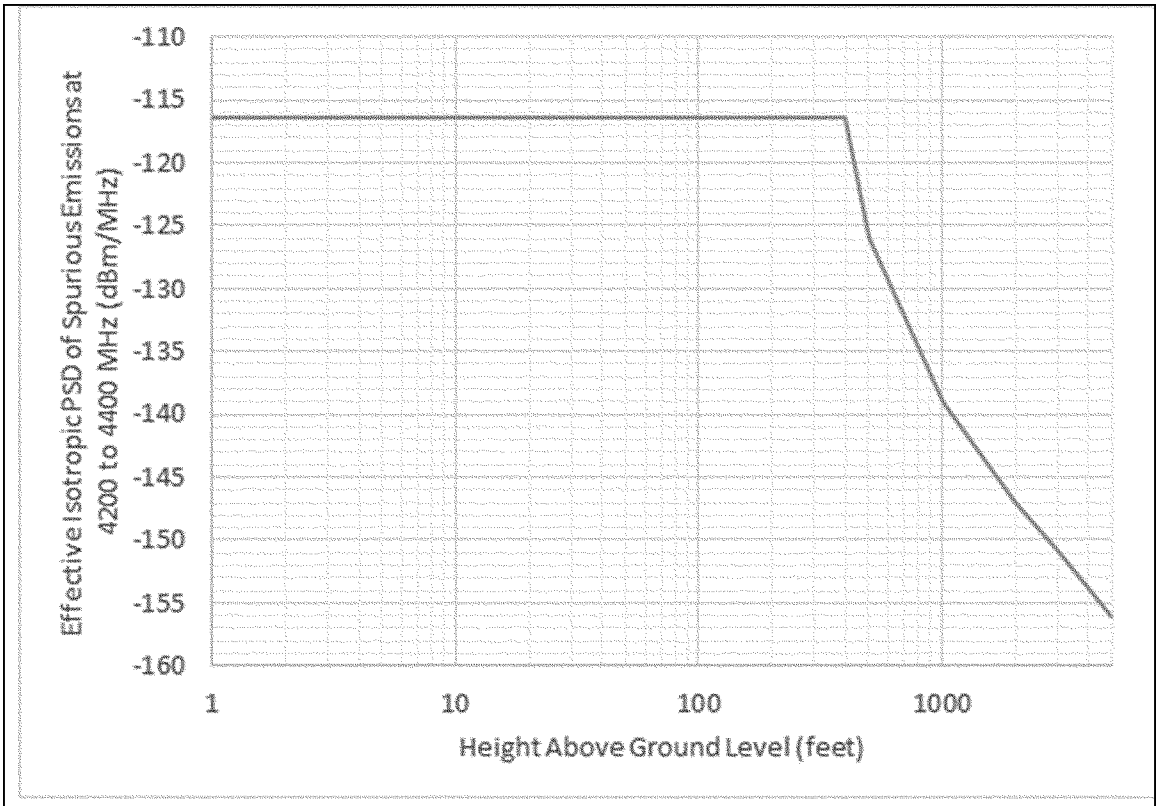
Figure 1 to paragraph (g)(2)(i)—*Fundamental Effective Isotropic PSD at Outside Interface of Aircraft Antenna*



Height above ground (ft)	Effective Isotropic PSD (dBm/MHz)
Aircraft on the ground	-5
50	-5
100	-10
200	-17
500	-22
1000	-33
5000	-47

(ii) Tolerance to radio altimeter interference, for the spurious emissions (4.2–4.4 GHz), at or above the PSD curve threshold specified in figure 2 to paragraph (g)(2)(ii) of this AD.

Figure 2 to paragraph (g)(2)(ii)—*Spurious Effective Isotropic PSD at Outside Interface of Aircraft Antenna*



Aircraft Altitude (ft AGL)	Effective Isotropic PSD (dBm/MHz)
1	-116.50
400	-116.50
500	-126.00
1000	-139.00
2000	-147.00
3000	-151.00
5000	-156.00

(3) For purposes of this AD, a ''non-radio altimeter tolerant airplane'' is one for which the radio altimeter, as installed, does not demonstrate the tolerances specified in paragraphs (g)(2)(i) and (ii) of this AD.

(h) Retained Airplane Flight Manual (AFM) Revision

This paragraph restates the requirements of paragraph (h) of AD 2022–02–16.

(1) Within 2 days after March 16, 2022 (the effective date of AD 2022–06–16): Revise the Limitations Section of the existing AFM to include the information specified in figure 3 to paragraph (h)(1) of this AD. This may be done by inserting a copy of figure 3 to paragraph (h)(1) of this AD into the existing AFM.

Figure 3 to paragraph (h)(1)—*AFM Limitations Revision*

(Required by AD 2022-06-16)

Radio Altimeter 5G C-Band Interference, Takeoff, Approach, Landing, and Go-Around

The following limitations are required for dispatch or release to airports, and takeoff, approach, landing, and go-around on runways, in U.S. airspace in the presence of 5G C-Band wireless broadband interference as identified by NOTAM (NOTAMs will be issued to state the specific airports or approaches where the radio altimeter is unreliable due to the presence of 5G C-Band wireless broadband interference).

Takeoff, Approach, Landing, and Go-Around

Operators must use the Radio Altimeter 5G C-Band Interference, Takeoff, Approach, Landing, and Go-Around procedure contained in the Operating Procedures section of this AFM.

(2) Within 2 days after March 16, 2022 (the effective date of AD 2022–06–16): Revise the Operating Procedures Section of the existing AFM to include the information specified in figure 4 to paragraph (h)(2) of this AD. This may be done by inserting a copy of figure 4 to paragraph (h)(2) of this AD into the existing AFM.

Figure 4 to paragraph (h)(2)—*AFM Operating Procedures Revision*

(Required by AD 2022-06-16)

Radio Altimeter 5G C-Band Interference, Takeoff, Approach, Landing, and Go-Around

Takeoff

If autopilot does not engage above the minimum altitude, when at a safe altitude, select both flight director switches OFF, then ON, to re-engage. LNAV and VNAV may not engage or engage at an erroneous altitude after departure.

ILS Approaches

For ILS approaches, disconnect the autopilot and autothrottle, and place both flight director switches to OFF prior to glideslope intercept. Do not set RADIO minimums on the EFIS control panel, use BARO minimums only.

Non-Precision Approaches

Autopilot, autothrottles, and flight directors may be used. Do not use autothrottles if the autopilot is disengaged. Prior to descending below MDA, disconnect the autothrottle and disengage the autopilot.

Landing

Do not rely on radio altimeter-based altitude aural callouts during approach. Adjust operational (time of arrival) landing distance for manual speedbrake deployment.

During Go-Around and Missed Approach

If go-around is required, ensure thrust is increased to go-around power.

When the flight director switches are OFF, push either TO/GA switch to display the flight director bars. When able, turn both flight directors to ON.

TO/GA mode may not be available. Autopilot may not be available. Monitor pitch and roll modes for engagement.

(i) New Requirement: AFM Revision for Non-Radio Altimeter Tolerant Airplanes

For non-radio altimeter tolerant airplanes, do the actions specified in paragraphs (i)(1) and (2) of this AD.

(1) On or before June 30, 2023, revise the Limitations Section of the existing AFM to include the information specified in figure 5 to paragraph (i) of this AD. This may be done by inserting a copy of figure 5 to paragraph (i) of this AD into the existing AFM. Incorporating the AFM revision required by this paragraph terminates the AFM revision required by paragraph (h)(1) of this AD.

(2) Before further flight after incorporating the limitations specified in figure 5 to paragraph (i) of this AD, remove the AFM revision required by paragraph (h)(1) of this AD.

Figure 5 to paragraph (i)—*AFM Revision for Non-Radio Altimeter Tolerant Airplanes*

(Required by AD 20-**-**-**)**

Radio Altimeter 5G C-Band Interference, Takeoff, Approach, Landing, and Go-Around

Due to the presence of 5G C-Band wireless broadband interference, the following limitations are required for dispatch or release to airports, and takeoff, approach, landing, and go-around on runways, in the contiguous U.S. airspace.

Takeoff, Approach, Landing, and Go-Around

Operators must use the Radio Altimeter 5G C-Band Interference, Takeoff, Approach, Landing, and Go-Around procedure contained in the Operating Procedures section of this AFM.

(j) New Requirement: AFM Revision for Radio Altimeter Tolerant Airplanes

For radio altimeter tolerant airplanes, do the actions specified in paragraphs (j)(1) and (2) of this AD.

(1) On or before June 30, 2023, revise the Limitations Section of the existing AFM to include the information specified in figure 6 to paragraph (j) of this AD. This may be done by inserting a copy of figure 6 to paragraph (j) of this AD into the existing AFM. Incorporating the AFM revision required by this paragraph terminates the AFM revision required by paragraph (h)(1) of this AD.

(2) Before further flight after incorporating the limitations specified in figure 6 to paragraph (j) of this AD, remove the AFM revision required by paragraph (h)(1) of this AD.

Figure 6 to paragraph (j)—*AFM Revision for Radio Altimeter Tolerant Airplanes*

(Required by AD 20-**-**-**)**

Radio Altimeter 5G C-Band Interference, Takeoff, Approach, Landing, and Go-Around

Due to the presence of 5G C-Band wireless broadband interference, the following limitations are required for dispatch or release to airports, and takeoff, approach, landing, and go-around on runways, in the contiguous U.S. airspace unless operating at a 5G C-Band mitigated airport as identified in an FAA *Domestic Notice*.

Takeoff, Approach, Landing, and Go-Around

Operators must use the Radio Altimeter 5G C-Band Interference, Takeoff, Approach, Landing, and Go-Around procedure contained in the Operating Procedures section of this AFM.

(k) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Operational Safety Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or responsible Flight Standards Office, as appropriate. If sending information directly to the manager of the Operational Safety Branch, send it to the attention of the person identified in paragraph (m) of this AD. Information may be emailed to: *AMOC@faa.gov.*

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the responsible Flight Standards Office.

(3) AMOCs approved for AD 2021–23–12, Amendment 39–21810 (86 FR 69984, December 9, 2021) providing relief for specific radio altimeter installations are approved as AMOCs for the requirements specified in paragraph (h) of this AD until June 30, 2023.

(l) Related Information

For more information about this AD, contact Brett Portwood, Continued Operational Safety Technical Advisor, COS Program Management Section, Operational Safety Branch, FAA, 3960 Paramount Boulevard, Lakewood, CA 90712–4137; phone: 817–222–5390; email: *operationalsafety@faa.gov*.

(m) Material Incorporated by Reference

None.

Issued on April 28, 2023.

Michael Linegang,

Acting Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2023–09430 Filed 5–1–23; 4:15 pm]

BILLING CODE 4910–13–C

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2023–0672; Project Identifier AD–2022–01429–T]

RIN 2120–AA64

Airworthiness Directives; The Boeing Company Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to supersede Airworthiness Directive (AD) 2022–04–05, which applies to all The Boeing Company Model 757 airplanes and Model 767 airplanes. AD 2022–04–05 requires revising the limitations and operating procedures sections of the existing airplane flight manual (AFM) to incorporate specific operating procedures for landing distance calculations, instrument landing system (ILS) approaches, non-precision approaches, speedbrake deployment, and go-around and missed approaches, when in the presence of 5G C-Band interference as identified by Notices to Air Missions (NOTAMs). Since the FAA issued AD 2022–04–05, the FAA determined that additional limitations are needed due to the continued deployment of new 5G C-Band base stations whose signals are expected to cover most of the contiguous United States at transmission frequencies between 3.7–3.98 GHz. This proposed AD would require revising the limitations and operating procedures sections of the existing AFM to incorporate specific operating procedures for landing distance calculations, ILS approaches, non-precision approaches, speedbrake deployment, and go-around and missed approaches, due to the presence of 5G C-Band interference. The FAA is proposing this AD to address the unsafe condition on these products.

DATES: The FAA must receive comments on this proposed AD by May 23, 2023.

ADDRESSES: You may send comments, using the procedures found in 14 CFR 11.43 and 11.45, by any of the following methods:

- *Federal eRulemaking Portal:* Go to regulations.gov. Follow the instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.
- *Hand Delivery:* Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

AD Docket: You may examine the AD docket at regulations.gov under Docket No. FAA–2023–0672; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this NPRM, any comments received, and other information. The street address for Docket Operations is listed above.

FOR FURTHER INFORMATION CONTACT: Brett Portwood, Continued Operational Safety Technical Advisor, COS Program Management Section, Operational Safety Branch, FAA, 3960 Paramount Boulevard, Lakewood, CA 90712–4137; phone: 817–222–5390; email: *operationalsafety@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under **ADDRESSES**. Include ''Docket No. FAA–2023–0672; Project Identifier AD–2022–01429–T'' at the beginning of your comments. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend the proposal because of those comments.

Except for Confidential Business Information (CBI) as described in the following paragraph, and other information as described in 14 CFR 11.35, the FAA will post all comments received, without change, to regulations.gov, including any personal information you provide. The agency will also post a report summarizing each substantive verbal contact received about this proposed AD.

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Background

The FAA issued AD 2021–23–12, Amendment 39–21810 (86 FR 69984, December 9, 2021) (AD 2021–23–12), for all transport and commuter category airplanes equipped with a radio altimeter. AD 2021–23–12 was prompted by a determination that radio altimeters cannot be relied upon to perform their intended function if they experience interference from wireless broadband operations in the 3.7–3.98 GHz frequency band (5G C-Band). AD 2021–23–12 requires revising the limitations section of the existing AFM to incorporate limitations prohibiting certain operations requiring radio altimeter data when in the presence of 5G C-Band interference as identified by NOTAMs. The agency issued AD 2021–23–12 because radio altimeter anomalies that are undetected by the automation or pilot, particularly close to the ground (*e.g.,* landing flare), could lead to loss of continued safe flight and landing.

The FAA subsequently identified an additional hazard presented by 5G C-Band interference on The Boeing Company Model 757 and Model 767 airplanes and issued AD 2022–04–05, Amendment 39–21947 (87 FR 8152, February 14, 2022) (AD 2022–04–05). AD 2022–04–05 was prompted by a determination that, during approach, landings, and go-arounds, as a result of 5G C-band interference, certain airplane systems may not properly function, resulting in increased flightcrew workload while on approach with the flight director, autothrottle, or autopilot engaged. AD 2022–04–05 requires revising the limitations and operating procedures sections of the existing AFM to incorporate specific operating procedures for landing distance calculations, ILS approaches, non-precision approaches, speedbrake deployment, and go-around and missed approaches, when in the presence of 5G C-Band interference as identified by NOTAMs. The agency issued AD 2022–

02–16 to address 5G C-Band interference that could result in increased flightcrew workload and could lead to reduced ability of the flightcrew to maintain safe flight and landing of the airplane.

Actions Since AD 2022–04–05 Was Issued

Since issuing AD 2022–04–05, the FAA determined that additional limitations are needed due to the continued deployment of new 5G C-Band base stations whose signals are expected to cover most of the contiguous United States at transmission frequencies between 3.7–3.98 GHz. Therefore, the FAA issued an NPRM, Docket No. FAA–2022–1647 (88 FR 1520, January 11, 2023) (the NPRM), proposing to supersede AD 2021–23–12. In the NPRM, the FAA proposed to retain most of the operational prohibitions required by AD 2021–23–12 until June 30, 2023; on or before June 30, 2023, operators would be required to revise their existing AFM to prohibit these operations unless the airplane has a radio altimeter meeting proposed minimum performance levels (a defined power spectral density (PSD) curve as well as a defined aggregate spurious emission level) and is operating at a 5G C-Band mitigated airport (5G CMA). In the NPRM, the FAA also proposed to require all airplanes operating under 14 CFR part 121 to have a radio altimeter meeting the proposed minimum performance standards by February 1, 2024.

Since the NPRM was published, the FAA has determined that a PSD curve is a more appropriate method to define performance than a single fixed emission level. The proposed PSD curve more accurately reflects differences in radio altimeter susceptibility to interfering emissions at different altitude levels. The FAA plans to issue guidance on how to show compliance with both the fundamental PSD curve and spurious PSD curve, including the data to be submitted, for the FAA to approve the method used.

2022–04–05 relies on the FAA's use of NOTAMs to identify 5G C-band interference at certain airports in the U.S. airspace. As explained in more detail in the NPRM, those NOTAMs are no longer the best means of communicating the location of the 5G C-Band environment. Therefore, this proposed AD would retain the AFM limitations and operating procedures required by AD 2022–04–05 until June 30, 2023. On or before June 30, 2023, this proposed AD would require operators to replace the limitations with limitations prohibiting the same operations, except the prohibitions would not be tied to NOTAMs but instead would depend on whether the airplane is operated at a 5G CMA as identified by an FAA Domestic Notice. Because the 5G C-Band Interference operating procedure required by AD 2022–04–05 references AD 2021–23–12 for certain prohibited ILS approaches, this proposed AD would require operators to replace the procedure with an operating procedure containing the same information, except it would list the specific prohibited ILS approaches.

FAA's Determination

The FAA is issuing this NPRM after determining that the unsafe condition described previously is likely to exist or develop on other products of the same type design.

Proposed AD Requirements in This NPRM

This proposed AD would retain the AFM revisions required by AD 2022–04–05 until June 30, 2023. On or before June 30, 2023, this proposed AD would require replacing those AFM revisions with limitations requiring the same procedures for dispatch or release to airports, and approach, landing, and go-around on runways, at all airports for non-radio altimeter tolerant airplanes. For radio altimeter tolerant airplanes, the procedures would not be required at 5G CMAs as identified in an FAA Domestic Notice. The minimum performance levels in this proposed AD for determining whether an airplane is radio altimeter tolerant are the same minimum performance levels proposed in the NPRM, except the FAA has replaced the proposed fixed emission level with a proposed PSD curve emission threshold that more accurately reflects differences in radio altimeter susceptibility to interfering emissions at different altitude levels.

Paragraph (l)(3) of this proposed AD specifies that AMOCs approved for AD 2021–23–12 providing relief for specific radio altimeter installations would be approved as AMOCs for the requirements specified in paragraph (h) of this proposed AD until June 30, 2023.

Interim Action

The FAA considers that this AD, if adopted as proposed, would be an interim action. Once the Technical Standard Order (TSO) standard for radio altimeters is established, which will follow the existing international technical consensus on the establishment of the minimum operational performance standards (MOPS), the FAA anticipates that the MOPS will be incorporated into the TSO. The FAA also anticipates that aircraft incorporating equipment approved under the new Radio Altimeter TSO will be able to operate in both 5G CMAs and non-5G CMAs with no 5G C-Band-related AFM limitations. Once a new radio altimeter TSO is developed, approved, and available, the FAA might consider additional rulemaking.

Costs of Compliance

The cost information below describes the costs to change the AFM. Although this proposed AD would largely maintain the AFM limitations currently required by AD 2022–04–05, the FAA acknowledges that this proposed AD may also impose costs on some aircraft operators from having to change their conduct to comply with the amended AFM. However, the FAA lacks the data necessary to quantify the costs associated with aircraft operators changing their conduct. The FAA is seeking public comment on these costs so the agency can more fully account for the impact of this regulatory action.

The FAA estimates that this AD, if adopted as proposed, would affect 1,108 airplanes of U.S. registry.[1] The FAA estimates the following costs to comply with this proposed AD:

[1] This is the number of Boeing Model 757 and 767 airplanes on the FAA's registry as of 12/1/2022.

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
AFM revision (retained actions from AD 2022–04–05).	1 work-hour × $85 per hour[2] = $85	$0	$85	$94,180
New AFM revisions (new proposed action)	1 work-hour × $85 per hour = $85	0	85	[3] 94,180

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the Agency's authority.

The FAA is issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701: General requirements. Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

The FAA has determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that the proposed regulation:

(1) Is not a ''significant regulatory action'' under Executive Order 12866,

(2) Would not affect intrastate aviation in Alaska, and

(3) Would not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA proposes to amend 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by:

■ a. Removing Airworthiness Directive (AD) 2022–04–05, Amendment 39–21947 (87 FR 8152, February 14, 2022), and

■ b. Adding the following new AD:

The Boeing Company Airplanes: Docket No. FAA–2023–0672; Project Identifier AD–2022–01429–T.

(a) Comments Due Date

The FAA must receive comments on this airworthiness directive (AD) by May 23, 2023.

(b) Affected ADs

This AD replaces AD 2022–04–05, Amendment 39–21947 (87 FR 8152, February 14, 2022) (AD 2022–04–05).

(c) Applicability

This AD applies to all The Boeing Company airplanes identified in paragraphs (c)(1) and (2) of this AD, certificated in any category.

(1) Model 757–200, –200PF, –200CB, and –300 series airplanes.

(2) Model 767–200, –300, –300F, –400ER, and –2C series airplanes.

(d) Subject

Air Transport Association (ATA) of America Code 34, Navigation.

(e) Unsafe Condition

This AD was prompted by a determination that radio altimeters cannot be relied upon to perform their intended function if they experience interference from wireless broadband operations in the 3.7–3.98 GHz frequency band (5G C-Band), and a determination that, during approach, landings, and go-arounds, as a result of this interference, certain airplane systems may not properly function, resulting in increased flightcrew workload while on approach with the flight director, autothrottle, or autopilot engaged. The FAA is issuing this AD to address 5G C-Band interference that could result in increased flightcrew workload and could lead to reduced ability of the flightcrew to maintain safe flight and landing of the airplane.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Definitions

(1) For purposes of this AD, a ''5G C-Band mitigated airport'' (5G CMA) is an airport at which the telecommunications companies have agreed to voluntarily limit their 5G deployment at the request of the FAA, as identified by an FAA Domestic Notice.

(2) For purposes of this AD, a ''radio altimeter tolerant airplane'' is one for which the radio altimeter, as installed, demonstrates the tolerances specified in paragraphs (g)(2)(i) and (ii) of this AD, using a method approved by the FAA.

(i) Tolerance to radio altimeter interference, for the fundamental emissions (3.7–3.98 GHz), at or above the power spectral density (PSD) curve threshold specified in figure 1 to paragraph (g)(2)(i) of this AD.

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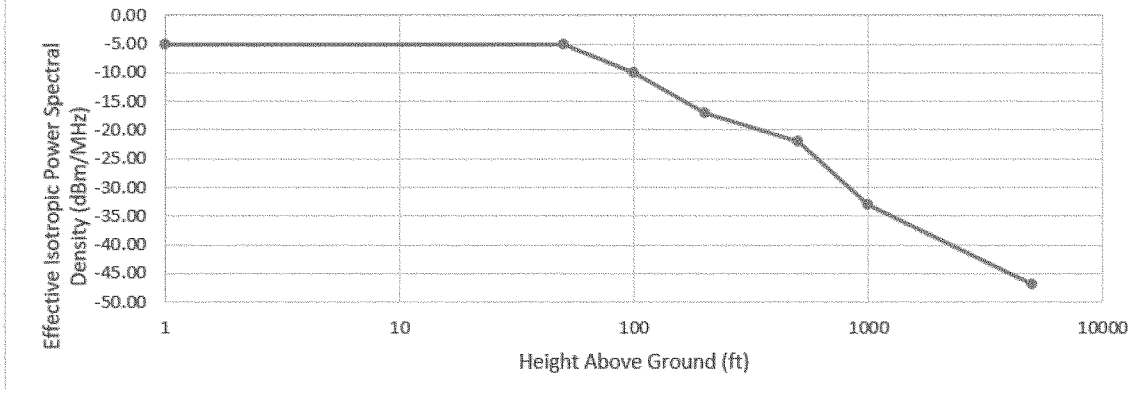
Figure 1 to paragraph (g)(2)(i)—*Fundamental Effective Isotropic PSD at Outside Interface of Aircraft Antenna*

[2] The labor rate of $85 per hour is the average wage rate for an aviation mechanic.

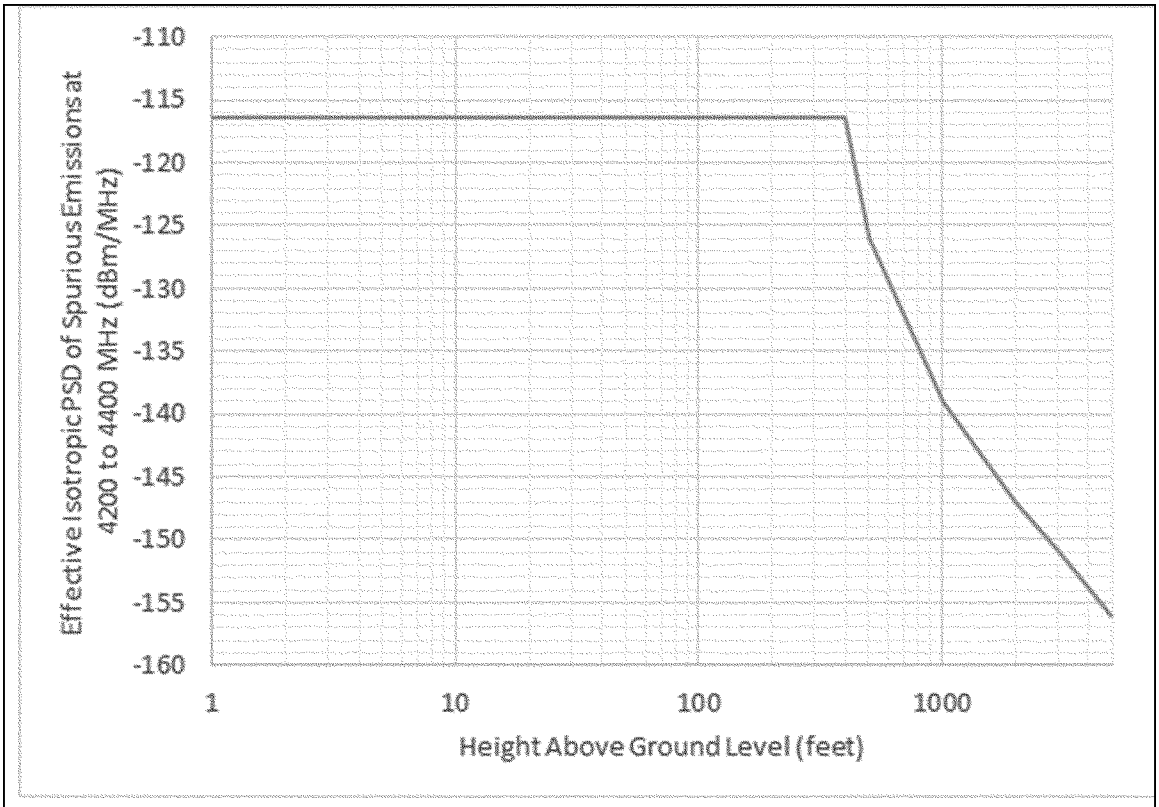
[3] The estimated cost for this revision would not constitute a significant economic impact (even for small entities) because $85 is a minimal cost compared to the regular costs of maintaining and operating a Model 757 or 767 transport category airplane.



Height above ground (ft)	Effective Isotropic PSD (dBm/MHz)
Aircraft on the ground	-5
50	-5
100	-10
200	-17
500	-22
1000	-33
5000	-47

Figure 2 to paragraph (g)(2)(ii)—*Spurious Effective Isotropic PSD at Outside Interface of Aircraft Antenna*

(ii) Tolerance to radio altimeter interference, for the spurious emissions (4.2–4.4 GHz), at or above the PSD curve threshold specified in figure 2 to paragraph (g)(2)(ii) of this AD.



Aircraft Altitude (ft AGL)	Effective Isotropic PSD (dBm/MHz)
1	-116.50
400	-116.50
500	-126.00
1000	-139.00
2000	-147.00
3000	-151.00
5000	-156.00

(3) For purposes of this AD, a ''non-radio altimeter tolerant airplane'' is one for which the radio altimeter, as installed, does not demonstrate the tolerances specified in paragraphs (g)(2)(i) and (ii) of this AD.

(h) Retained Airplane Flight Manual (AFM) Revision

This paragraph restates the requirements of paragraph (g) of AD 2022–04–05.

(1) Within 2 days after February 14, 2022 (the effective date of AD 2022–04–05): Revise the Limitations Section of the existing AFM to include the information specified in figure 3 to paragraph (h)(1) of this AD. This may be done by inserting a copy of figure 3 to paragraph (h)(1) of this AD into the existing AFM.

Figure 3 to paragraph (h)(1)—*AFM Limitations Revisions*

(Required by AD 2022-04-05)

Radio Altimeter 5G C-Band Interference, Approach, Landing, and Go-Around

The following limitations are required for dispatch or release to airports, and approach, landing, and go-around on runways, in U.S. airspace in the presence of 5G C-Band wireless broadband interference as identified by NOTAM (NOTAMs will be issued to state the specific airports or approaches where the radio altimeter is unreliable due to the presence of 5G C-Band wireless broadband interference).

Approach, Landing, and Go-Around

Operators must use the Radio Altimeter 5G C-Band Interference, Approach, Landing, and Go-Around procedure contained in the Operating Procedures Section of this AFM.

(2) Within 2 days after February 14, 2022 (the effective date of AD 2022–04–05): Revise the Operating Procedures Section of the existing AFM to include the information specified in figure 4 to paragraph (h)(2) of this AD. This may be done by inserting a copy of figure 4 to paragraph (h)(2) of this AD into the Operating Procedures Section of the existing AFM.

Figure 4 to paragraph (h)(2)—*AFM Operating Procedures Revision*

(Required by AD 2022-04-05)

Radio Altimeter 5G C-Band Interference, Approach, Landing, and Go-Around

Landing Distance Calculations

For airplanes with Yaw Damper Stabilizer Trim module (YSM), adjust the operational (time of arrival) landing distance for manual speedbrake deployment if MAX MANUAL braking is required. When using autobrakes, no correction is needed since the calculations already take into account that manual speedbrake deployment may be needed.

ILS Approaches

For ILS approaches not prohibited by AD 2021-23-12, disconnect the autopilot and autothrottle, and place both flight director switches to OFF prior to glideslope intercept.

Non-Precision Approaches

Non-precision instrument approaches can be conducted using VNAV or V/S with flight directors, autopilot, and autothrottle to published minimums.

During Landing

For airplanes with Yaw Damper Stabilizer Trim module (YSM), if MAX MANUAL braking is required, manually deploy the speedbrake if it does not deploy automatically.

During Go-Around and Missed Approach

If the flight director is ON, cycle to OFF, then ON, as needed.
If the flight director is OFF, turn ON, as needed.

(i) New Requirement: AFM Limitations Revision for Non-Radio Altimeter Tolerant Airplanes

For non-radio altimeter tolerant airplanes, do the actions specified in paragraphs (i)(1) and (2) of this AD.

(1) On or before June 30, 2023, revise the Limitations Section of the existing AFM to include the information specified in figure 5 to paragraph (i) of this AD. This may be done by inserting a copy of figure 5 to paragraph (i) of this AD into the existing AFM. Incorporating the AFM revision required by this paragraph terminates the AFM revision required by paragraph (h)(1) of this AD.

(2) Before further flight after incorporating the limitations specified in figure 5 to paragraph (i) of this AD, remove the AFM revision required by paragraph (h)(1) of this AD.

Figure 5 to paragraph (i)—*AFM Limitations Revision for Non-Radio Altimeter Tolerant Airplanes*

(Required by AD 20-**-**-**)**

Radio Altimeter 5G C-Band Interference, Approach, Landing, and Go-Around

Due to the presence of 5G C-Band wireless broadband interference, the following limitations are required for dispatch or release to airports, and approach, landing, and go-around on runways, in the contiguous U.S. airspace.

Approach, Landing, and Go-Around

Operators must use the Radio Altimeter 5G C-Band Interference, Approach, Landing, and Go-Around procedure contained in the Operating Procedures Section of this AFM.

(j) New Requirement: AFM Limitations Revision for Radio Altimeter Tolerant Airplanes

For radio altimeter tolerant airplanes, do the actions specified in paragraphs (j)(1) and (2) of this AD.

(1) On or before June 30, 2023, revise the Limitations Section of the existing AFM to include the information specified in figure 6 to paragraph (j) of this AD. This may be done by inserting a copy of figure 6 to paragraph (j) of this AD into the existing AFM. Incorporating the AFM revision required by this paragraph terminates the AFM revision required by paragraph (h)(1) of this AD.

(2) Before further flight after incorporating the limitations specified in figure 6 to paragraph (j) of this AD, remove the AFM revision required by paragraph (h)(1) of this AD.

Figure 6 to paragraph (j)—*AFM Limitations Revision for Radio Altimeter Tolerant Airplanes*

(Required by AD 20-**-**-**)**

Radio Altimeter 5G C-Band Interference, Approach, Landing, and Go-Around

Due to the presence of 5G C-Band wireless broadband interference, the following limitations are required for dispatch or release to airports, and approach, landing, and go-around on runways, in the contiguous U.S. airspace unless operating at a 5G C-Band mitigated airport as identified in an FAA *Domestic Notice*.

Approach, Landing, and Go-Around

Operators must use the Radio Altimeter 5G C-Band Interference, Approach, Landing, and Go-Around procedure contained in the Operating Procedures Section of this AFM.

(k) New Requirement: AFM Operating Procedures Revision

For all airplanes, do the actions specified in paragraphs (k)(1) and (2) of this AD.

(1) On or before June 30, 2023, revise the Operating Procedures Section of the existing AFM to include the information specified in figure 7 to paragraph (k) of this AD. This may be done by inserting a copy of figure 7 to paragraph (k) of this AD into the existing AFM. Incorporating the AFM revision required by this paragraph terminates the AFM revision required by paragraph (h)(2) of this AD.

(2) Before further flight after incorporating the operating procedures specified in figure 7 to paragraph (k) of this AD, remove the AFM revision required by paragraph (h)(2) of this AD.

Figure 7 to paragraph (k)—*AFM Operating Procedures Revision*

(Required by AD 20-**-**-**)**

Radio Altimeter 5G C-Band Interference, Approach, Landing, and Go-Around

Landing Distance Calculations
For airplanes with Yaw Damper Stabilizer Trim module (YSM), adjust the operational (time of arrival) landing distance for manual speedbrake deployment if MAX MANUAL braking is required. When using autobrakes, no correction is needed since the calculations already take into account that manual speedbrake deployment may be needed.

ILS Approaches
For ILS approaches other than SA CAT I, SA CAT II, CAT II, and CAT III, disconnect the autopilot and autothrottle, and place both flight director switches to OFF prior to glideslope intercept.

Non-Precision Approaches
Non-precision instrument approaches can be conducted using VNAV or V/S with flight directors, autopilot, and autothrottle to published minimums.

During Landing
For airplanes with Yaw Damper Stabilizer Trim module (YSM), if MAX MANUAL braking is required, manually deploy the speedbrake if it does not deploy automatically.

During Go-Around and Missed Approach
If the flight director is ON, cycle to OFF, then ON, as needed.
If the flight director is OFF, turn ON, as needed.

(l) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Operational Safety Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or responsible Flight Standards Office, as appropriate. If sending information directly to the manager of the Operational Safety Branch, send it to the attention of the person identified in paragraph (m) of this AD. Information may be emailed to: *AMOC@faa.gov.*

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the responsible Flight Standards Office.

(3) AMOCs approved for AD 2021–23–12, Amendment 39–21810 (86 FR 69984, December 9, 2021) providing relief for specific radio altimeter installations are approved as AMOCs for the requirements specified in paragraph (h) of this AD until June 30, 2023.

(m) Related Information

For more information about this AD, contact Brett Portwood, Continued Operational Safety Technical Advisor, COS Program Management Section, Operational Safety Branch, FAA, 3960 Paramount Boulevard, Lakewood, CA 90712–4137; phone: 817–222–5390; email: *operationalsafety@faa.gov.*

(m) Material Incorporated by Reference

None.

Issued on April 28, 2023.

Michael Linegang,

Acting Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2023–09435 Filed 5–1–23; 4:15 pm]

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2023–0923; Project Identifier AD–2022–01432–T]

RIN 2120–AA64

Airworthiness Directives; The Boeing Company Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to supersede Airworthiness Directive (AD) 2022–09–18, which applies to all The Boeing Company Model 707, 717, and 727 airplanes; Model DC–8, DC–9, and DC–10 airplanes; Model MD–10 and MD–11 airplanes; Model DC–9–81 (MD–81), DC–9–82 (MD–82), DC–9–83 (MD–83), DC–9–87 (MD–87), and MD–88

airplanes; and Model MD 90–30 airplanes. AD 2022–09–18 requires revising the limitations and operating procedures sections of the existing airplane flight manual (AFM) to incorporate specific operating procedures for, depending on the airplane model, instrument landing system (ILS) approaches, non-precision approaches, ground spoiler deployment, and go-around and missed approaches, when in the presence of 5G C Band interference as identified by Notices to Air Missions (NOTAMs). Since the FAA issued AD 2022–09–18, the FAA determined that additional limitations are needed due to the continued deployment of new 5G C-Band base stations whose signals are expected to cover most of the contiguous United States at transmission frequencies between 3.7–3.98 GHz. This proposed AD would require revising the limitations and operating procedures sections of the AFM to incorporate specific operating procedures for, depending on the airplane model, ILS approaches, non-precision approaches, ground spoiler deployment, and go-around and missed approaches, due to the presence of 5G C-Band interference. The FAA is proposing this AD to address the unsafe condition on these products.

DATES: The FAA must receive comments on this proposed AD by May 23, 2023.

ADDRESSES: You may send comments, using the procedures found in 14 CFR 11.43 and 11.45, by any of the following methods:

- *Federal eRulemaking Portal:* Go to *regulations.gov*. Follow the instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.
- *Hand Delivery:* Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

AD Docket: You may examine the AD docket at *regulations.gov* under Docket No. FAA–2023–0923; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this NPRM, any comments received, and other information. The street address for Docket Operations is listed above.

FOR FURTHER INFORMATION CONTACT: Brett Portwood, Continued Operational Safety Technical Advisor, COS Program Management Section, Operational Safety Branch, FAA, 3960 Paramount Boulevard, Lakewood, CA 90712–4137; phone: 817–222–5390; email: *operationalsafety@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under **ADDRESSES**. Include ''Docket No. FAA–2023–0923; Project Identifier AD–2022–01432–T'' at the beginning of your comments. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend the proposal because of those comments.

Except for Confidential Business Information (CBI) as described in the following paragraph, and other information as described in 14 CFR 11.35, the FAA will post all comments received, without change, to *regulations.gov*, including any personal information you provide. The agency will also post a report summarizing each substantive verbal contact received about this proposed AD.

Confidential Business Information

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this NPRM contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this NPRM, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as ''PROPIN.'' The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this NPRM. Submissions containing CBI should be sent to Brett Portwood, Continued Operational Safety Technical Advisor, COS Program Management Section, Operational Safety Branch, FAA, 3960 Paramount Boulevard, Lakewood, CA 90712–4137; phone: 817–222–5390; email: *operationalsafety@faa.gov.* Any commentary that the FAA receives that is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Background

The FAA issued AD 2021–23–12, Amendment 39–21810 (86 FR 69984, December 9, 2021) (AD 2021–23–12), for all transport and commuter category airplanes equipped with a radio altimeter. AD 2021–23–12 was prompted by a determination that radio altimeters cannot be relied upon to perform their intended function if they experience interference from wireless broadband operations in the 3.7–3.98 GHz frequency band (5G C-Band). AD 2021–23–12 requires revising the limitations section of the existing AFM to incorporate limitations prohibiting certain operations requiring radio altimeter data when in the presence of 5G C-Band interference as identified by NOTAMs. The agency issued AD 2021–23–12 because radio altimeter anomalies that are undetected by the automation or pilot, particularly close to the ground (*e.g.,* landing flare), could lead to loss of continued safe flight and landing.

The FAA subsequently identified an additional hazard presented by 5G C-Band interference on The Boeing Company Model 707, 717, and 727 airplanes; Model DC–8, DC–9, and DC–10 airplanes; Model MD–10 and MD–11 airplanes; Model DC–9–81 (MD–81), DC–9–82 (MD–82), DC–9–83 (MD–83), DC–9–87 (MD–87), and MD–88 airplanes; and Model MD–90–30 airplanes, and issued AD 2022–09–18, Amendment 39–22038 (87 FR 31097, May 23, 2022) (AD 2022–09–18). AD 2022–09–18 was prompted by a determination that, during approach, landings, and go-arounds, as a result of 5G C-Band interference, certain airplane systems may not properly function, resulting in increased flightcrew workload while on approach with the flight director, autothrottle, or autopilot engaged. AD 2022–09–18 requires revising the limitations and operating procedures sections of the existing AFM to incorporate specific operating procedures for, depending on the airplane model, ILS approaches, non-precision approaches, ground spoiler deployment, and go-around and missed approaches, when in the presence of 5G C-Band interference as identified by NOTAMs. The agency issued AD 2022–09–18 to address 5G C-Band interference that could result in increased flightcrew workload and could lead to reduced ability of the flightcrew to maintain safe flight and landing of the airplane.

Actions Since AD 2022–09–18 Was Issued

Since issuing AD 2022–09–18, the FAA determined that additional

limitations are needed due to the continued deployment of new 5G C-Band base stations whose signals are expected to cover most of the contiguous United States at transmission frequencies between 3.7–3.98 GHz. Therefore, the FAA issued an NPRM, Docket No. FAA–2022–1647 (88 FR 1520, January 11, 2023) (the NPRM), proposing to supersede AD 2021–23–12. In the NPRM, the FAA proposed to retain most of the operational prohibitions required by AD 2021–23–12 until June 30, 2023; on or before June 30, 2023, operators would be required to revise their existing AFM to prohibit these operations unless the airplane has a radio altimeter meeting proposed minimum performance levels (a defined power spectral density (PSD) curve as well as a defined aggregate spurious emission level) and is operating at a 5G C-Band mitigated airport (5G CMA). In the NPRM, the FAA also proposed to require all airplanes operating under 14 CFR part 121 to have a radio altimeter meeting the proposed minimum performance standards by February 1, 2024.

Since the NPRM was published, the FAA has determined that a PSD curve is a more appropriate method to define performance than a single fixed emission level. The proposed PSD curve more accurately reflects differences in radio altimeter susceptibility to interfering emissions at different altitude levels. The FAA plans to issue guidance on how to show compliance with both the fundamental PSD curve and spurious PSD curve, including the data to be submitted, for the FAA to approve the method used.

AD 2022–09–18 relies on the FAA's use of NOTAMs to identify 5G C-band interference at certain airports in the U.S. airspace. As explained in more detail in the NPRM, those NOTAMs are no longer the best means of communicating the location of the 5G C-Band environment. Therefore, this proposed AD would retain the AFM limitations and operating procedures required by AD 2022–09–18 until June 30, 2023. On or before June 30, 2023, this proposed AD would require operators to replace the limitations with limitations prohibiting the same operations, except the prohibitions would not be tied to NOTAMs but instead would depend on whether the airplane is operated at a 5G CMA as identified by an FAA Domestic Notice. Because the applicable 5G C-Band Interference operating procedures required by AD 2022–09–18 reference AD 2021–23–12 for certain prohibited ILS approaches, this proposed AD would require operators to replace the procedure with an operating procedure containing the same information, except it would list the specific prohibited ILS approaches.

FAA's Determination

The FAA is issuing this NPRM after determining that the unsafe condition described previously is likely to exist or develop on other products of the same type design.

Proposed AD Requirements in This NPRM

This proposed AD would retain the AFM revisions required by AD 2022–09–18 until June 30, 2023. On or before June 30, 2023, this proposed AD would require replacing those AFM revisions with limitations requiring the same procedures for ILS approaches, non-precision approaches, ground spoiler deployment, and go-around and missed approaches, at all airports for non-radio altimeter tolerant airplanes. For radio altimeter tolerant airplanes, the procedures would not be required at 5G CMAs as identified in an FAA Domestic Notice. The minimum performance levels in this proposed AD for determining whether an airplane is radio altimeter tolerant are the same minimum performance levels proposed in the NPRM, except the FAA has replaced the proposed fixed emission level with a proposed PSD curve emission threshold that more accurately reflects differences in radio altimeter susceptibility to interfering emissions at different altitude levels.

Paragraph (m)(3) of this proposed AD specifies that AMOCs approved for AD 2021–23–12 providing relief for specific radio altimeter installations would be approved as AMOCs for the requirements specified in paragraph (h) of this proposed AD until June 30, 2023.

Interim Action

The FAA considers that this AD, if adopted as proposed, would be an interim action. Once the Technical Standard Order (TSO) standard for radio altimeters is established, which will follow the existing international technical consensus on the establishment of the minimum operational performance standards (MOPS), the FAA anticipates that the MOPS will be incorporated into the TSO. The FAA also anticipates that aircraft incorporating equipment approved under the new Radio Altimeter TSO will be able to operate in both 5G CMAs and non-5G CMAs with no 5G C-Band-related AFM limitations. Once a new radio altimeter TSO is developed, approved, and available, the FAA might consider additional rulemaking.

Costs of Compliance

The cost information below describes the costs to change the AFM. Although this proposed AD would largely maintain the AFM limitations currently required by AD 2022–09–18, the FAA acknowledges that this proposed AD may also impose costs on some aircraft operators from having to change their conduct to comply with the amended AFM. However, the FAA lacks the data necessary to quantify the costs associated with aircraft operators changing their conduct. The FAA is seeking public comment on these costs so the agency can more fully account for the impact of this regulatory action.

The FAA estimates that this AD, if adopted as proposed, would affect 476 airplanes of U.S. registry.[1] The FAA estimates the following costs to comply with this proposed AD:

[1] This is the number of Boeing Model 707, 717, and 727 airplanes; Model DC–8, DC–9, and DC–10 airplanes; Model MD 10 and MD–11 airplanes; Model DC–9–81 (MD–81), DC–9–82 (MD–82), DC–9–83 (MD–83), DC–9–87 (MD–87), and MD–88 airplanes; and Model MD 90–30 airplanes on the FAA's registry as of December 1, 2022.

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
AFM revision (retained actions from AD 2022–09–18).	1 work-hour × $85 per hour[2] = $85	$0	$85	$40,460
New AFM revisions (new proposed action)	1 work-hour × $85 per hour = $85	0	85	[3] 40,460

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the Agency's authority.

The FAA is issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701: General requirements. Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

The FAA has determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that the proposed regulation:

(1) Is not a ''significant regulatory action'' under Executive Order 12866,

(2) Would not affect intrastate aviation in Alaska, and

(3) Would not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA proposes to amend 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by:

■ a. Removing Airworthiness Directive (AD) 2022–09–18, Amendment 39–22038 (87 FR 31097, May 23, 2022), and

■ b. Adding the following new AD:

The Boeing Company Airplanes: Docket No. FAA–2023–0923; Project Identifier AD–2022–01432–T.

(a) Comments Due Date

The FAA must receive comments on this airworthiness directive (AD) by May 23, 2023.

(b) Affected ADs

This AD replaces AD 2022–09–18, Amendment 39–22038 (87 FR 31097, May 23, 2022) (AD 2022–09–18).

(c) Applicability

This AD applies to all The Boeing Company airplanes identified in paragraphs (c)(1) through (9) of this AD, certificated in any category.

(1) Model 707–100 Long Body, –200, –100B Long Body, and –100B Short Body series airplanes, and Model 707–300, –300B, –300C, and –400 series airplanes.

(2) Model 717–200 airplanes.

(3) Model 727, 727C, 727–100, 727–100C, 727–200, and 727–200F series airplanes.

(4) Model DC–8–11, DC–8–12, DC–8–21, DC–8–31, DC–8–32, DC–8–33, DC–8–41, DC–8–42, DC–8–43, DC–8–51, DC–8–52, DC–8–53, DC–8–55, DC–8F–54, DC–8F–55, DC–8–61, DC–8–62, DC–8–63, DC–8–61F, DC–8–62F, DC–8–63F, DC–8–71, DC–8–72, DC–8–73, DC–8–71F, DC–8–72F, and DC–8–73F airplanes.

(5) Model DC–9–11, DC–9–12, DC–9–13, DC–9–14, DC–9–15, DC–9–15F, DC–9–21, DC–9–31, DC–9–32, DC–9–32 (VC–9C), DC–9–32F, DC–9–32F (C–9A, C–9B), DC–9–33F, DC–9–34, DC–9–34F, DC–9–41, and DC–9–51 airplanes.

(6) Model DC–10–10, DC–10–10F, DC–10–15, DC–10–30, DC–10–30F (KC–10A and KDC–10), DC–10–40, and DC–10–40F airplanes.

(7) Model MD–10–10F and MD–10–30F airplanes.

(8) Model MD–11 and MD–11F airplanes.

(9) Model DC–9–81 (MD–81), DC–9–82 (MD–82), DC–9–83 (MD–83), DC–9–87 (MD–87), MD–88, and MD–90–30 airplanes.

(d) Subject

Air Transport Association (ATA) of America Code 34, Navigation.

(e) Unsafe Condition

This AD was prompted by a determination that radio altimeters cannot be relied upon to perform their intended function if they experience interference from wireless broadband operations in the 3.7–3.98 GHz frequency band (5G C-Band), and a determination that during approach, landings, and go-arounds, as a result of this interference, certain airplane systems may not properly function, resulting in increased flightcrew workload while on approach with the flight director, autothrottle, or autopilot engaged. The FAA is issuing this AD to address 5G C-Band interference that could result in increased flightcrew workload and could lead to reduced ability of the flightcrew to maintain safe flight and landing of the airplane.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Definitions

(1) For purposes of this AD, a ''5G C-Band mitigated airport'' (5G CMA) is an airport at which the telecommunications companies have agreed to voluntarily limit their 5G deployment at the request of the FAA, as identified by an FAA Domestic Notice.

(2) For purposes of this AD, a ''radio altimeter tolerant airplane'' is one for which the radio altimeter, as installed, demonstrates the tolerances specified in paragraphs (g)(2)(i) and (ii) of this AD, using a method approved by the FAA.

(i) Tolerance to radio altimeter interference, for the fundamental emissions (3.7–3.98 GHz), at or above the power spectral density (PSD) curve threshold specified in figure 1 to paragraph (g)(2)(i) of this AD.

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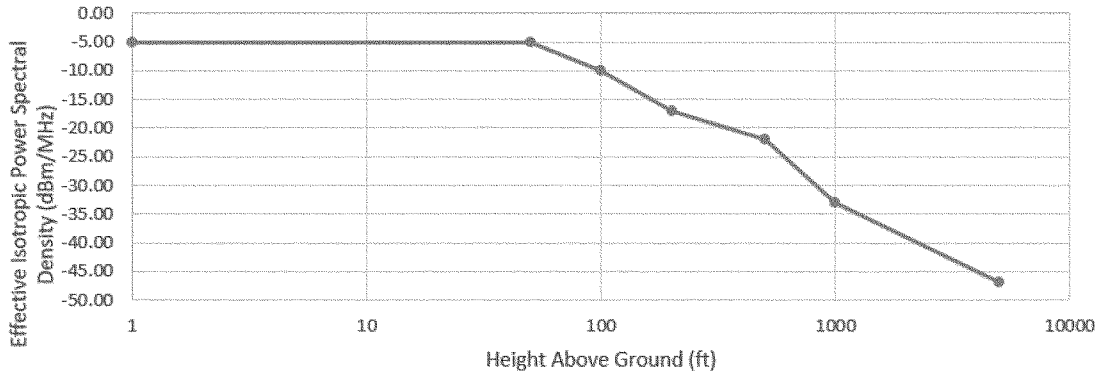
[2] The labor rate of $85 per hour is the average wage rate for an aviation mechanic.

[3] The estimated cost for this revision would not constitute a significant economic impact (even for small entities) because $85 is a minimal cost compared to the regular costs of maintaining and operating a 707, 717, 727, DC–8, DC–9, DC–10, MD 10, MD–11, DC–9–81, DC–9–82, DC–9–83, DC–9–87, MD–88, or MD–90–30 transport category airplane.

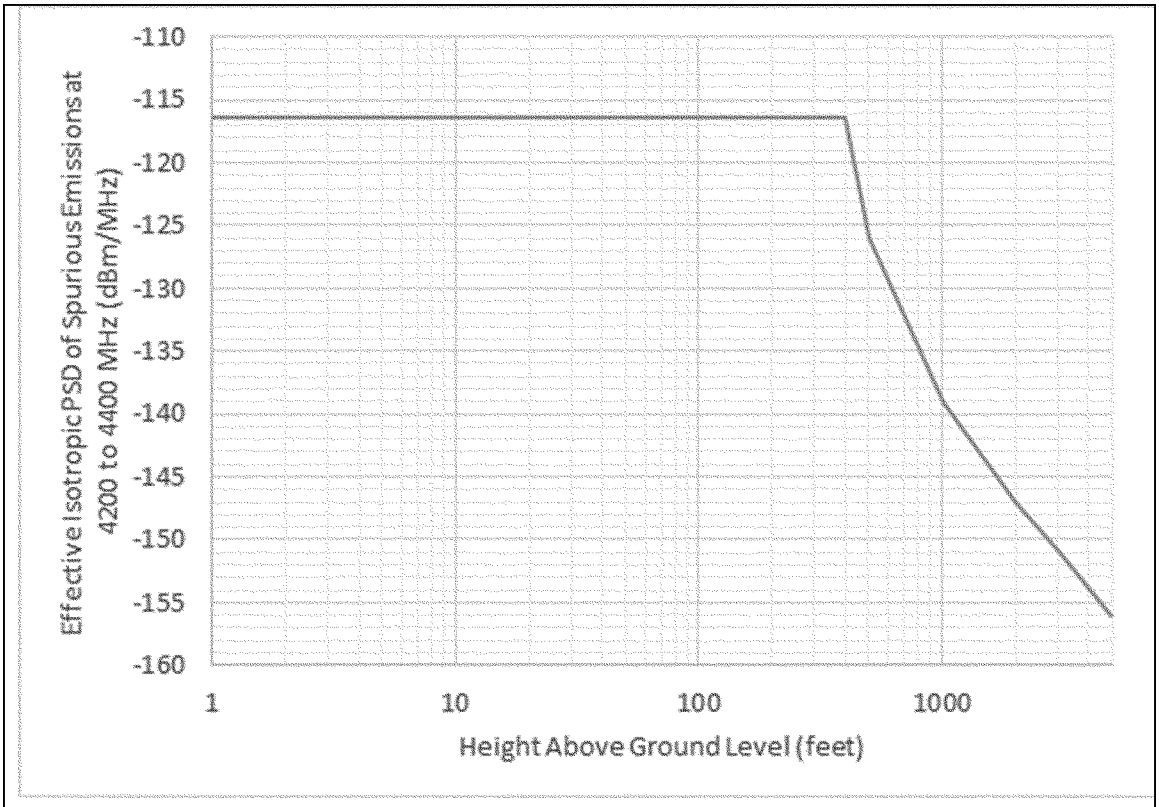
Figure 1 to paragraph (g)(2)(i)—*Fundamental Effective Isotropic PSD at Outside Interface of Aircraft Antenna*



Height above ground (ft)	Effective Isotropic PSD (dBm/MHz)
Aircraft on the ground	-5
50	-5
100	-10
200	-17
500	-22
1000	-33
5000	-47

(ii) Tolerance to radio altimeter interference, for the spurious emissions (4.2–4.4 GHz), at or above the PSD curve threshold specified in figure 2 to paragraph (g)(2)(ii) of this AD.

Figure 2 to paragraph (g)(2)(ii)—*Spurious Effective Isotropic PSD at Outside Interface of Aircraft Antenna*



Aircraft Altitude (ft AGL)	Effective Isotropic PSD (dBm/MHz)
1	-116.50
400	-116.50
500	-126.00
1000	-139.00
2000	-147.00
3000	-151.00
5000	-156.00

(3) For purposes of this AD, a ''non-radio altimeter tolerant airplane'' is one for which the radio altimeter, as installed, does not demonstrate the tolerances specified in paragraphs (g)(2)(i) and (ii) of this AD.

(h) Retained Airplane Flight Manual (AFM) Revision-Limitations

This paragraph restates the requirements of paragraph (g) of AD 2022–09–18.

(1) For airplanes identified in paragraphs (c)(1) and (c)(3) through (6) of this AD: Within 2 days after May 23, 2022 (the effective date of AD 2022–09–18), revise the Limitations Section of the existing AFM to include the information specified in figure 3 to paragraph (h)(1) of this AD. This may be done by inserting a copy of figure 3 to paragraph (h)(1) of this AD into the existing AFM.

Figure 3 to paragraph (h)(1)—*AFM Limitations Revision for Model 707, 727, DC–8, DC–9 (except DC–9–81 (MD–81), DC–9–82 (MD–82), DC–9–83 (MD–83), and DC–9–87 (MD–87)), and DC–10*

(Required by AD 2022-09-18)

Radio Altimeter 5G C-Band Interference, Approach Procedures

The following limitations are required for ILS approaches on runways in U.S. airspace in the presence of 5G C-Band wireless broadband interference as identified by NOTAM (NOTAMs will be issued to state the specific airports or approaches where the radio altimeter is unreliable due to the presence of 5G C-Band wireless broadband interference).

ILS Approaches

Operators must use the Radio Altimeter 5G C-Band Interference, ILS Approaches procedure contained in the Operating Procedures Section of this AFM.

(2) For airplanes identified in paragraphs (c)(2), (7), and (8) of this AD: Within 2 days after May 23, 2022 (the effective date of AD 2022–09–18), revise the Limitations Section of the existing AFM to include the information specified in figure 4 to paragraph (h)(2) of this AD. This may be done by inserting a copy of figure 4 to paragraph (h)(2) of this AD into the Limitations Section of the existing AFM.

Figure 4 to paragraph (h)(2)—*AFM Limitations Revision for Model 717, MD–10, and MD–11*

(Required by AD 2022-09-18)

Radio Altimeter 5G C-Band Interference, Approach, Landing, and Go-Around Procedures

The following limitations are required for approaches, landings, or go-arounds on runways, in U.S. airspace in the presence of 5G C-Band wireless broadband interference as identified by NOTAM (NOTAMs will be issued to state the specific airports or approaches where the radio altimeter is unreliable due to the presence of 5G C-Band wireless broadband interference).

ILS and Non Precision Approaches, Landing, and Go-Around

Operators must use the Radio Altimeter 5G C-Band Interference, Approach, Landing, and Go-Around procedures contained in the Operating Procedures Section of this AFM.

(3) For airplanes identified in paragraph (c)(9) of this AD: Within 2 days after May 23, 2022 (the effective date of AD 2022–09–18), revise the Limitations Section of the existing AFM to include the information specified in figure 5 to paragraph (h)(3) of this AD. This may be done by inserting a copy of figure 5 to paragraph (h)(3) of this AD into the Limitations Section of the existing AFM.

Figure 5 to paragraph (h)(3)—*AFM Limitations Revision for Model DC–9–81 (MD–81), DC–9–82 (MD–82), DC–9–83 (MD–83), DC–9–87 (MD–87), MD–88, and MD–90–30*

(Required by AD 2022-09-18)

Radio Altimeter 5G C-Band Interference, Approach Procedures

The following limitations are required for approaches in U.S. airspace in the presence of 5G C-Band wireless broadband interference as identified by NOTAM (NOTAMs will be issued to state the specific airports or approaches where the radio altimeter is unreliable due to the presence of 5G C-Band wireless broadband interference).

ILS and Non Precision Approaches

Operators must use the Radio Altimeter 5G C-Band Interference, Approaches procedures contained in the Operating Procedures Section of this AFM.

(i) Retained AFM Revision-Operating Procedures

This paragraph restates the requirements of paragraph (h) of AD 2022–09–18.

(1) For airplanes identified in paragraphs (c)(1) and (3) through (6) of this AD: Within 2 days after May 23, 2022 (the effective date of AD 2022–09–18), revise the Operating Procedures Section of the existing AFM to include the information specified in figure 6 to paragraph (i)(1) of this AD. This may be done by inserting a copy of figure 6 to paragraph (i)(1) of this AD into the Operating Procedures Section of the existing AFM.

Figure 6 to paragraph (i)(1)—*AFM Operating Procedures Revision for Model 707, 727, DC–8, DC–9 (except DC–9–81 (MD–81), DC–9–82 (MD–82), DC–9–83 (MD–83), and DC–9–87 (MD–87)), and DC–10*

(Required by AD 2022-09-18)

Radio Altimeter 5G C-Band Interference, ILS Approaches

ILS Approaches

For ILS approaches not prohibited by AD 2021-23-12, disconnect the autopilot and autothrottles, and place both flight director switches to OFF prior to glideslope intercept.

(2) For airplanes identified in paragraph (c)(2) of this AD: Within 2 days after May 23, 2022 (the effective date of AD 2022–09–18), revise the Operating Procedures Section of the existing AFM to include the information specified in figure 7 to paragraph (i)(2) of this AD. This may be done by inserting a copy of figure 7 to paragraph (i)(2) of this AD into the Operating Procedures Section of the existing AFM.

Figure 7 to paragraph (i)(2)—*AFM Operating Procedures Revision for Model 717*

(Required by AD 2022-09-18)

Radio Altimeter 5G C-Band Interference, Approach, Landing, and Go-Around

ILS Approaches

For ILS approaches not prohibited by AD 2021-23-12, disconnect the autopilot prior to glideslope intercept.

Note: Possible erroneous radio altimeter indications may affect autothrottles and flight director guidance; manually intervene if necessary.

Non-Precision Approaches

Non-precision instrument approaches can be conducted using LNAV/VNAV with flight directors, autopilot, and autothrottle to published BARO minimums.

Landing

For landing, the Auto Ground Spoiler function may require manual extension. If manual extension is required, calculate landing distance requirements as specified in Appendix 3, Auto Ground Spoiler System Inop, of this AFM.

During Go-Around and Missed Approach

If go-around is required, initial flight director pitch guidance will provide proper speed and pitch targets, but, under certain 5G interference conditions, the flight director cannot be commanded from the Flight Control Panel (FCP) to provide speed or heading guidance, and may not provide altitude capture guidance. If this guidance is not available, manually comply with missed approach procedures, including altitude constraints.

(3) For airplanes identified in paragraph (c)(7) of this AD: Within 2 days after May 23, 2022 (the effective date of AD 2022–09–18), revise the Operating Procedures Section of the existing AFM to include the information specified in figure 8 to paragraph (i)(3) of this AD. This may be done by inserting a copy of figure 8 to paragraph (i)(3) of this AD into the Operating Procedures Section of the existing AFM.

Figure 8 to paragraph (i)(3)—*AFM Operating Procedures Revision for Model MD–10*

(Required by AD 2022-09-18)

Radio Altimeter 5G C-Band Interference, Approach, Landing, and Go-Around

ILS Approaches

For ILS approaches not prohibited by AD 2021-23-12, disconnect the autopilot prior to glideslope intercept.

Note: Possible erroneous radio altimeter indications may affect autothrottles and flight director guidance; manually intervene if necessary.

Non-Precision Approaches

Non-precision instrument approaches can be conducted using LNAV/VNAV with flight directors, autopilot, and autothrottle to published BARO minimums.

Landing

For landing, the Auto Ground Spoiler function may require manual extension. If manual extension is required, calculate landing distance requirements according to the following tables, as applicable.

SERIES 10
50/EXT ESTIMATED LANDING DISTANCES (FEET)
USE MANUAL SPOILERS

Weight 1000 LB		260	280	300	320	340	360	380	400
S.L.	DRY	2800	2900	3030	3160	3290	3410	3540	3660
STD=15°C	WET	3670	3810	3990	4190	4370	4540	4730	4900
2000 FT	DRY	2920	3030	3170	3310	3450	3580	3720	3840
STD=11°C	WET	3840	3990	4190	4400	4600	4780	4980	5170
4000 FT	DRY	3060	3170	3320	3480	3620	3760	3920	4050
STD=7°C	WET	4040	4190	4410	4630	4850	5040	5260	5460
6000 FT	DRY	3210	3330	3490	3650	3820	3960	4130	4270
STD=3°C	WET	4240	4410	4650	4890	5120	5330	5570	5780
8000 FT	DRY	3360	3490	3670	3840	4020	4180	4360	4520
STD=-1°C	WET	4460	4650	4900	5160	5410	5640	5900	6130
10000 FT	DRY	3530	3670	3860	4060	4250	4420	4610	4780
STD=-5°C	WET	4690	4910	5180	5460	5730	5980	6260	6510

NOTE: Standard day, no wind, zero slope, three engines at maximum reverse thrust to 80 KIAS, then reverse idle to 60 KIAS, then forward idle to stop. (Includes Air Run Distance)

CORRECTIONS:

Temperature: Valid from STD -20°C to STD +40°C

FEET PER °C	DRY	WET
BELOW standard day	-7	-10
ABOVE standard day	+37	+44

Slope: Valid from -2% downhill to +2% uphill

FEET PER 1% SLOPE	DRY	WET
UPHILL	-46	-96
DOWNHILL	+257	+459

Wind: Valid from -10 knot tailwind to +20 knot headwind

FEET PER KNOT	DRY	WET
HEADWIND	-20	-34
TAILWIND	+50	+68

SERIES 10
35/EXT ESTIMATED LANDING DISTANCES (FEET)
USE MANUAL SPOILERS

Weight 1000 LB		260	280	300	320	340	360	380	400
S.L.	DRY	2800	2900	3030	3170	3300	3420	3560	3680
STD=15°C	WET	3710	3850	4050	4250	4450	4620	4820	4990
2000 FT	DRY	2930	3030	3180	3330	3470	3600	3740	3870
STD=11°C	WET	3890	4040	4260	4480	4680	4870	5080	5270
4000 FT	DRY	3070	3180	3330	3490	3640	3790	3940	4080
STD=7°C	WET	4090	4260	4480	4720	4940	5150	5370	5580
6000 FT	DRY	3210	3340	3500	3670	3840	3990	4160	4310
STD=3°C	WET	4300	4490	4730	4980	5220	5440	5690	5910
8000 FT	DRY	3380	3510	3680	3870	4050	4210	4400	4560
STD=-1°C	WET	4530	4730	4990	5260	5530	5770	6030	6280
10000 FT	DRY	3550	3690	3880	4090	4280	4460	4650	4830

STD=-5°C	WET	4790	5000	5280	5580	5860	6120	6410	6670
NOTE: Standard day, no wind, zero slope, three engines at maximum reverse thrust to 80 KIAS, then reverse idle to 60 KIAS, then forward idle to stop. (Includes Air Run Distance)									

CORRECTIONS:

Temperature: Valid from STD -20°C to STD +40°C

FEET PER °C	DRY	WET
BELOW standard day	-7	-10
ABOVE standard day	+17	+25

Slope: Valid from -2% downhill to +2% uphill

FEET PER 1% SLOPE	DRY	WET
UPHILL	-47	-99
DOWNHILL	+125	+300

Wind: Valid from -10 knot tailwind to +20 knot headwind

FEET PER KNOT	DRY	WET
HEADWIND	-20	-34
TAILWIND	+30	+51

SERIES 30
50/EXT ESTIMATED LANDING DISTANCES (FEET)
USE MANUAL SPOILERS

Weight 1000 LB		340	360	380	400	420	440	460	480
S.L.	DRY	3380	3530	3670	3800	3910	4050	4210	4370
STD=15°C	WET	4500	4700	4900	5100	5270	5470	5690	5920
2000 FT	DRY	3550	3710	3850	4000	4120	4270	4440	4610
STD=11°C	WET	4740	4960	5180	5390	5570	5790	6030	6280
4000 FT	DRY	3740	3900	4060	4220	4350	4510	4710	4910
STD=7°C	WET	5010	5250	5480	5710	5910	6150	6440	6720
6000 FT	DRY	3930	4110	4280	4450	4590	4770	5010	5240
STD=3°C	WET	5290	5550	5800	6050	6260	6520	6860	7200
8000 FT	DRY	4140	4330	4510	4720	4910	5120	5390	5650

STD=-1°C	WET	5590	5860	6130	6430	6710	7020	7390	7770
10000 FT	DRY	4370	4570	4770	5010	5260	5510	5800	6110
STD=-5°C	WET	5910	6210	6500	6840	7200	7560	7970	8410
NOTE: Standard day, no wind, zero slope, three engines at maximum reverse thrust to 80 KIAS, then reverse idle to 60 KIAS, then forward idle to stop. (Includes Air Run Distance)									

CORRECTIONS:

Temperature: Valid from STD -20°C to STD +40°C

FEET PER °C	DRY	WET
BELOW standard day	-10	-14
ABOVE standard day	+23	+34

Slope: Valid from -2% downhill to +2% uphill

FEET PER 1% SLOPE	DRY	WET
UPHILL	-54	-116
DOWNHILL	+168	+380

Wind: Valid from -10 knot tailwind to +20 knot headwind

FEET PER KNOT	DRY	WET
HEADWIND	-25	-41
TAILWIND	+79	+63

SERIES 30
35/EXT ESTIMATED LANDING DISTANCES (FEET)
USE MANUAL SPOILERS

Weight 1000 LB		340	360	380	400	420	440	460	480
S.L.	DRY	3500	3650	3810	3950	4070	4220	4390	4560
STD=15°C	WET	4700	4920	5140	5360	5540	5760	6010	6250
2000 FT	DRY	3680	3840	4010	4160	4300	4460	4640	4820
STD=11°C	WET	4960	5190	5440	5670	5870	6110	6380	6640
4000 FT	DRY	3870	4040	4230	4400	4540	4720	4930	5150
STD=7°C	WET	5250	5500	5770	6020	6240	6500	6810	7120

6000 FT	DRY	4080	4270	4460	4650	4800	4990	5250	5510
STD=3°C	WET	5550	5830	6110	6390	6620	6910	7270	7640
8000 FT	DRY	4300	4500	4710	4930	5140	5370	5650	5930
STD=-1°C	WET	5870	6170	6480	6800	7100	7430	7840	8240
10000 FT	DRY	4540	4760	4990	5250	5500	5780	6090	6400
STD=-5°C	WET	6210	6540	6870	7250	7610	8010	8460	8900
NOTE: Standard day, no wind, zero slope, three engines at maximum reverse thrust to 80 KIAS, then reverse idle to 60 KIAS, then forward idle to stop. (Includes Air Run Distance)									

CORRECTIONS:

Temperature: Valid from STD -20°C to STD +40°C

FEET PER °C	DRY	WET
BELOW standard day	-10	-15
ABOVE standard day	+26	+37

Slope: Valid from -2% downhill to +2% uphill

FEET PER 1% SLOPE	DRY	WET
UPHILL	-58	-120
DOWNHILL	+179	+411

Wind: Valid from -10 knot tailwind to +20 knot headwind

FEET PER KNOT	DRY	WET
HEADWIND	-26	-42
TAILWIND	+86	+68

During Go-Around and Missed Approach

If go-around is required, initial flight director pitch guidance will provide proper speed and pitch targets, but, under certain 5G interference conditions, the flight director cannot be commanded from the Flight Control Panel (FCP) to provide speed or heading guidance, and may not provide altitude capture guidance. If this guidance is not available, manually comply with missed approach procedures, including altitude constraints.

(4) For airplanes identified in paragraph (c)(8) of this AD: Within 2 days after the effective date of this AD, revise the Operating Procedures Section of the existing AFM to include the information specified in figure 9 to paragraph (i)(4) of this AD. This may be

done by inserting a copy of figure 9 to paragraph (i)(4) of this AD into the Operating Procedures Section of the existing AFM.

Figure 9 to paragraph (i)(4)—*AFM Operating Procedures Revision for Model MD–11*

(Required by AD 2022-09-18)

Radio Altimeter 5G C-Band Interference, Approach, Landing, and Go-Around

ILS Approaches

For ILS approaches not prohibited by AD 2021-23-12, disconnect the autopilot prior to glideslope intercept.

Note: Possible erroneous radio altimeter indications may affect autothrottles and flight director guidance; manually intervene if necessary.

Non-Precision Approaches

Non-precision instrument approaches can be conducted using LNAV/VNAV with flight directors, autopilot, and autothrottle to published BARO minimums.

Landing

For landing, the Auto Ground Spoiler function may require manual extension. If manual extension is required, calculate landing distance requirements according to the following tables, as applicable.

50/EXT ESTIMATED LANDING DISTANCES (FEET)
USE MAN SPOILERS

General Electric CF6-80C2 Engines

Weight 1000 LB		360	380	400	420	440	460	480	500
S.L.	DRY	4315	4480	4650	4803	4949	5126	5274	5453
STD=15°C	WET	5156	5388	5604	5805	6008	6240	6443	6677
2000 FT	DRY	4520	4695	4876	5039	5195	5384	5542	5734
STD=11°C	WET	5466	5688	5927	6140	6355	6605	6827	7084
4000 FT	DRY	4738	4925	5118	5292	5459	5661	5830	6036
STD=7°C	WET	5777	6021	6275	6510	6743	7007	7241	7527
6000 FT	DRY	4975	5175	5381	5568	5747	5963	6145	6367
STD=3°C	WET	6125	6392	6658	6917	7166	7449	7710	7999
8000 FT	DRY	5229	5443	5663	5864	6057	6290	6486	6725
STD=-1°C	WET	6497	6787	7084	7354	7628	7939	8212	8538
10000 FT	DRY	5505	5734	5972	6188	6418	6693	6931	7208
STD=-5°C	WET	6920	7220	7544	7842	8155	8532	8853	9223

NOTE: Standard day, no wind, zero slope, three engines at maximum reverse thrust to 80 KIAS, then reverse idle to 60 KIAS, then forward idle to stop (includes air run distances).

CORRECTIONS:

Temperature: Valid from STD -20°C to STD +40°C

FEET PER °C	DRY	WET
BELOW standard day	-12	-14
ABOVE standard day	+25	+35

Slope: Valid from -2% downhill to +2% uphill

FEET PER 1% SLOPE	DRY	WET
UPHILL	-84	-137
DOWNHILL	+229	+444

Wind: Valid from -10 knot tailwind to +20 knot headwind

FEET PER KNOT	DRY	WET
HEADWIND	-32	-46
TAILWIND	+83	+132

35/EXT ESTIMATED LANDING DISTANCES (FEET)

USE MAN SPOILERS

General Electric CF6-80C2 Engines

Weight 1000 LB		360	380	400	420	440	460	480	500
S.L.	DRY	4632	4803	4974	5155	5340	5496	5685	5855
STD=15°C	WET	5577	5795	6020	6257	6502	6717	6969	7197
2000 FT	DRY	4856	5039	5221	5414	5613	5780	5983	6165
STD=11°C	WET	5890	6131	6373	6631	6893	7128	7394	7642
4000 FT	DRY	5096	5291	5486	5693	5906	6085	6304	6500
STD=7°C	WET	6249	6509	6763	7037	7317	7571	7864	8133
6000 FT	DRY	5357	5566	5775	5998	6227	6420	6655	6867
STD=3°C	WET	6631	6914	7190	7489	7798	8060	8380	8674
8000 FT	DRY	5637	5862	6087	6326	6574	6782	7037	7317
STD=-1°C	WET	7047	7348	7660	7980	8308	8600	8943	9324
10000 FT	DRY	5943	6185	6428	6687	6963	7267	7546	7854
STD=-5°C	WET	7513	7841	8166	8522	8888	9294	9675	10074

NOTE: Standard day, no wind, zero slope, three engines at maximum reverse thrust to 80 KIAS, then reverse idle to 60 KIAS, then forward idle to stop (includes air run distances).

CORRECTIONS:

Temperature: Valid from STD -20°C to STD +40°C

FEET PER °C	DRY	WET
BELOW standard day	-13	-16
ABOVE standard day	+29	+39

Slope: Valid from -2% downhill to +2% uphill

FEET PER 1% SLOPE	DRY	WET
UPHILL	-94	-155
DOWNHILL	+275	+522

Wind: Valid from -10 knot tailwind to +20 knot headwind

FEET PER KNOT	DRY	WET
HEADWIND	-35	-50
TAILWIND	+95	+143

50/EXT ESTIMATED LANDING DISTANCES (FEET)
USE MAN SPOILERS

Pratt & Whitney PW-4460/PW-4462 Engines

Weight 1000 LB		360	380	400	420	440	460	480	500
S.L.	DRY	4316	4476	4641	4791	4963	5113	5262	5443
STD=15°C	WET	5050	5269	5498	5710	5922	6157	6371	6626
2000 FT	DRY	4526	4697	4875	5036	5190	5377	5535	5728
STD=11°C	WET	5343	5585	5824	6053	6282	6531	6760	7035
4000 FT	DRY	4751	4935	5125	5297	5463	5663	5832	6038
STD=7°C	WET	5664	5914	6185	6425	6673	6943	7189	7477
6000 FT	DRY	4993	5190	5394	5580	5757	5973	6154	6375
STD=3°C	WET	6003	6284	6566	6826	7094	7392	7651	7969
8000 FT	DRY	5253	5465	5684	5883	6075	6307	6503	6741
STD=-1°C	WET	6382	6677	6983	7266	7550	7869	8158	8494
10000 FT	DRY	5534	5762	5998	6214	6443	6718	6955	7232
STD=-5°C	WET	6783	7107	7440	7749	8076	8457	8797	9182

NOTE: Standard day, no wind, zero slope, three engines at maximum reverse thrust to 60 KIAS, then forward idle to stop (includes air run distances).

CORRECTIONS:

Temperature: Valid from STD -20°C to STD +40°C

FEET PER °C	DRY	WET
BELOW standard day	-11	-13
ABOVE standard day	+25	+34

Slope: Valid from -2% downhill to +2% uphill

FEET PER 1% SLOPE	DRY	WET
UPHILL	-83	-138
DOWNHILL	+228	+443

Wind: Valid from -10 knot tailwind to +20 knot headwind

FEET PER KNOT	DRY	WET
HEADWIND	-33	-45
TAILWIND	+83	+128

35/EXT ESTIMATED LANDING DISTANCES (FEET)
USE MAN SPOILERS
Pratt & Whitney PW-4460/PW-4462 Engines

Weight 1000 LB		360	380	400	420	440	460	480	500
S.L.	DRY	4622	4790	4958	5138	5326	5484	5677	5850
STD=15°C	WET	5422	5661	5902	6154	6422	6647	6923	7169
2000 FT	DRY	4856	5035	5215	5406	5605	5773	5979	6165
STD=11°C	WET	5755	6005	6265	6533	6812	7062	7353	7626
4000 FT	DRY	5105	5298	5491	5696	5908	6087	6307	6506
STD=7°C	WET	6102	6386	6659	6950	7251	7511	7825	8121
6000 FT	DRY	5373	5581	5788	6009	6238	6430	6665	6879
STD=3°C	WET	6493	6787	7084	7397	7724	8013	8345	8656
8000 FT	DRY	5662	5885	6109	6347	6594	6802	7056	7285
STD=-1°C	WET	6907	7220	7543	7887	8236	8548	8916	9254
10000 FT	DRY	5975	6216	6458	6716	6992	7296	7575	7882
STD=-5°C	WET	7353	7703	8047	8423	8815	9243	9646	10082

NOTE: Standard day, no wind, zero slope, three engines at maximum reverse thrust to 60 KIAS, then forward idle to stop (includes air run distances).

CORRECTIONS:

Temperature: Valid from STD -20°C to STD +40°C

FEET PER °C	DRY	WET
BELOW standard day	-11	-15
ABOVE standard day	+28	+39

Slope: Valid from -2% downhill to +2% uphill

FEET PER 1% SLOPE	DRY	WET
UPHILL	-93	-151
DOWNHILL	+273	+524

Wind: Valid from -10 knot tailwind to +20 knot headwind

FEET PER KNOT	DRY	WET
HEADWIND	-35	-48
TAILWIND	+94	+140

During Go-Around and Missed Approach

If go-around is required, initial flight director pitch guidance will provide proper speed and pitch targets, but, under certain 5G interference conditions, the flight director cannot be commanded from the Flight Control Panel (FCP) to provide speed or heading guidance, and may not provide altitude capture guidance. If this guidance is not available, manually comply with missed approach procedures, including altitude constraints.

(5) For airplanes identified in paragraph (c)(9) of this AD: Within 2 days after the effective date of this AD, revise the Operating Procedures Section of the existing AFM to include the information specified in figure 10 to paragraph (i)(5) of this AD. This may be done by inserting a copy of figure 10 to paragraph (i)(5) of this AD into the Operating Procedures Section of the existing AFM.

Figure 10 to paragraph (i)(5)—*AFM Operating Procedures Revision for Model DC–9–81 (MD–81), DC–9–82 (MD–82), DC–9–83 (MD–83), DC–9–87 (MD–87), MD–88, and MD–90–30*

(Required by AD 2022-09-18)

Radio Altimeter 5G C-Band Interference, Approaches

ILS Approaches

For ILS approaches not prohibited by AD 2021-23-12, disconnect the autopilot and autothrottles, and place both flight director switches to OFF prior to glideslope intercept.

Note: Possible erroneous radio altimeter indications may affect autopilot, autothrottles, and flight director guidance; manually intervene if necessary.

Non-Precision Approaches

Non-precision instrument approaches can be conducted using LNAV/VNAV with flight directors, autopilot, and autothrottle to published BARO minimums.

(j) New Requirement: AFM Limitations Revision for Non-Radio Altimeter Tolerant Airplanes

(1) For non-radio altimeter tolerant airplanes identified in paragraphs (c)(1) and (c)(3) through (6) of this AD, do the actions specified in paragraphs (j)(1)(i) and (ii) of this AD.

(i) On or before June 30, 2023, revise the Limitations Section of the existing AFM to include the information specified in figure 11 to paragraph (j)(1) of this AD. This may be done by inserting a copy of figure 11 to paragraph (j)(1) of this AD into the existing AFM. Incorporating the AFM revision required by this paragraph terminates the AFM revision required by paragraph (h)(1) of this AD.

(ii) Before further flight after incorporating the limitations specified in figure 11 to paragraph (j)(1) of this AD, remove the AFM revision required by paragraph (h)(1) of this AD.

Figure 11 to paragraph (j)(1)—*AFM Limitations Revision for Model 707, 727, DC–8, DC–9 (except DC–9–81 (MD–81), DC–9–82 (MD–82), DC–9–83 (MD–83), and DC–9–87 (MD–87)), and DC–10*

(Required by AD 20-**-**-**)**

Radio Altimeter 5G C-Band Interference, Approach Procedures

Due to the presence of 5G C-Band wireless broadband interference, the following limitations are required for ILS approaches on runways in the contiguous U.S. airspace.

ILS Approaches

Operators must use the Radio Altimeter 5G C-Band Interference, ILS Approaches procedure contained in the Operating Procedures Section of this AFM.

(2) For non-radio altimeter tolerant airplanes identified in paragraphs (c)(2), (7), and (8) of this AD, do the actions specified in paragraphs (j)(2)(i) and (ii) of this AD.

(i) On or before June 30, 2023, revise the Limitations Section of the existing AFM to include the information specified in figure 12 to paragraph (j)(2) of this AD. This may be done by inserting a copy of figure 12 to paragraph (j)(2) of this AD into the existing AFM. Incorporating the AFM revision required by this paragraph terminates the AFM revision required by paragraph (h)(2) of this AD.

(ii) Before further flight after incorporating the limitations specified in figure 12 to paragraph (j)(2) of this AD, remove the AFM revision required by paragraph (h)(2) of this AD.

Figure 12 to paragraph (j)(2)—*AFM Limitations Revision for Model 717, MD–10, and MD–11*

(Required by AD 20-**-**-**)**

Radio Altimeter 5G C-Band Interference, Approach, Landing, and Go-Around Procedures

Due to the presence of 5G C-Band wireless broadband interference, the following limitations are required for approaches, landings, or go-arounds on runways, in the contiguous U.S. airspace.

ILS and Non Precision Approaches, Landing, and Go-Around

Operators must use the Radio Altimeter 5G C-Band Interference, Approach, Landing, and Go-Around procedures contained in the Operating Procedures Section of this AFM.

(3) For non-radio altimeter tolerant airplanes identified in paragraph (c)(9) of this AD, do the actions specified in paragraphs (j)(3)(i) and (ii) of this AD.

(i) On or before June 30, 2023, revise the Limitations Section of the existing AFM to include the information specified in figure 13 to paragraph (j)(3) of this AD. This may be done by inserting a copy of figure 13 to paragraph (j)(3) of this AD into the existing AFM. Incorporating the AFM revision required by this paragraph terminates the AFM revision required by paragraph (h)(3) of this AD.

(ii) Before further flight after incorporating the limitations specified in figure 13 to paragraph (j)(3) of this AD, remove the AFM revision required by paragraph (h)(3) of this AD.

Figure 13 to paragraph (j)(3)—*AFM Limitations Revision for Model DC–9–81 (MD–81), DC–9–82 (MD–82), DC–9–83 (MD–83), DC–9–87 (MD–87), MD–88, and MD–90–30*

(Required by AD 20-**-**-**)**

Radio Altimeter 5G C-Band Interference, Approach Procedures

Due to the presence of 5G C-Band wireless broadband interference, the following limitations are required for approaches in the contiguous U.S. airspace.

ILS and Non Precision Approaches

Operators must use the Radio Altimeter 5G C-Band Interference, Approaches procedures contained in the Operating Procedures Section of this AFM.

(k) New Requirement: AFM Limitations Revision for Radio Altimeter Tolerant Airplanes

(1) For radio altimeter tolerant airplanes identified in paragraphs (c)(1) and (c)(3) through (6) of this AD, do the actions specified in paragraphs (k)(1)(i) and (ii) of this AD.

(i) On or before June 30, 2023, revise the Limitations Section of the existing AFM to include the information specified in figure 14 to paragraph (k)(1) of this AD. This may be done by inserting a copy of figure 14 to paragraph (k)(1) of this AD into the existing AFM. Incorporating the AFM revision required by this paragraph terminates the AFM revision required by paragraph (h)(1) of this AD.

(ii) Before further flight after incorporating the limitations specified in figure 14 to paragraph (k)(1) of this AD, remove the AFM revision required by paragraph (h)(1) of this AD.

Figure 14 to paragraph (k)(1)—*AFM Limitations Revision for Model 707, 727, DC–8, DC–9 (except DC–9–81 (MD–81), DC–9–82 (MD–82), DC–9–83 (MD–83), and DC–9–87 (MD–87)), and DC–10*

(Required by AD 20-**-**-**)**

Radio Altimeter 5G C-Band Interference, Approach Procedures
Due to the presence of 5G C-Band wireless broadband interference, the following limitations are required for ILS approaches on runways in the contiguous U.S. airspace unless operating at a 5G C-Band mitigated airport as identified in an FAA *Domestic Notice*.

ILS Approaches
Operators must use the Radio Altimeter 5G C-Band Interference, ILS Approaches procedure contained in the Operating Procedures Section of this AFM.

(2) For radio altimeter tolerant airplanes identified in paragraphs (c)(2), (7), and (8) of this AD, do the actions specified in paragraphs (k)(2)(i) and (ii) of this AD.

(i) On or before June 30, 2023, revise the Limitations Section of the existing AFM to include the information specified in figure 15 to paragraph (k)(2) of this AD. This may be done by inserting a copy of figure 15 to paragraph (k)(2) of this AD into the existing AFM. Incorporating the AFM revision required by this paragraph terminates the AFM revision required by paragraph (h)(2) of this AD.

(ii) Before further flight after incorporating the limitations specified in figure 15 to paragraph (k)(2) of this AD, remove the AFM revision required by paragraph (h)(2) of this AD.

Figure 15 to paragraph (k)(2)—*AFM Limitations Revision for Model 717, MD–10, and MD–11*

(Required by AD 20-**-**-**)**

Radio Altimeter 5G C-Band Interference, Approach, Landing, and Go-Around Procedures
Due to the presence of 5G C-Band wireless broadband interference, the following limitations are required for approaches, landings, or go-arounds on runways, in the contiguous U.S. airspace unless operating at a 5G C-Band mitigated airport as identified in an FAA *Domestic Notice*.

ILS and Non Precision Approaches, Landing, and Go-Around
Operators must use the Radio Altimeter 5G C-Band Interference, Approach, Landing, and Go-Around procedures contained in the Operating Procedures Section of this AFM.

(3) For radio altimeter tolerant airplanes identified in paragraph (c)(9) of this AD, do the actions specified in paragraphs (k)(3)(i) and (ii) of this AD.

(i) On or before June 30, 2023, revise the Limitations Section of the existing AFM to include the information specified in figure 16 to paragraph (k)(3) of this AD. This may be done by inserting a copy of figure 16 to paragraph (k)(3) of this AD into the existing AFM. Incorporating the AFM revision required by this paragraph terminates the AFM revision required by paragraph (h)(3) of this AD.

(ii) Before further flight after incorporating the limitations specified in figure 16 to paragraph (k)(3) of this AD, remove the AFM revision required by paragraph (h)(3) of this AD.

Figure 16 to paragraph (k)(3)—*AFM Limitations Revision for Model DC–9–81 (MD–81), DC–9–82 (MD–82), DC–9–83 (MD–83), DC–9–87 (MD–87), MD–88, and MD–90–30*

(Required by AD 20-**-**-**)**

Radio Altimeter 5G C-Band Interference, Approach Procedures
Due to the presence of 5G C-Band wireless broadband interference, the following limitations are required for approaches in the contiguous U.S. airspace unless operating at a 5G C-Band mitigated airport as identified in an FAA *Domestic Notice*.

ILS and Non Precision Approaches
Operators must use the Radio Altimeter 5G C-Band Interference, Approaches procedures contained in the Operating Procedures Section of this AFM.

(l) New Requirement: AFM Operating Procedures Revision

(1) For airplanes identified in paragraphs (c)(1) and (3) through (6) of this AD, do the actions specified in paragraphs (l)(1)(i) and (ii) of this AD.

(i) On or before June 30, 2023, revise the Operating Procedures Section of the existing AFM to include the information specified in figure 17 to paragraph (l)(1) of this AD. This may be done by inserting a copy of figure 17 to paragraph (l)(1) of this AD into the Operating Procedures Section of the existing AFM. Incorporating the AFM revision required by this paragraph terminates the AFM revision required by paragraph (i)(1) of this AD.

(ii) Before further flight after incorporating the limitations specified in figure 17 to paragraph (l)(1) of this AD, remove the AFM revision required by paragraph (i)(1) of this AD.

Figure 17 to paragraph (1)(1)—*AFM Operating Procedures Revision for Model 707, 727, DC–8, DC–9 (except DC–9–81 (MD–81), DC–9–82 (MD–82), DC–9–83 (MD–83), and DC–9–87 (MD–87)), and DC–10*

(Required by AD 20-**-**-**)**

Radio Altimeter 5G C-Band Interference, ILS Approaches

ILS Approaches

For ILS approaches other than SA CAT I, SA CAT II, CAT II, and CAT III, disconnect the autopilot and autothrottles, and place both flight director switches to OFF prior to glideslope intercept.

(2) For airplanes identified in paragraph (c)(2) of this AD, do the actions specified in paragraphs (l)(2)(i) and (ii) of this AD.

(i) On or before June 30, 2023, revise the Operating Procedures Section of the existing AFM to include the information specified in figure 18 to paragraph (l)(2) of this AD. This may be done by inserting a copy of figure 18 to paragraph (l)(2) of this AD into the Operating Procedures Section of the existing AFM. Incorporating the AFM revision required by this paragraph terminates the AFM revision required by paragraph (i)(2) of this AD.

(ii) Before further flight after incorporating the limitations specified in figure 18 to paragraph (l)(2) of this AD, remove the AFM revision required by paragraph (i)(2) of this AD.

Figure 18 to paragraph (l)(2)—*AFM Operating Procedures Revision for Model 717*

(Required by AD 20-**-**-**)**

Radio Altimeter 5G C-Band Interference, Approach, Landing, and Go-Around

ILS Approaches

For ILS approaches other than SA CAT I, SA CAT II, CAT II, and CAT III, disconnect the autopilot prior to glideslope intercept.

Note: Possible erroneous radio altimeter indications may affect autothrottles and flight director guidance; manually intervene if necessary.

Non-Precision Approaches

Non-precision instrument approaches can be conducted using LNAV/VNAV with flight directors, autopilot, and autothrottle to published BARO minimums.

Landing

For landing, the Auto Ground Spoiler function may require manual extension. If manual extension is required, calculate landing distance requirements as specified in Appendix 3, Auto Ground Spoiler System Inop, of this AFM.

During Go-Around and Missed Approach

If go-around is required, initial flight director pitch guidance will provide proper speed and pitch targets, but, under certain 5G interference conditions, the flight director cannot be commanded from the Flight Control Panel (FCP) to provide speed or heading guidance, and may not provide altitude capture guidance. If this guidance is not available, manually comply with missed approach procedures, including altitude constraints.

(3) For airplanes identified in paragraph (c)(7) of this AD, do the actions specified in paragraphs (l)(3)(i) and (ii) of this AD.

(i) On or before June 30, 2023, revise the Operating Procedures Section of the existing AFM to include the information specified in figure 19 to paragraph (l)(3) of this AD. This may be done by inserting a copy of figure 19 to paragraph (l)(3) of this AD into the Operating Procedures Section of the existing AFM. Incorporating the AFM revision required by this paragraph terminates the AFM revision required by paragraph (i)(3) of this AD.

(ii) Before further flight after incorporating the limitations specified in figure 19 to paragraph (l)(3) of this AD, remove the AFM revision required by paragraph (i)(3) of this AD.

Figure 19 to paragraph (l)(3)—*AFM Operating Procedures Revision for Model MD–10*

(Required by AD 20-**-**)**

Radio Altimeter 5G C-Band Interference, Approach, Landing, and Go-Around

ILS Approaches

For ILS approaches other than SA CAT I, SA CAT II, CAT II, and CAT III, disconnect the autopilot prior to glideslope intercept.

Note: Possible erroneous radio altimeter indications may affect autothrottles and flight director guidance; manually intervene if necessary.

Non-Precision Approaches

Non-precision instrument approaches can be conducted using LNAV/VNAV with flight directors, autopilot, and autothrottle to published BARO minimums.

Landing

For landing, the Auto Ground Spoiler function may require manual extension. If manual extension is required, calculate landing distance requirements according to the following tables, as applicable.

SERIES 10
50/EXT ESTIMATED LANDING DISTANCES (FEET)
USE MANUAL SPOILERS

Weight 1000 LB		260	280	300	320	340	360	380	400
S.L.	DRY	2800	2900	3030	3160	3290	3410	3540	3660
STD=15°C	WET	3670	3810	3990	4190	4370	4540	4730	4900
2000 FT	DRY	2920	3030	3170	3310	3450	3580	3720	3840
STD=11°C	WET	3840	3990	4190	4400	4600	4780	4980	5170
4000 FT	DRY	3060	3170	3320	3480	3620	3760	3920	4050
STD=7°C	WET	4040	4190	4410	4630	4850	5040	5260	5460
6000 FT	DRY	3210	3330	3490	3650	3820	3960	4130	4270
STD=3°C	WET	4240	4410	4650	4890	5120	5330	5570	5780
8000 FT	DRY	3360	3490	3670	3840	4020	4180	4360	4520
STD=-1°C	WET	4460	4650	4900	5160	5410	5640	5900	6130

10000 FT	DRY	3530	3670	3860	4060	4250	4420	4610	4780
STD=-5°C	WET	4690	4910	5180	5460	5730	5980	6260	6510
NOTE: Standard day, no wind, zero slope, three engines at maximum reverse thrust to 80 KIAS, then reverse idle to 60 KIAS, then forward idle to stop. (Includes Air Run Distance)									

CORRECTIONS:

Temperature: Valid from STD -20°C to STD +40°C

FEET PER °C	DRY	WET
BELOW standard day	-7	-10
ABOVE standard day	+37	+44

Slope: Valid from -2% downhill to +2% uphill

FEET PER 1% SLOPE	DRY	WET
UPHILL	-46	-96
DOWNHILL	+257	+459

Wind: Valid from -10 knot tailwind to +20 knot headwind

FEET PER KNOT	DRY	WET
HEADWIND	-20	-34
TAILWIND	+50	+68

SERIES 10
35/EXT ESTIMATED LANDING DISTANCES (FEET)
USE MANUAL SPOILERS

Weight 1000 LB		260	280	300	320	340	360	380	400
S.L.	DRY	2800	2900	3030	3170	3300	3420	3560	3680
STD=15°C	WET	3710	3850	4050	4250	4450	4620	4820	4990
2000 FT	DRY	2930	3030	3180	3330	3470	3600	3740	3870
STD=11°C	WET	3890	4040	4260	4480	4680	4870	5080	5270
4000 FT	DRY	3070	3180	3330	3490	3640	3790	3940	4080

STD=7°C	WET	4090	4260	4480	4720	4940	5150	5370	5580
6000 FT	DRY	3210	3340	3500	3670	3840	3990	4160	4310
STD=3°C	WET	4300	4490	4730	4980	5220	5440	5690	5910
8000 FT	DRY	3380	3510	3680	3870	4050	4210	4400	4560
STD=-1°C	WET	4530	4730	4990	5260	5530	5770	6030	6280
10000 FT	DRY	3550	3690	3880	4090	4280	4460	4650	4830
STD=-5°C	WET	4790	5000	5280	5580	5860	6120	6410	6670
NOTE: Standard day, no wind, zero slope, three engines at maximum reverse thrust to 80 KIAS, then reverse idle to 60 KIAS, then forward idle to stop. (Includes Air Run Distance)									

CORRECTIONS:

Temperature: Valid from STD -20°C to STD +40°C

FEET PER °C	DRY	WET
BELOW standard day	-7	-10
ABOVE standard day	+17	+25

Slope: Valid from -2% downhill to +2% uphill

FEET PER 1% SLOPE	DRY	WET
UPHILL	-47	-99
DOWNHILL	+125	+300

Wind: Valid from -10 knot tailwind to +20 knot headwind

FEET PER KNOT	DRY	WET
HEADWIND	-20	-34
TAILWIND	+30	+51

SERIES 30
50/EXT ESTIMATED LANDING DISTANCES (FEET)
USE MANUAL SPOILERS

Weight 1000 LB		340	360	380	400	420	440	460	480
S.L.	DRY	3380	3530	3670	3800	3910	4050	4210	4370
STD=15°C	WET	4500	4700	4900	5100	5270	5470	5690	5920
2000 FT	DRY	3550	3710	3850	4000	4120	4270	4440	4610

STD=11°C	WET	4740	4960	5180	5390	5570	5790	6030	6280
4000 FT	DRY	3740	3900	4060	4220	4350	4510	4710	4910
STD=7°C	WET	5010	5250	5480	5710	5910	6150	6440	6720
6000 FT	DRY	3930	4110	4280	4450	4590	4770	5010	5240
STD=3°C	WET	5290	5550	5800	6050	6260	6520	6860	7200
8000 FT	DRY	4140	4330	4510	4720	4910	5120	5390	5650
STD=-1°C	WET	5590	5860	6130	6430	6710	7020	7390	7770
10000 FT	DRY	4370	4570	4770	5010	5260	5510	5800	6110
STD=-5°C	WET	5910	6210	6500	6840	7200	7560	7970	8410
NOTE: Standard day, no wind, zero slope, three engines at maximum reverse thrust to 80 KIAS, then reverse idle to 60 KIAS, then forward idle to stop. (Includes Air Run Distance)									

CORRECTIONS:

Temperature: Valid from STD -20°C to STD +40°C

FEET PER °C	DRY	WET
BELOW standard day	-10	-14
ABOVE standard day	+23	+34

Slope: Valid from -2% downhill to +2% uphill

FEET PER 1% SLOPE	DRY	WET
UPHILL	-54	-116
DOWNHILL	+168	+380

Wind: Valid from -10 knot tailwind to +20 knot headwind

FEET PER KNOT	DRY	WET
HEADWIND	-25	-41
TAILWIND	+79	+63

SERIES 30
35/EXT ESTIMATED LANDING DISTANCES (FEET)
USE MANUAL SPOILERS

Weight 1000 LB	340	360	380	400	420	440	460	480

S.L.	DRY	3500	3650	3810	3950	4070	4220	4390	4560
STD=15°C	WET	4700	4920	5140	5360	5540	5760	6010	6250
2000 FT	DRY	3680	3840	4010	4160	4300	4460	4640	4820
STD=11°C	WET	4960	5190	5440	5670	5870	6110	6380	6640
4000 FT	DRY	3870	4040	4230	4400	4540	4720	4930	5150
STD=7°C	WET	5250	5500	5770	6020	6240	6500	6810	7120
6000 FT	DRY	4080	4270	4460	4650	4800	4990	5250	5510
STD=3°C	WET	5550	5830	6110	6390	6620	6910	7270	7640
8000 FT	DRY	4300	4500	4710	4930	5140	5370	5650	5930
STD=-1°C	WET	5870	6170	6480	6800	7100	7430	7840	8240
10000 FT	DRY	4540	4760	4990	5250	5500	5780	6090	6400
STD=-5°C	WET	6210	6540	6870	7250	7610	8010	8460	8900
NOTE: Standard day, no wind, zero slope, three engines at maximum reverse thrust to 80 KIAS, then reverse idle to 60 KIAS, then forward idle to stop. (Includes Air Run Distance)									

CORRECTIONS:

Temperature: Valid from STD -20°C to STD +40°C

FEET PER °C	DRY	WET
BELOW standard day	-10	-15
ABOVE standard day	+26	+37

Slope: Valid from -2% downhill to +2% uphill

FEET PER 1% SLOPE	DRY	WET
UPHILL	-58	-120
DOWNHILL	+179	+411

Wind: Valid from -10 knot tailwind to +20 knot headwind

FEET PER KNOT	DRY	WET
HEADWIND	-26	-42
TAILWIND	+86	+68

During Go-Around and Missed Approach

If go-around is required, initial flight director pitch guidance will provide proper speed and pitch targets, but, under certain 5G interference conditions, the flight director cannot be commanded from the Flight Control Panel (FCP) to provide speed or heading guidance, and may not provide altitude capture guidance. If this guidance is not available, manually comply with missed approach procedures, including altitude constraints.

(4) For airplanes identified in paragraph (c)(8) of this AD, do the actions specified in paragraphs (l)(4)(i) and (ii) of this AD.

(i) On or before June 30, 2023, revise the Operating Procedures Section of the existing AFM to include the information specified in figure 20 to paragraph (l)(4) of this AD. This may be done by inserting a copy of figure 20 to paragraph (l)(4) of this AD into the Operating Procedures Section of the existing AFM. Incorporating the AFM revision required by this paragraph terminates the AFM revision required by paragraph (i)(4) of this AD.

(ii) Before further flight after incorporating the limitations specified in figure 20 to paragraph (l)(4) of this AD, remove the AFM revision required by paragraph (i)(4) of this AD.

Figure 20 to paragraph (l)(4)—*AFM Operating Procedures Revision for Model MD–11*

(Required by AD 20-**-**-**)**

Radio Altimeter 5G C-Band Interference, Approach, Landing, and Go-Around

ILS Approaches

For ILS approaches other than SA CAT I, SA CAT II, CAT II, and CAT III, disconnect the autopilot prior to glideslope intercept.

Note: Possible erroneous radio altimeter indications may affect autothrottles and flight director guidance; manually intervene if necessary.

Non-Precision Approaches

Non-precision instrument approaches can be conducted using LNAV/VNAV with flight directors, autopilot, and autothrottle to published BARO minimums.

Landing

For landing, the Auto Ground Spoiler function may require manual extension. If manual extension is required, calculate landing distance requirements according to the following tables, as applicable.

50/EXT ESTIMATED LANDING DISTANCES (FEET)
USE MAN SPOILERS

General Electric CF6-80C2 Engines

Weight 1000 LB		360	380	400	420	440	460	480	500
S.L.	DRY	4315	4480	4650	4803	4949	5126	5274	5453
STD=15°C	WET	5156	5388	5604	5805	6008	6240	6443	6677
2000 FT	DRY	4520	4695	4876	5039	5195	5384	5542	5734
STD=11°C	WET	5466	5688	5927	6140	6355	6605	6827	7084
4000 FT	DRY	4738	4925	5118	5292	5459	5661	5830	6036
STD=7°C	WET	5777	6021	6275	6510	6743	7007	7241	7527
6000 FT	DRY	4975	5175	5381	5568	5747	5963	6145	6367
STD=3°C	WET	6125	6392	6658	6917	7166	7449	7710	7999
8000 FT	DRY	5229	5443	5663	5864	6057	6290	6486	6725

STD=-1°C	WET	6497	6787	7084	7354	7628	7939	8212	8538
10000 FT	DRY	5505	5734	5972	6188	6418	6693	6931	7208
STD=-5°C	WET	6920	7220	7544	7842	8155	8532	8853	9223
NOTE: Standard day, no wind, zero slope, three engines at maximum reverse thrust to 80 KIAS, then reverse idle to 60 KIAS, then forward idle to stop (includes air run distances).									

CORRECTIONS:

Temperature: Valid from STD -20°C to STD +40°C

FEET PER °C	DRY	WET
BELOW standard day	-12	-14
ABOVE standard day	+25	+35

Slope: Valid from -2% downhill to +2% uphill

FEET PER 1% SLOPE	DRY	WET
UPHILL	-84	-137
DOWNHILL	+229	+444

Wind: Valid from -10 knot tailwind to +20 knot headwind

FEET PER KNOT	DRY	WET
HEADWIND	-32	-46
TAILWIND	+83	+132

35/EXT ESTIMATED LANDING DISTANCES (FEET)
USE MAN SPOILERS

General Electric CF6-80C2 Engines

Weight 1000 LB		360	380	400	420	440	460	480	500
S.L.	DRY	4632	4803	4974	5155	5340	5496	5685	5855
STD=15°C	WET	5577	5795	6020	6257	6502	6717	6969	7197
2000 FT	DRY	4856	5039	5221	5414	5613	5780	5983	6165
STD=11°C	WET	5890	6131	6373	6631	6893	7128	7394	7642
4000 FT	DRY	5096	5291	5486	5693	5906	6085	6304	6500
STD=7°C	WET	6249	6509	6763	7037	7317	7571	7864	8133
6000 FT	DRY	5357	5566	5775	5998	6227	6420	6655	6867

STD=3°C	WET	6631	6914	7190	7489	7798	8060	8380	8674
8000 FT	DRY	5637	5862	6087	6326	6574	6782	7037	7317
STD=-1°C	WET	7047	7348	7660	7980	8308	8600	8943	9324
10000 FT	DRY	5943	6185	6428	6687	6963	7267	7546	7854
STD=-5°C	WET	7513	7841	8166	8522	8888	9294	9675	10074
NOTE: Standard day, no wind, zero slope, three engines at maximum reverse thrust to 80 KIAS, then reverse idle to 60 KIAS, then forward idle to stop (includes air run distances).									

CORRECTIONS:

Temperature: Valid from STD -20°C to STD +40°C

FEET PER °C	DRY	WET
BELOW standard day	-13	-16
ABOVE standard day	+29	+39

Slope: Valid from -2% downhill to +2% uphill

FEET PER 1% SLOPE	DRY	WET
UPHILL	-94	-155
DOWNHILL	+275	+522

Wind: Valid from -10 knot tailwind to +20 knot headwind

FEET PER KNOT	DRY	WET
HEADWIND	-35	-50
TAILWIND	+95	+143

50/EXT ESTIMATED LANDING DISTANCES (FEET)
USE MAN SPOILERS

Pratt & Whitney PW-4460/PW-4462 Engines

Weight 1000 LB		360	380	400	420	440	460	480	500
S.L.	DRY	4316	4476	4641	4791	4963	5113	5262	5443
STD=15°C	WET	5050	5269	5498	5710	5922	6157	6371	6626
2000 FT	DRY	4526	4697	4875	5036	5190	5377	5535	5728
STD=11°C	WET	5343	5585	5824	6053	6282	6531	6760	7035
4000 FT	DRY	4751	4935	5125	5297	5463	5663	5832	6038

STD=7°C	WET	5664	5914	6185	6425	6673	6943	7189	7477
6000 FT	DRY	4993	5190	5394	5580	5757	5973	6154	6375
STD=3°C	WET	6003	6284	6566	6826	7094	7392	7651	7969
8000 FT	DRY	5253	5465	5684	5883	6075	6307	6503	6741
STD=-1°C	WET	6382	6677	6983	7266	7550	7869	8158	8494
10000 FT	DRY	5534	5762	5998	6214	6443	6718	6955	7232
STD=-5°C	WET	6783	7107	7440	7749	8076	8457	8797	9182
NOTE: Standard day, no wind, zero slope, three engines at maximum reverse thrust to 60 KIAS, then forward idle to stop (includes air run distances).									

CORRECTIONS:

Temperature: Valid from STD -20°C to STD +40°C

FEET PER °C	DRY	WET
BELOW standard day	-11	-13
ABOVE standard day	+25	+34

Slope: Valid from -2% downhill to +2% uphill

FEET PER 1% SLOPE	DRY	WET
UPHILL	-83	-138
DOWNHILL	+228	+443

Wind: Valid from -10 knot tailwind to +20 knot headwind

FEET PER KNOT	DRY	WET
HEADWIND	-33	-45
TAILWIND	+83	+128

35/EXT ESTIMATED LANDING DISTANCES (FEET)
USE MAN SPOILERS

Pratt & Whitney PW-4460/PW-4462 Engines

Weight 1000 LB		360	380	400	420	440	460	480	500
S.L.	DRY	4622	4790	4958	5138	5326	5484	5677	5850
STD=15°C	WET	5422	5661	5902	6154	6422	6647	6923	7169
2000 FT	DRY	4856	5035	5215	5406	5605	5773	5979	6165
STD=11°C	WET	5755	6005	6265	6533	6812	7062	7353	7626
4000 FT	DRY	5105	5298	5491	5696	5908	6087	6307	6506
STD=7°C	WET	6102	6386	6659	6950	7251	7511	7825	8121
6000 FT	DRY	5373	5581	5788	6009	6238	6430	6665	6879
STD=3°C	WET	6493	6787	7084	7397	7724	8013	8345	8656
8000 FT	DRY	5662	5885	6109	6347	6594	6802	7056	7285
STD=-1°C	WET	6907	7220	7543	7887	8236	8548	8916	9254
10000 FT	DRY	5975	6216	6458	6716	6992	7296	7575	7882
STD=-5°C	WET	7353	7703	8047	8423	8815	9243	9646	10082

NOTE: Standard day, no wind, zero slope, three engines at maximum reverse thrust to 60 KIAS, then forward idle to stop (includes air run distances).

CORRECTIONS:

Temperature: Valid from STD -20°C to STD +40°C

FEET PER °C	DRY	WET
BELOW standard day	-11	-15
ABOVE standard day	+28	+39

Slope: Valid from -2% downhill to +2% uphill

FEET PER 1% SLOPE	DRY	WET
UPHILL	-93	-151
DOWNHILL	+273	+524

Wind: Valid from -10 knot tailwind to +20 knot headwind

FEET PER KNOT	DRY	WET
HEADWIND	-35	-48
TAILWIND	+94	+140

During Go-Around and Missed Approach

If go-around is required, initial flight director pitch guidance will provide proper speed and pitch targets, but, under certain 5G interference conditions, the flight director cannot be commanded from the Flight Control Panel (FCP) to provide speed or heading guidance, and may not provide altitude capture guidance. If this guidance is not available, manually comply with missed approach procedures, including altitude constraints.

(5) For airplanes identified in paragraph (c)(9) of this AD, do the actions specified in paragraphs (l)(5)(i) and (ii) of this AD.

(i) On or before June 30, 2023, revise the Operating Procedures Section of the existing AFM to include the information specified in figure 21 to paragraph (l)(5) of this AD. This may be done by inserting a copy of figure 21 to paragraph (l)(5) of this AD into the Operating Procedures Section of the existing AFM. Incorporating the AFM revision required by this paragraph terminates the AFM revision required by paragraph (i)(5) of this AD.

(ii) Before further flight after incorporating the limitations specified in figure 21 to paragraph (l)(5) of this AD, remove the AFM revision required by paragraph (i)(5) of this AD.

Figure 21 to paragraph (l)(5)—*AFM Operating Procedures Revision for Model DC–9–81 (MD–81), DC–9–82 (MD–82), DC–9–83 (MD–83), DC–9–87 (MD–87), MD–88, and MD–90–30*

(Required by AD 20-**-**-**)**

Radio Altimeter 5G C-Band Interference, Approaches

ILS Approaches

For ILS approaches other than SA CAT I, SA CAT II, CAT II, and CAT III, disconnect the autopilot and autothrottles, and place both flight director switches to OFF prior to glideslope intercept.

Note: Possible erroneous radio altimeter indications may affect autopilot, autothrottles, and flight director guidance; manually intervene if necessary.

Non-Precision Approaches

Non-precision instrument approaches can be conducted using LNAV/VNAV with flight directors, autopilot, and autothrottle to published BARO minimums.

(m) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Operational Safety Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or responsible Flight Standards Office, as appropriate. If sending information directly to the manager of the Operational Safety Branch, send it to the attention of the person identified in paragraph (n) of this AD. Information may be emailed to: *AMOC@faa.gov*.

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the responsible Flight Standards Office.

(3) AMOCs approved for AD 2021–23–12, Amendment 39–21810 (86 FR 69984, December 9, 2021) providing relief for specific radio altimeter installations are approved as AMOCs for the requirements specified in paragraph (h) of this AD until June 30, 2023.

(n) Related Information

For more information about this AD, contact Brett Portwood, Continued Operational Safety Technical Advisor, COS Program Management Section, Operational Safety Branch, FAA, 3960 Paramount Boulevard, Lakewood, CA 90712–4137; phone: 817–222–5390; email: *operationalsafety@faa.gov*.

(o) Material Incorporated by Reference

None.

Issued on April 28, 2023.

Michael Linegang,

Acting Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2023–09431 Filed 5–1–23; 4:15 pm]

BILLING CODE 4910–13–C

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2023–0671; Project Identifier AD–2022–01428–T]

RIN 2120–AA64

Airworthiness Directives; The Boeing Company Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to supersede Airworthiness Directive (AD) 2022–03–20, which applies to all The Boeing Company Model 737–8, 737–9, and 737–8200 airplanes. AD 2022–03–20 requires revising the limitations and operating procedures sections of the existing airplane flight manual (AFM) to incorporate limitations prohibiting the use of certain minimum equipment list (MEL) items, and to incorporate operating procedures for calculating takeoff and landing distances, when in the presence of 5G C-Band interference as identified by Notices to Air Missions (NOTAMs). Since the FAA issued AD 2022–03–20, the FAA determined that additional limitations are needed due to the continued deployment of new 5G C-Band base stations whose signals are expected to cover most of the contiguous United States at transmission frequencies between 3.7–3.98 GHz. This proposed AD would require revising the limitations section of the existing AFM to incorporate limitations prohibiting the use of certain MEL items, and would retain the operating procedures from AD 2022–03–20 for calculating takeoff and landing distances, due to the presence of 5G C-Band interference. The FAA is proposing this AD to address the unsafe condition on these products.

DATES: The FAA must receive comments on this proposed AD by May 23, 2023.

ADDRESSES: You may send comments, using the procedures found in 14 CFR 11.43 and 11.45, by any of the following methods:

- *Federal eRulemaking Portal:* Go to *regulations.gov*. Follow the instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.
- *Hand Delivery:* Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

AD Docket: You may examine the AD docket at *regulations.gov* under Docket No. FAA–2023–0671; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this NPRM, any comments received, and other information. The street address for Docket Operations is listed above.

FOR FURTHER INFORMATION CONTACT: Brett Portwood, Continued Operational Safety Technical Advisor, COS Program Management Section, Operational Safety Branch, FAA, 3960 Paramount Boulevard, Lakewood, CA 90712–4137;

phone: 817–222–5390; email: *operationalsafety@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under **ADDRESSES**. Include ''Docket No. FAA–2023–0671; Project Identifier AD–2022–01428–T'' at the beginning of your comments. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend the proposal because of those comments.

Except for Confidential Business Information (CBI) as described in the following paragraph, and other information as described in 14 CFR 11.35, the FAA will post all comments received, without change, to *regulations.gov*, including any personal information you provide. The agency will also post a report summarizing each substantive verbal contact received about this proposed AD.

Confidential Business Information

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this NPRM contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this NPRM, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as ''PROPIN.'' The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this NPRM. Submissions containing CBI should be sent to Brett Portwood, Continued Operational Safety Technical Advisor, COS Program Management Section, Operational Safety Branch, FAA, 3960 Paramount Boulevard, Lakewood, CA 90712–4137; phone: 817–222–5390; email: *operationalsafety@faa.gov.* Any commentary that the FAA receives that is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Background

The FAA issued AD 2021–23–12, Amendment 39–21810 (86 FR 69984, December 9, 2021) (AD 2021–23–12), for all transport and commuter category airplanes equipped with a radio altimeter. AD 2021–23–12 was prompted by a determination that radio altimeters cannot be relied upon to perform their intended function if they experience interference from wireless broadband operations in the 3.7–3.98 GHz frequency band (5G C-Band). AD 2021–23–12 requires revising the limitations section of the existing AFM to incorporate limitations prohibiting certain operations requiring radio altimeter data when in the presence of 5G C-Band interference as identified by NOTAMs. The agency issued AD 2021–23–12 because radio altimeter anomalies that are undetected by the automation or pilot, particularly close to the ground (*e.g.,* landing flare), could lead to loss of continued safe flight and landing.

The FAA subsequently identified an additional hazard presented by 5G C-Band interference on The Boeing Company Model 737–8, 737–9, and 737–8200 airplanes and issued AD 2022–03–20, Amendment 39–21937 (87 FR 4787, January 31, 2022) (AD 2022–03–20). AD 2022–03–20 was prompted by a determination that as a result of 5G C-Band interference, certain airplane systems may not properly function, resulting in longer than normal landing or rejected takeoff distances, due to the effect on thrust reverser deployment, spoilers, speedbrake deployment, and increased idle thrust, regardless of the approach type or weather. AD 2022–03–20 requires revising the limitations and operating procedures sections of the existing AFM to incorporate limitations prohibiting the use of certain MEL items, and to incorporate operating procedures for calculating takeoff and landing distances, when in the presence of 5G C-Band interference as identified by NOTAMs. The agency issued AD 2022–03–20 to address degraded deceleration performance, which could lead to a runway excursion.

Actions Since AD 2022–03–20 Was Issued

Since issuing AD 2022–03–20, the FAA determined that additional limitations are needed due to the continued deployment of new 5G C-Band base stations whose signals are expected to cover most of the contiguous United States at transmission frequencies between 3.7–3.98 GHz. Therefore, the FAA issued an NPRM, Docket No. FAA–2022–1647 (88 FR 1520, January 11, 2023) (the NPRM), proposing to supersede AD 2021–23–12. In the NPRM, the FAA proposed to retain most of the operational prohibitions required by AD 2021–23–12 until June 30, 2023; on or before June 30, 2023, operators would be required to revise their existing AFM to prohibit these operations unless the airplane has a radio altimeter meeting proposed minimum performance levels (a defined power spectral density (PSD) curve as well as a defined aggregate spurious emission level) and is operating at a 5G C-Band mitigated airport (5G CMA). In the NPRM, the FAA also proposed to require all airplanes operating under 14 CFR part 121 to have a radio altimeter meeting the proposed minimum performance standards by February 1, 2024.

Since the NPRM was published, the FAA has determined that a PSD curve is a more appropriate method to define performance than a single fixed emission level. The proposed PSD curve more accurately reflects differences in radio altimeter susceptibility to interfering emissions at different altitude levels. The FAA plans to issue guidance on how to show compliance with both the fundamental PSD curve and spurious PSD curve, including the data to be submitted, for the FAA to approve the method used.

AD 2022–03–20 relies on the FAA's use of NOTAMs to identify 5G C-band interference at certain airports in the U.S. airspace. As explained in more detail in the NPRM, those NOTAMs are no longer the best means of communicating the location of the 5G C-Band environment. Therefore, this proposed AD would retain the AFM limitations required by AD 2022–03–20 until June 30, 2023. On or before June 30, 2023, this proposed AD would require operators to replace the limitations with limitations prohibiting the same operations, except the prohibitions would not be tied to NOTAMs but instead would depend on whether the airplane is operated at a 5G CMA as identified by an FAA Domestic Notice. Because the 5G C-Band Interference operating procedure required by AD 2022–03–20 does not reference NOTAMs, this proposed AD would retain that operating procedure requirement with no change.

FAA's Determination

The FAA is issuing this NPRM after determining that the unsafe condition described previously is likely to exist or develop on other products of the same type design.

Proposed AD Requirements in This NPRM

This proposed AD would retain the requirements of AD 2022–03–20 until June 30, 2023. On or before June 30, 2023, this proposed AD would require

replacing those AFM limitations with limitations prohibiting the same dispatching or releasing to airports, and takeoff or landings on runways, and use of certain MEL items at all airports for non-radio altimeter tolerant airplanes. For radio altimeter tolerant airplanes, the prohibited operations would be allowed at 5G CMAs as identified in an FAA Domestic Notice. The minimum performance levels in this proposed AD for determining whether an airplane is radio altimeter tolerant are the same minimum performance levels proposed in the NPRM, except the FAA has replaced the proposed fixed emission level with a proposed PSD curve emission threshold that more accurately reflects differences in radio altimeter susceptibility to interfering emissions at different altitude levels.

Paragraph (k)(3) of this proposed AD specifies that AMOCs approved for AD 2021–23–12 providing relief for specific radio altimeter installations are approved as AMOCs for the requirements specified in paragraph (h) of this proposed AD until June 30, 2023. After June 30, 2023 operators with AMOCs approved for AD 2021–23–12 would be required to incorporate the 5G C-Band Interference operating procedure specified in paragraph (h)(2) of this proposed AD. The new AFM limitations, which would be required by paragraph (i) or (j) of this proposed AD, specify that operators must comply with this 5G C-Band Interference operating procedure.

Interim Action

The FAA considers that this AD, if adopted as proposed, would be an interim action. Once the Technical Standard Order (TSO) standard for radio altimeters is established, which will follow the existing international technical consensus on the establishment of the minimum operational performance standards (MOPS), the FAA anticipates that the MOPS will be incorporated into the TSO. The FAA also anticipates that aircraft incorporating equipment approved under the new Radio Altimeter TSO will be able to operate in both 5G CMAs and non-5G CMAs with no 5G C-Band-related AFM limitations. Once a new radio altimeter TSO is developed, approved, and available, the FAA might consider additional rulemaking.

Costs of Compliance

The cost information below describes the costs to change the AFM. Although this proposed AD would largely maintain the AFM limitations currently required by AD 2022–03–20, the FAA acknowledges that this proposed AD may also impose costs on some aircraft operators from having to change their conduct to comply with the amended AFM. However, the FAA lacks the data necessary to quantify the costs associated with aircraft operators changing their conduct. The FAA is seeking public comment on these costs so the agency can more fully account for the impact of this regulatory action.

The FAA estimates that this AD, if adopted as proposed, would affect 276 airplanes of U.S. registry.[1] The FAA estimates the following costs to comply with this proposed AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
AFM revision (retained actions from AD 2022–03–20).	1 work-hour[2] × $85 per hour = $85	$0	$85	$23,460
New AFM revisions (new proposed action)	1 work-hour × $85 per hour = $85	0	85	[3] 23,460

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the Agency's authority.

The FAA is issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701: General requirements. Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

The FAA has determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that the proposed regulation:

(1) Is not a ''significant regulatory action'' under Executive Order 12866,

(2) Would not affect intrastate aviation in Alaska, and

(3) Would not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA proposes to amend 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by:

■ a. Removing Airworthiness Directive (AD) 2022–03–20, Amendment 39–21937 (87 FR 4787, January 31, 2022), and

■ b. Adding the following new AD:

[1] This is the number of Boeing Model 737–8, 737–9, and 737–8200 airplanes on the FAA's registry as of December 1, 2022.

[2] The labor rate of $85 per hour is the average wage rate for an aviation mechanic.

[3] The estimated cost for this revision would not constitute a significant economic impact (even for small entities) because $85 is a minimal cost compared to the regular costs of maintaining and operating a Model 737–8, 737–9, or 737–8200 transport category airplane.

The Boeing Company Airplanes: Docket No. FAA–2023–0671; Project Identifier AD–2022–01428–T.

(a) Comments Due Date

The FAA must receive comments on this airworthiness directive (AD) by May 23, 2023.

(b) Affected ADs

This AD replaces AD 2022–03–20, Amendment 39–21937 (87 FR 4787, January 31, 2022) (AD 2022–03–20).

(c) Applicability

This AD applies to all The Boeing Company 737–8, 737–9, and 737–8200 airplanes, certificated in any category.

(d) Subject

Air Transport Association (ATA) of America Code 34, Navigation.

(e) Unsafe Condition

This AD was prompted by a determination that radio altimeters cannot be relied upon to perform their intended function if they experience interference from wireless broadband operations in the 3.7–3.98 GHz frequency band (5G C-Band), and a determination that, during takeoffs and landings, as a result of this interference, certain airplane systems may not properly function, resulting in longer than normal landing or rejected takeoff distances due to the effect on thrust reverser deployment, spoilers, speedbrake deployment, and increased idle thrust, regardless of the approach type or weather. The FAA is issuing this AD to address degraded deceleration performance, which could lead to a runway excursion.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

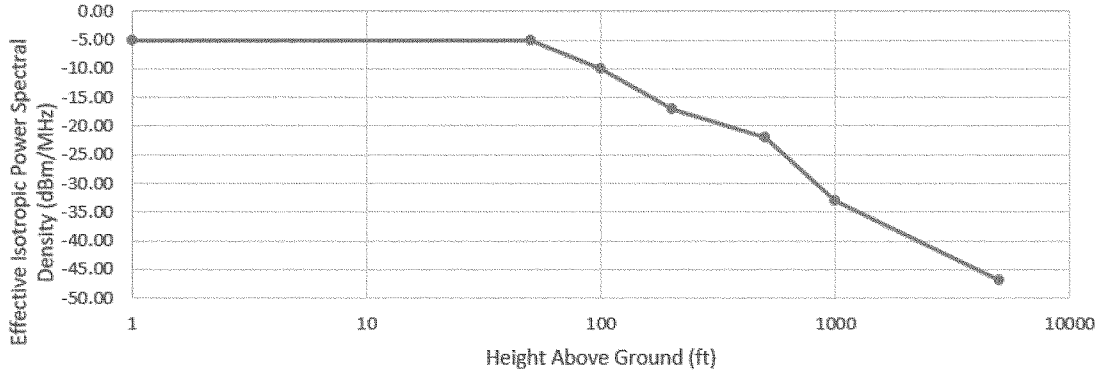
(g) Definitions

(1) For purposes of this AD, a ''5G C-Band mitigated airport'' (5G CMA) is an airport at which the telecommunications companies have agreed to voluntarily limit their 5G deployment at the request of the FAA, as identified by an FAA Domestic Notice.

(2) For purposes of this AD, a ''radio altimeter tolerant airplane'' is one for which the radio altimeter, as installed, demonstrates the tolerances specified in paragraphs (g)(2)(i) and (ii) of this AD, using a method approved by the FAA.

(i) Tolerance to radio altimeter interference, for the fundamental emissions (3.7–3.98 GHz), at or above the power spectral density (PSD) curve threshold specified in figure 1 to paragraph (g)(2)(i) of this AD.

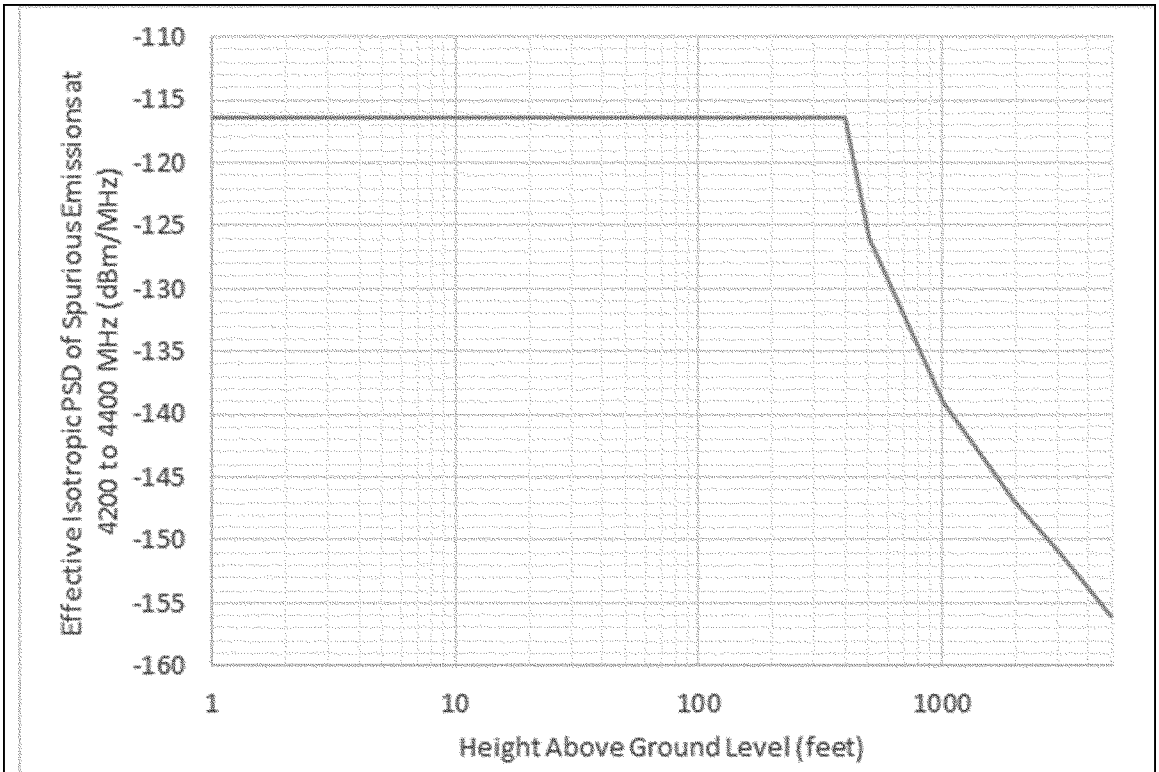
Figure 1 to paragraph (g)(2)(i)—*Fundamental Effective Isotropic PSD at Outside Interface of Aircraft Antenna*



Height above ground (ft)	Effective Isotropic PSD (dBm/MHz)
Aircraft on the ground	-5
50	-5
100	-10
200	-17
500	-22
1000	-33
5000	-47

(ii) Tolerance to radio altimeter interference, for the spurious emissions (4.2–4.4 GHz), at or above the PSD curve threshold specified in figure 2 to paragraph (g)(2)(ii) of this AD.

Figure 2 to paragraph (g)(2)(ii)—*Spurious Effective Isotropic PSD at Outside Interface of Aircraft Antenna*



Aircraft Altitude (ft AGL)	Effective Isotropic PSD (dBm/MHz)
1	-116.50
400	-116.50
500	-126.00
1000	-139.00
2000	-147.00
3000	-151.00
5000	-156.00

(3) For purposes of this AD, a ''non-radio altimeter tolerant airplane'' is one for which the radio altimeter, as installed, does not demonstrate the tolerances specified in paragraphs (g)(2)(i) and (ii) of this AD.

(4) Runway condition codes are defined in figure 3 to paragraph (g)(4) of this AD.

Figure 3 to paragraph (g)(4)—*Runway Condition Codes*

Runway Condition Code	Runway Condition Description	Reported Braking Action
6	Dry	Dry
5	Wet (smooth, grooved, or porous friction course (PFC)) or frost 3 mm (0.12 inch) or less of: water, slush, dry snow, or wet snow	Good
4	Compacted snow at or below -15°C (5°F) outside air temperature (OAT)	Good to medium
3	Wet (slippery), dry snow, or wet snow (any depth) over compacted snow Greater than 3 mm (0.12 inch) of: dry snow or wet snow Compacted snow at OAT warmer than -15°C (5°F)	Medium
2	Greater than 3 mm (0.12 inch) of: water or slush	Medium to poor
1	Ice	Poor
0	Wet ice, water on top of compacted snow, dry snow, or wet snow over ice	Nil

(h) Retained Airplane Flight Manual (AFM) Revision

This paragraph restates the requirements of paragraph (h) of AD 2022–03–20.

(1) Within 2 days after January 31, 2022 (the effective date of AD 2022–03–20): Revise the Limitations Section of the existing AFM to include the information specified in figure 4 to paragraph (h)(1) of this AD. This may be done by inserting a copy of figure 4 to paragraph (h)(1) of this AD into the existing AFM.

Figure 4 to paragraph (h)(1)—*AFM Limitations Revisions*

(Required by AD 2022-03-20)

Radio Altimeter 5G C-Band Interference, Takeoff and Landing Performance

The following limitations are required for dispatch or release to airports, and takeoff or landing on runways, in U.S. airspace in the presence of 5G C-Band wireless broadband interference as identified by NOTAM (NOTAMs will be issued to state the specific airports or approaches where the radio altimeter is unreliable due to the presence of 5G C-Band wireless broadband interference).

Minimum Equipment List (MEL)

Dispatch or release with any of the following MEL items is prohibited:

- 32-42-01 – Antiskid Systems
- 32-42-02 – Alternate Antiskid Valves
- 32-42-03 – Automatic Brake System
- 32-44-01 – Parking Brake Valve

Landing Operations on Runways with Condition Code 1 or 0

Dispatch or release to, or takeoff or landing on, runways with a runway condition code of 1 or 0 is prohibited.

Takeoff and Landing Performance

Operators must use the 5G C-Band Interference Takeoff Performance and Landing Distance Calculations procedure contained in the Operating Procedures Section of this AFM.

(2) Within 2 days after January 31, 2022 (the effective date of AD 2022–03–20): Revise the Operating Procedures Section of the existing AFM to include the information specified in figure 5 to paragraph (h)(2) of this AD. This may be done by inserting a copy of figure 5 to paragraph (h)(2) of this AD into the existing AFM.

Figure 5 to paragraph (h)(2)—*AFM Operating Procedures Revision*

(Required by AD 2022-03-20)

5G C-Band Interference Takeoff Performance and Landing Distance Calculations

Dispatch Guidance – Takeoff Performance

Stopping distance during a rejected takeoff (RTO) can be significantly increased due to the following potential effects on airplane systems:

- Limited spoiler extension
- Higher engine idle
- Thrust reversers may not deploy

For the increased stopping distance during an RTO, refer to the Departure Airport, Takeoff Performance section below.

Dispatch Guidance – Destination or Alternate Airport – Landing Performance

Calculate the required landing distance (select Method A or Method B).

Method A: Use of normal landing performance increased by a predetermined percentage

Use Prior to Descent, Required Landing Distance section below.

Method B: Use of the Non-Normal Configuration Landing Distance table for SPOILERS

Use the SPOILERS Non-Normal Configuration Landing Distance table in the Performance chapter of the AFM, or the applicable table below, for flaps 30 or flaps 40.

- Use the distance for MAX MANUAL braking configurations with the appropriate runway condition at estimated time of arrival.
- Apply all of the appropriate distance adjustments to include the reverse thrust adjustment for no reverse (NO REV).

For runway condition codes 6 and 5, obtain the required landing distance by using the higher of:

- The resulting unfactored distance increased by 15%, or
- The normal dispatch calculations.

For runway condition codes 4 and 3, increase the resulting unfactored distance by 15% to obtain the required landing distance.

For runway condition code 2, increase the resulting unfactored distance by 30% to obtain the required landing distance.

End of Method B

Departure Airport, Takeoff Performance

Select Method 1 or 2 to adjust the accelerate stop distance available (ASDA).

Note: Both methods provide an acceptable margin of safety.

Method 1: Adjust the ASDA by a predetermined value.

Adjust the ASDA by using the following adjustment:

Runway Condition Code	Runway Condition Description	Subtract from ASDA
6	Dry	950 feet
5	Wet skid resistant*	2,600 feet
5, 4, or 3	Wet/dry snow/wet snow/compact snow/slippery	3,700 feet
2	Slush or standing water	4,900 feet

*Provided approval to use wet skid resistant data has been received from the appropriate regulatory authority in accordance with the AFM.

Use the adjusted ASDA and complete the takeoff performance calculations using actual departure runway conditions and actual departure environmental conditions. Do not take credit for use of reverse thrust when calculating takeoff performance.

End of Method 1

Method 2: Adjust the ASDA by a predetermined factor.

Multiply the ASDA by the following factor:

Runway Condition Code	Runway Condition Description	ASDA Factor
6	Dry	0.86
5	Wet skid resistant*	0.76
5, 4, or 3	Wet/dry snow/wet snow/compact snow/slippery	0.71
2	Slush or standing water	0.65

*Provided approval to use wet skid resistant data has been received from the appropriate regulatory authority in accordance with the AFM.

Use the adjusted ASDA and complete the takeoff performance calculations using actual departure runway conditions and actual departure environmental conditions. Do not take credit for use of reverse thrust when calculating takeoff performance.

End of Method 2

Prior to takeoff:

Verify normal radio altimeter indications.

Climb out:

- TO/GA mode may not be available

- Monitor pitch mode engagement
- Monitor roll mode engagement
- Autopilot may not engage

Prior to Descent, Required Landing Distance

Do a time of arrival (en route) landing distance assessment using Method A or B. Use the SPOILERS Non-Normal Configuration Landing Distance table in the Performance chapter of the AFM, or the applicable table below, for flaps 30 or flaps 40.

Method A: Use of normal landing performance and increase by a predetermined percentage.

Use the Normal Configuration Landing Distance table for flaps 30 or flaps 40.

Note: The distances and adjustments shown in the Normal Configuration Landing Distance tables are factored and have been increased 15%.

Select the appropriate runway condition.

Select the distance for the MAX MANUAL braking configuration.

Apply all of the appropriate distance adjustments.

Note: Do not apply adjustments for reverse thrust.

To obtain the required landing distance, increase the resulting factored distance by the percentage below in Table 1 based on the runway condition code or runway braking action.

Table 1

Runway Condition Code	Reported Braking Action	Percentage
6	Dry	23%
5	Good	63%
4	Good to medium	56%
3	Medium	65%
2	Medium to poor	113%

Determine autobrake settings using the Determine Autobrake Settings section below.

End of Method A

Method B: Use of the Non-Normal Configuration Landing Distance table for SPOILERS

Use the SPOILERS Non-Normal Configuration Landing Distance table in the Performance chapter of the AFM, or the applicable table below, for flaps 30 or flaps 40.

Select the appropriate runway condition.

Select the distance for MAX MANUAL braking configuration.

Apply all of the appropriate distance adjustments including the reverse thrust adjustment for no reverse (NO REV).

For runway condition codes 6 to 3, increase the resulting unfactored distance by 15% to obtain the required landing distance.

For runway condition code 2, increase the resulting unfactored distance by 30% to obtain the required landing distance.

Determine autobrake settings using the Determine Autobrake Settings section below.

SPOILERS Non-Normal Configuration Landing Distance Tables

737-8 and 737-8200 One Position Tailskid, FLAPS 30, VREF30

	Landing Distances and Adjustments (Feet)								
	Reference Distance	Weight Adjustment	Altitude Adjustment*	Wind Adjustment per 10 Knots	Slope Adjustment per 1%	Temperature Adjustment per 10°C	Approach Speed Adjustment	Reverse Thrust Adjustment	
Runway Condition Code	150,000 LB Landing Weight	Per 10,000 LB Above / Below 150,000 LB	Per 1,000 ft STD / HIGH	Head / Tail Wind	Down / Up Hill	Above / Below ISA	per 5 KTS above VREF	One Reverser	No Reverser
6	4870	250 / -270	130 / 170	-210 / 680	80 / -70	130 / -130	310	180	280
5	6300	420 / -410	230 / 320	-330 / 1160	200 / -170	210 / -210	420	610	1300
4	6890	430 / -430	240 / 330	-350 / 1210	260 / -210	210 / -210	420	740	1620
3	7330	450 / -450	250 / 340	-360 / 1270	310 / -250	220 / -220	420	910	2090
2	8290	610 / -570	330 / 460	-470 / 1660	440 / -340	280 / -280	450	1530	4410

737-8 and 737-8200 Two Position Tailskid, FLAPS 30, VREF30

	Landing Distances and Adjustments (Feet)								
	Reference Distance	Weight Adjustment	Altitude Adjustment*	Wind Adjustment per 10 Knots	Slope Adjustment per 1%	Temperature Adjustment per 10°C	Approach Speed Adjustment	Reverse Thrust Adjustment	
Runway Condition Code	150,000 LB Landing Weight	Per 10,000 LB Above / Below 150,000 LB	Per 1,000 ft STD / HIGH	Head / Tail Wind	Down / Up Hill	Above / Below ISA	per 5 KTS above VREF	One Reverser	No Reverser
6	4670	250 / -250	130 / 170	-210 / 670	80 / -70	120 / -120	300	160	250
5	6030	410 / -380	220 / 320	-320 / 1130	190 / -160	200 / -200	410	550	1170
4	6610	420 / -400	230 / 330	-340 / 1180	240 / -200	200 / -200	410	680	1480
3	7050	430 / -420	240 / 340	-360 / 1240	300 / -240	210 / -200	410	850	1960
2	7980	590 / -540	330 / 460	-460 / 1640	420 / -330	270 / -270	450	1430	4110

737-9 FLAPS 30, VREF30

	Landing Distances and Adjustments (Feet)								
	Reference Distance	Weight Adjustment	Altitude Adjustment*	Wind Adjustment per 10 Knots	Slope Adjustment per 1%	Temperature Adjustment per 10°C	Approach Speed Adjustment	Reverse Thrust Adjustment	
Runway Condition Code	160,000 LB Landing Weight	Per 10,000 LB Above / Below 160,000 LB	Per 1,000 ft STD / HIGH	Head / Tail Wind	Down / Up Hill	Above / Below ISA	per 5 KTS above VREF	One Reverser	No Reverser
6	5030	250 / -250	140 / 170	-210 / 690	90 / -80	130 / -130	310	170	270
5	6530	410 / -380	250 / 330	-340 / 1180	220 / -180	210 / -210	420	610	1290
4	7090	420 / -400	260 / 340	-350 / 1230	270 / -220	220 / -220	420	720	1560
3	7550	430 / -420	270 / 350	-370 / 1290	330 / -260	220 / -220	420	880	1990
2	8530	590 / -530	360 / 480	-480 / 1690	460 / -360	290 / -290	460	1480	4070

737-8 and 737-8200 One Position Tailskid, FLAPS 40, VREF40

	Landing Distances and Adjustments (Feet)								
	Reference Distance	Weight Adjustment	Altitude Adjustment*	Wind Adjustment per 10 Knots	Slope Adjustment per 1%	Temperature Adjustment per 10°C	Approach Speed Adjustment	Reverse Thrust Adjustment	
Runway Condition Code	150,000 LB Landing Weight	Per 10,000 LB Above / Below 150,000 LB	Per 1,000 ft STD / HIGH	Head / Tail Wind	Down / Up Hill	Above / Below ISA	per 5 KTS above VREF	One Reverser	No Reverser
6	4630	300 / -250	140 / 170	-210 / 670	90 / -80	120 / -120	330	160	250
5	5860	490 / -380	230 / 310	-320 / 1110	190 / -160	190 / -190	420	510	1070
4	6450	500 / -390	230 / 320	-340 / 1170	250 / -200	190 / -190	420	640	1380
3	6900	510 / -420	240 / 330	-350 / 1230	310 / -240	200 / -200	410	800	1830
2	7670	670 / -520	320 / 450	-450 / 1610	410 / -320	260 / -260	450	1260	3430

737-8 and 737-8200 Two Position Tailskid, FLAPS 40, VREF40

	Landing Distances and Adjustments (Feet)								
	Reference Distance	Weight Adjustment	Altitude Adjustment*	Wind Adjustment per 10 Knots	Slope Adjustment per 1%	Temperature Adjustment per 10°C	Approach Speed Adjustment	Reverse Thrust Adjustment	
Runway Condition Code	150,000 LB Landing Weight	Per 10,000 LB Above / Below 150,000 LB	Per 1,000 ft STD / HIGH	Head / Tail Wind	Down / Up Hill	Above / Below ISA	per 5 KTS above VREF	One Reverser	No Reverser
6	4600	310 / -250	140 / 170	-210 / 670	90 / -70	120 / -120	330	160	250
5	5830	500 / -370	230 / 310	-320 / 1110	190 / -160	190 / -190	420	510	1060
4	6420	510 / -390	240 / 320	-330 / 1160	250 / -200	190 / -190	420	630	1370
3	6870	520 / -410	250 / 330	-350 / 1220	310 / -240	200 / -200	410	800	1820
2	7630	680 / -520	330 / 450	-450 / 1610	410 / -320	260 / -260	450	1250	3400

737-9 FLAPS 40, VREF40

	Landing Distances and Adjustments (Feet)								
	Reference Distance	Weight Adjustment	Altitude Adjustment*	Wind Adjustment per 10 Knots	Slope Adjustment per 1%	Temperature Adjustment per 10°C	Approach Speed Adjustment	Reverse Thrust Adjustment	
Runway Condition Code	160,000 LB Landing Weight	Per 10,000 LB Above / Below 160,000 LB	Per 1,000 ft STD / HIGH	Head / Tail Wind	Down / Up Hill	Above / Below ISA	per 5 KTS above VREF	One Reverser	No Reverser
6	4920	330 / -250	150 / 180	-210 / 680	90 / -80	130 / -130	330	170	260
5	6280	520 / -370	250 / 340	-330 / 1160	210 / -180	200 / -200	430	550	1150
4	6850	520 / -390	250 / 340	-350 / 1200	270 / -220	210 / -210	430	660	1410
3	7300	540 / -410	260 / 350	-360 / 1260	330 / -260	210 / -210	430	820	1830
2	8140	690 / -510	340 / 470	-460 / 1650	450 / -340	270 / -270	460	1290	3420

*For landing distance at or below 8,000 ft pressure altitude, apply the STD adjustment. For altitudes higher than 8,000 ft, first apply the STD adjustment to derive a new reference landing distance for 8,000 ft then apply the HIGH adjustment to this new reference distance.

Reference distance is based on MAX MANUAL braking, sea level, standard day, no wind or slope and maximum reverse thrust.

Reference distance includes a distance from threshold to touchdown associated with a flare time of 7 seconds.

Distances are based on SPOILERS failure distances which conservatively approximates the effects of 5G interference after the Reverse Thrust Adjustment for no Reversers is applied.

Actual (unfactored) distances are shown.

Note: per procedure, MAX MANUAL braking is not required for normal operations.

End of Method B

Determine Autobrake Settings

- Determine desired AUTOBRAKE setting by using the normal configuration landing distance.

  Note: Normal manual or normal autobrakes can be used. The use of maximum brakes is not needed except as stated in the During Landing section below.

During Approach

- Monitor radio altimeters for anomalies.
- Monitor performance of autopilot and autothrottle. If the autopilot or autothrottle is not performing as expected, disconnect both the autopilot and autothrottle and apply manual inputs to ensure proper control of flight path.

At DA(H), MDA(H), or the Missed Approach Point

- If suitable visual reference is established, disengage the autopilot and autothrottle and continue for a normal manual landing.

- If a go-around is needed, do the go-around and the missed approach procedure either in manual or automatic flight.

During Landing

- Radio altitude-based altitude aural callouts during approach may not be available or may be erroneous.
- Manual deployment of the speedbrakes may be needed.
- If the thrust reversers do not deploy, immediately ensure the speedbrakes are extended, apply manual braking, and modulate as needed for the existing runway conditions.

Note: In some conditions, maximum manual braking may be needed throughout the entire landing roll.

During Go-around and Missed Approach

- TO/GA mode may not be available.
- Monitor thrust and verify that thrust increases.
- Monitor pitch mode engagement.
- Monitor roll mode engagement.
- Autopilot may not engage.

(i) New Requirement: AFM Revision for Non-Radio Altimeter Tolerant Airplanes

For non-radio altimeter tolerant airplanes, do the actions specified in paragraphs (i)(1) and (2) of this AD.

(1) On or before June 30, 2023, revise the Limitations Section of the existing AFM to include the information specified in figure 6 to paragraph (i) of this AD. This may be done by inserting a copy of figure 6 to paragraph (i) of this AD into the existing AFM. Incorporating the AFM revision required by this paragraph terminates the AFM revision required by paragraph (h)(1) of this AD.

(2) Before further flight after incorporating the limitations specified in figure 6 to paragraph (i) of this AD, remove the AFM revision required by paragraph (h)(1) of this AD.

Figure 6 to paragraph (i)—*AFM Revision for Non-Radio Altimeter Tolerant Airplanes*

(Required by AD 20-**-**-**)**

Radio Altimeter 5G C-Band Interference, Takeoff and Landing Performance

Due to the presence of 5G C-Band wireless broadband interference, the following limitations are required for dispatch or release to airports, and takeoff or landing on runways, in the contiguous U.S. airspace.

Minimum Equipment List (MEL)

Dispatch or release with any of the following MEL items is prohibited:

- 32-42-01 – Antiskid Systems
- 32-42-02 – Alternate Antiskid Valves
- 32-42-03 – Automatic Brake System
- 32-44-01 – Parking Brake Valve

Landing Operations on Runways with Condition Code 1 or 0

Dispatch or release to, or takeoff or landing on, runways with a runway condition code of 1 or 0 is prohibited.

Takeoff and Landing Performance

Operators must use the 5G C-Band Interference Takeoff Performance and Landing Distance Calculations procedure contained in the Operating Procedures Section of this AFM.

(j) New Requirement: AFM Revision for Radio Altimeter Tolerant Airplanes

For radio altimeter tolerant airplanes, do the actions specified in paragraphs (j)(1) and (2) of this AD.

(1) On or before June 30, 2023, revise the Limitations Section of the existing AFM to include the information specified in figure 7 to paragraph (j) of this AD. This may be done by inserting a copy of figure 7 to paragraph (j) of this AD into the existing AFM. Incorporating the AFM revision required by this paragraph terminates the AFM revision required by paragraph (h)(1) of this AD.

(2) Before further flight after incorporating the limitations specified in figure 7 to paragraph (j) of this AD, remove the AFM revision required by paragraph (h)(1) of this AD.

Figure 7 to paragraph (j)—*AFM Revision for Radio Altimeter Tolerant Airplanes*

(Required by AD 20-**-**-**)**

Radio Altimeter 5G C-Band Interference, Takeoff and Landing Performance

Due to the presence of 5G C-Band wireless broadband interference, the following limitations are required for dispatch or release to airports, and takeoff or landing on runways, in the contiguous U.S. airspace, unless operating at a 5G C-Band mitigated airport as identified in an FAA *Domestic Notice*.

Minimum Equipment List (MEL)

Dispatch or release with any of the following MEL items is prohibited:

- 32-42-01 – Antiskid Systems
- 32-42-02 – Alternate Antiskid Valves
- 32-42-03 – Automatic Brake System
- 32-44-01 – Parking Brake Valve

Landing Operations on Runways with Condition Code 1 or 0

Dispatch or release to, or takeoff or landing on, runways with a runway condition code of 1 or 0 is prohibited.

Takeoff and Landing Performance

Operators must use the 5G C-Band Interference Takeoff Performance and Landing Distance Calculations procedure contained in the Operating Procedures Section of this AFM.

(k) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Operational Safety Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or responsible Flight Standards Office, as appropriate. If sending information directly to the manager of the Operational Safety Branch, send it to the attention of the person identified in paragraph (m) of this AD. Information may be emailed to: *AMOC@faa.gov*.

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the responsible Flight Standards Office.

(3) AMOCs approved for AD 2021–23–12, Amendment 39–21810 (86 FR 69984, December 9, 2021) providing relief for specific radio altimeter installations are approved as AMOCs for the requirements specified in paragraph (h) of this AD until June 30, 2023.

(l) Related Information

For more information about this AD, contact Brett Portwood, Continued Operational Safety Technical Advisor, COS Program Management Section, Operational Safety Branch, FAA, 3960 Paramount Boulevard, Lakewood, CA 90712–4137; phone: 817–222–5390; email: *operationalsafety@faa.gov*.

(m) Material Incorporated by Reference

None.

Issued on April 28, 2023.

Michael Linegang,

Acting Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2023–09434 Filed 5–1–23; 4:15 pm]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2023–0670; Project Identifier AD–2022–01427–T]

RIN 2120–AA64

Airworthiness Directives; The Boeing Company Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to supersede Airworthiness Directive (AD) 2022–03–05, which applies to all The Boeing Company Model 747–8F and 747–8 series airplanes and Model 777 airplanes. AD 2022–03–05 requires revising the limitations section of the existing airplane flight manual (AFM) to incorporate limitations prohibiting dispatching or releasing to airports, and approaches or landings on runways, when in the presence of 5G C-Band interference as identified by Notices to Air Missions (NOTAMs). Since the FAA issued AD 2022–03–05, the FAA determined that additional limitations are needed due to the continued deployment of new 5G C-Band base stations whose signals are expected to cover most of the contiguous United States at transmission frequencies between 3.7–3.98 GHz. This proposed AD would require revising the limitations section of the existing AFM to incorporate limitations prohibiting dispatching or releasing to airports, and approaches or landings on runways, due to the presence of 5G C-Band interference. The FAA is proposing this AD to address the unsafe condition on these products.

DATES: The FAA must receive comments on this proposed AD by May 23, 2023.

ADDRESSES: You may send comments, using the procedures found in 14 CFR 11.43 and 11.45, by any of the following methods:

- *Federal eRulemaking Portal:* Go to *regulations.gov*. Follow the instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

• *Hand Delivery:* Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

AD Docket: You may examine the AD docket at regulations.gov under Docket No. FAA–2023–0670; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this NPRM, any comments received, and other information. The street address for Docket Operations is listed above.

FOR FURTHER INFORMATION CONTACT: Brett Portwood, Continued Operational Safety Technical Advisor, COS Program Management Section, Operational Safety Branch, FAA, 3960 Paramount Boulevard, Lakewood, CA 90712–4137; phone: 817–222–5390; email: *operationalsafety@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under **ADDRESSES**. Include ''Docket No. FAA–2023–0670; Project Identifier AD–2022–01427–T'' at the beginning of your comments. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend the proposal because of those comments.

Except for Confidential Business Information (CBI) as described in the following paragraph, and other information as described in 14 CFR 11.35, the FAA will post all comments received, without change, to regulations.gov, including any personal information you provide. The agency will also post a report summarizing each substantive verbal contact received about this proposed AD.

Confidential Business Information

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this NPRM contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this NPRM, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as ''PROPIN.'' The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this NPRM. Submissions containing CBI should be sent to Brett Portwood, Continued Operational Safety Technical Advisor, COS Program Management Section, Operational Safety Branch, FAA, 3960 Paramount Boulevard, Lakewood, CA 90712–4137; phone: 817–222–5390; email: *operationalsafety@faa.gov.* Any commentary that the FAA receives that is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Background

The FAA issued AD 2021–23–12, Amendment 39–21810 (86 FR 69984, December 9, 2021) (AD 2021–23–12), for all transport and commuter category airplanes equipped with a radio altimeter. AD 2021–23–12 was prompted by a determination that radio altimeters cannot be relied upon to perform their intended function if they experience interference from wireless broadband operations in the 3.7–3.98 GHz frequency band (5G C-Band). AD 2021–23–12 requires revising the limitations section of the existing AFM to incorporate limitations prohibiting certain operations requiring radio altimeter data when in the presence of 5G C-Band interference as identified by NOTAMs. The agency issued AD 2021–23–12 because radio altimeter anomalies that are undetected by the automation or pilot, particularly close to the ground (*e.g.,* landing flare), could lead to loss of continued safe flight and landing.

The FAA subsequently identified an additional hazard presented by 5G C-Band interference on The Boeing Company Model 747–8F and 747–8 series airplanes and Model 777 airplanes and issued AD 2022–03–05, Amendment 39–21922 (87 FR 4150, January 27, 2022) (AD 2022–03–05). AD 2022–03–05 was prompted by a determination that radio altimeters cannot be relied upon to perform their intended function if they experience interference from wireless broadband operations in the 3.7–3.98 GHz frequency band (5G C-Band), and a determination that this interference may affect multiple airplane systems using radio altimeter data, including the pitch control laws, including those that provide tail strike protection, regardless of the approach type or weather. AD 2022–03–05 requires revising the limitations section of the existing AFM to incorporate limitations prohibiting dispatching or releasing to airports, and approaches or landings on runways, when in the presence of 5G C-Band interference as identified by NOTAMs. The agency issued AD 2022–03–05 to address missing or erroneous radio altimeter data, which, in combination with multiple flight deck effects, could lead to loss of continued safe flight and landing.

Actions Since AD 2022–03–05 Was Issued

Since issuing AD 2022–03–05, the FAA determined that additional limitations are needed due to the continued deployment of new 5G C-Band base stations whose signals are expected to cover most of the contiguous United States at transmission frequencies between 3.7–3.98 GHz. Therefore, the FAA issued an NPRM, Docket No. FAA–2022–1647 (88 FR 1520, January 11, 2023) (the NPRM), proposing to supersede AD 2021–23–12. In the NPRM, the FAA proposed to retain most of the operational prohibitions required by AD 2021–23–12 until June 30, 2023; on or before June 30, 2023, operators would be required to revise their existing AFM to prohibit these operations unless the airplane has a radio altimeter meeting proposed minimum performance levels (a defined power spectral density (PSD) curve as well as a defined aggregate spurious emission level) and is operating at a 5G C-Band mitigated airport (5G CMA). In the NPRM, the FAA also proposed to require all airplanes operating under 14 CFR part 121 to have a radio altimeter meeting the proposed minimum performance standards by February 1, 2024.

Since the NPRM was published, the FAA has determined that a PSD curve is a more appropriate method to define performance than a single fixed emission level. The proposed PSD curve more accurately reflects differences in radio altimeter susceptibility to interfering emissions at different altitude levels. The FAA plans to issue guidance on how to show compliance with both the fundamental PSD curve and spurious PSD curve, including the data to be submitted, for the FAA to approve the method used.

AD 2022–03–05 relies on the FAA's use of NOTAMs to identify 5G C-band interference at certain airports in the U.S. airspace. As explained in more detail in the NPRM, those NOTAMs are no longer the best means of communicating the location of the 5G C-Band environment. Therefore, this proposed AD would retain the AFM limitations required by AD 2022–03–05 until June 30, 2023. On or before June 30, 2023, this proposed AD would require operators to replace the

limitations with limitations prohibiting the same operations, except the prohibitions would not be tied to NOTAMs but instead would depend on whether the airplane is operated at a 5G CMA as identified by an FAA Domestic Notice.

FAA's Determination

The FAA is issuing this NPRM after determining that the unsafe condition described previously is likely to exist or develop on other products of the same type design.

Proposed AD Requirements in This NPRM

This proposed AD would retain the AFM revisions required by AD 2022–03–05 until June 30, 2023. On or before June 30, 2023, this proposed AD would require replacing those AFM limitations prohibiting the same dispatching or releasing to airports, and approaches or landings on runways. For radio altimeter tolerant airplanes, the prohibited operations would be allowed at 5G CMAs as identified in an FAA Domestic Notice. The minimum performance levels in this proposed AD for determining whether an airplane is radio altimeter tolerant are the same minimum performance levels proposed in the NPRM, except the FAA has replaced the proposed fixed emission level with a proposed PSD curve emission threshold that more accurately reflects differences in radio altimeter susceptibility to interfering emissions at different altitude levels.

Paragraph (k)(3) of this proposed AD specifies that AMOCs approved for AD 2021–23–12 providing relief for specific radio altimeter installations would be approved as AMOCs for the requirements specified in paragraph (h) of this proposed AD until June 30, 2023.

Interim Action

The FAA considers that this AD, if adopted as proposed, would be an interim action. Once the Technical Standard Order (TSO) standard for radio altimeters is established, which will follow the existing international technical consensus on the establishment of the minimum operational performance standards (MOPS), the FAA anticipates that the MOPS will be incorporated into the TSO. The FAA also anticipates that aircraft incorporating equipment approved under the new Radio Altimeter TSO will be able to operate in both 5G CMAs and non-5G CMAs with no 5G C-Band-related AFM limitations. Once a new radio altimeter TSO is developed, approved, and available, the FAA might consider additional rulemaking.

Costs of Compliance

The cost information below describes the costs to change the AFM. Although this proposed AD would largely maintain the AFM limitations currently required by AD 2022–03–05, the FAA acknowledges that this proposed AD may also impose costs on some aircraft operators from having to change their conduct to comply with the amended AFM. However, the FAA lacks the data necessary to quantify the costs associated with aircraft operators changing their conduct. The FAA is seeking public comment on these costs so the agency can more fully account for the impact of this regulatory action.

The FAA estimates that this AD, if adopted as proposed, would affect 347 airplanes of U.S. registry.[1] The FAA estimates the following costs to comply with this proposed AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
AFM revision (retained action from AD 2022–03–05).	1 work-hour × $85 per hour[2] = $85	$0	$85	$29,495
New AFM revision (new proposed action)	1 work-hour × $85 per hour = $85	0	85	[3] 29,495

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the Agency's authority.

The FAA is issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701: General requirements. Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

The FAA has determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that the proposed regulation:

(1) Is not a ''significant regulatory action'' under Executive Order 12866,

(2) Would not affect intrastate aviation in Alaska, and

(3) Would not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA proposes to amend 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by:

[1] This is the number of Boeing Model 747–8F and 747–8 series airplanes and Model 777 airplanes on the FAA's registry as of December 1, 2022.

[2] The labor rate of $85 per hour is the average wage rate for an aviation mechanic.

[3] The estimated cost for this revision would not constitute a significant economic impact (even for small entities) because $85 is a minimal cost compared to the regular costs of maintaining and operating a Model 747–8F, 747–8, or 777 transport category airplane.

■ a. Removing Airworthiness Directive (AD) 2022–03–05, Amendment 39–21922 (87 FR 4150, January 27, 2022), and
■ b. Adding the following new AD:

The Boeing Company Airplanes: Docket No. FAA–2023–0670; Project Identifier AD–2022–01427–T.

(a) Comments Due Date

The FAA must receive comments on this airworthiness directive (AD) by May 23, 2023.

(b) Affected ADs

This AD replaces AD 2022–03–05, Amendment 39–21922 (87 FR 4150, January 27, 2022) (AD 2022–03–05).

(c) Applicability

This AD applies to all The Boeing Company airplanes identified in paragraphs (c)(1) and (2) of this AD, certificated in any category.

(1) Model 747–8F and 747–8 series airplanes.

(2) Model 777–200, –200LR, –300, –300ER, and 777F series airplanes.

(d) Subject

Air Transport Association (ATA) of America Code 34, Navigation.

(e) Unsafe Condition

This AD was prompted by a determination that radio altimeters cannot be relied upon to perform their intended function if they experience interference from wireless broadband operations in the 3.7–3.98 GHz frequency band (5G C-Band), and a determination that this interference may affect other airplane systems using radio altimeter data, including the pitch control laws, including those that provide tail strike protection, regardless of the approach type or weather. The FAA is issuing this AD to address missing or erroneous radio altimeter data, which, in combination with multiple flight deck effects, could lead to loss of continued safe flight and landing.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Definitions

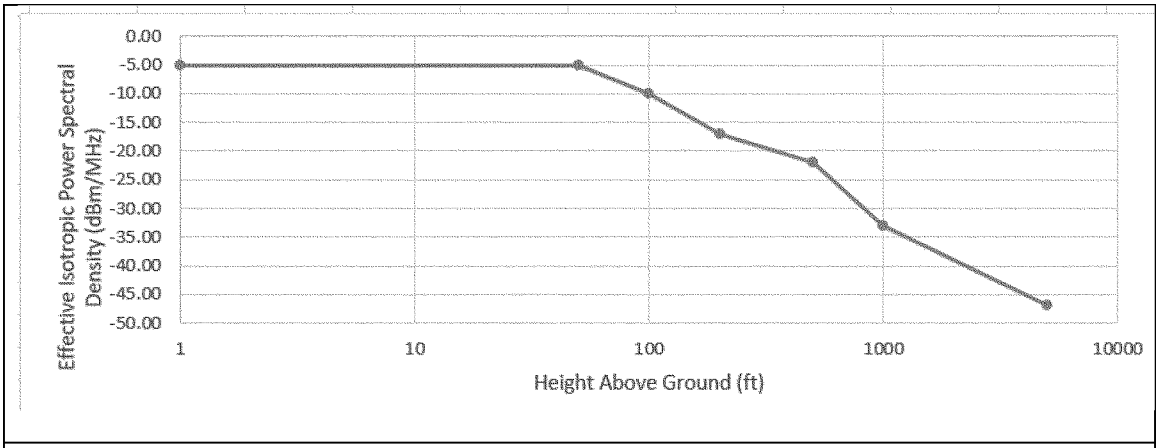
(1) For purposes of this AD, a ''5G C-Band mitigated airport'' (5G CMA) is an airport at which the telecommunications companies have agreed to voluntarily limit their 5G deployment at the request of the FAA, as identified by an FAA Domestic Notice.

(2) For purposes of this AD, a ''radio altimeter tolerant airplane'' is one for which the radio altimeter, as installed, demonstrates the tolerances specified in paragraphs (g)(2)(i) and (ii) of this AD, using a method approved by the FAA.

(i) Tolerance to radio altimeter interference, for the fundamental emissions (3.7–3.98 GHz), at or above the power spectral density (PSD) curve threshold specified in figure 1 to paragraph (g)(2)(i) of this AD.

BILLING CODE 4910–13–P

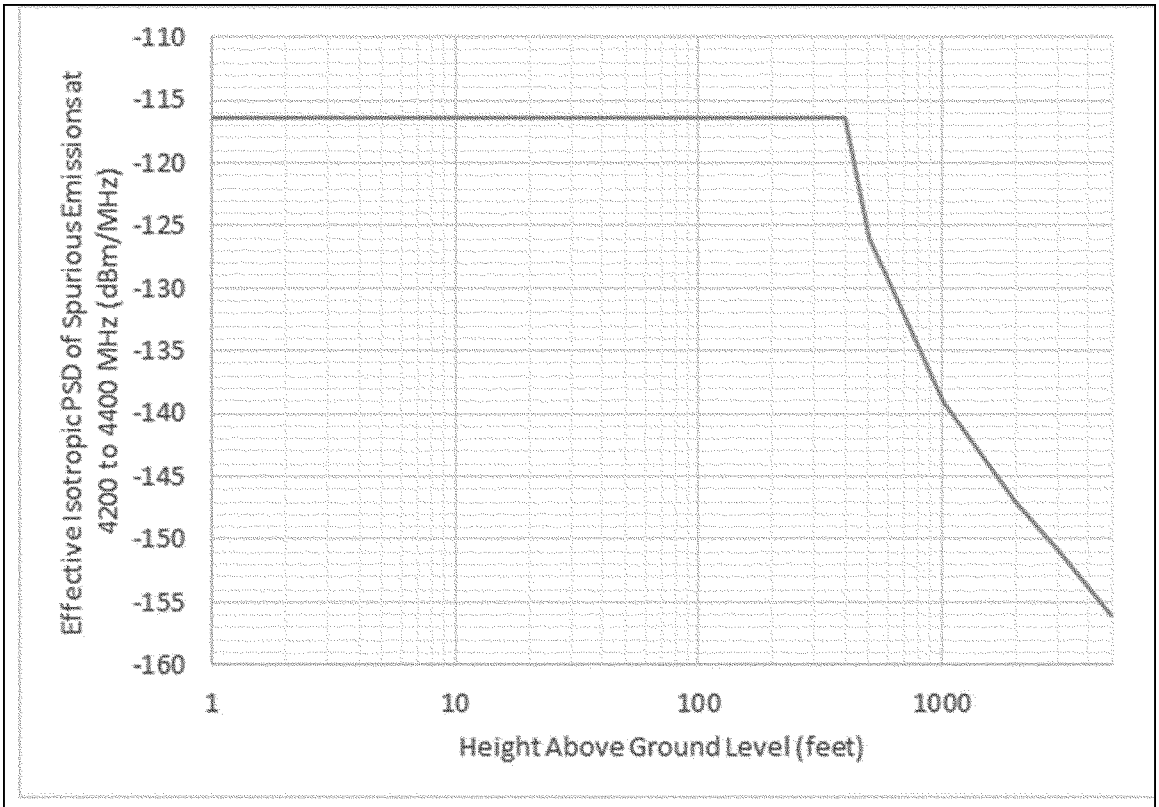
Figure 1 to paragraph (g)(2)(i)—*Fundamental Effective Isotropic PSD at Outside Interface of Aircraft Antenna*



Height above ground (ft)	Effective Isotropic PSD (dBm/MHz)
Aircraft on the ground	-5
50	-5
100	-10
200	-17
500	-22
1000	-33
5000	-47

(ii) Tolerance to radio altimeter interference, for the spurious emissions (4.2–4.4 GHz), at or above the PSD curve threshold specified in figure 2 to paragraph (g)(2)(ii) of this AD.

Figure 2 to paragraph (g)(2)(ii)—*Spurious Effective Isotropic PSD at Outside Interface of Aircraft Antenna*



Aircraft Altitude (ft AGL)	Effective Isotropic PSD (dBm/MHz)
1	-116.50
400	-116.50
500	-126.00
1000	-139.00
2000	-147.00
3000	-151.00
5000	-156.00

(3) For purposes of this AD, a ''non-radio altimeter tolerant airplane'' is one for which the radio altimeter, as installed, does not demonstrate the tolerances specified in paragraphs (g)(2)(i) and (ii) of this AD.

(h) Retained Airplane Flight Manual (AFM) Revision

This paragraph restates the requirements of paragraph (g) of AD 2022–03–05. Within 2 days after January 27, 2022 (the effective date of AD 2022–03–05): Revise the Limitations Section of the existing AFM to include the information specified in figure 3 to paragraph (h) of this AD. This may be done by inserting a copy of figure 3 to paragraph (h) of this AD into the existing AFM.

Figure 3 to paragraph (h)—*AFM Limitations Revisions*

(Required by AD 2022-03-05)

Approaches and Landings in the Presence of Radio Altimeter 5G C-Band Interference

Dispatching or releasing to airports, and approaches or landings on runways, in U.S. airspace in the presence of 5G C-Band wireless broadband interference as identified by NOTAM is prohibited (NOTAMs will be issued to state the specific airports or approaches where the radio altimeter is unreliable due to the presence of 5G C-Band wireless broadband interference).

(i) New Requirement: AFM Revision for Non-Radio Altimeter Tolerant Airplanes

For non-radio altimeter tolerant airplanes, do the actions specified in paragraphs (i)(1) and (2) of this AD.

(1) On or before June 30, 2023, revise the Limitations Section of the existing AFM to include the information specified in figure 4 to paragraph (i) of this AD. This may be done by inserting a copy of figure 4 to paragraph (i) of this AD into the existing AFM. Incorporating the AFM revision required by this paragraph terminates the AFM revision required by paragraph (h) of this AD.

(2) Before further flight after incorporating the limitations specified in figure 4 to paragraph (i) of this AD, remove the AFM revision required by paragraph (h) of this AD.

Figure 4 to paragraph (i)—*AFM Revision for Non-Radio Altimeter Tolerant Airplanes*

(Required by AD 20-**-**-**)**

Approaches and Landings in the Presence of Radio Altimeter 5G C-Band Interference

Due to the presence of 5G C-Band wireless broadband interference, dispatching or releasing to airports, and approaches or landings on runways, in the contiguous U.S. airspace is prohibited.

(j) New Requirement: AFM Revision for Radio Altimeter Tolerant Airplanes

For radio altimeter tolerant airplanes, do the actions specified in paragraphs (j)(1) and (2) of this AD.

(1) On or before June 30, 2023, revise the Limitations Section of the existing AFM to include the information specified in figure 5 to paragraph (j) of this AD. This may be done by inserting a copy of figure 5 to paragraph (j) of this AD into the existing AFM. Incorporating the AFM revision required by this paragraph terminates the AFM revision required by paragraph (h) of this AD.

(2) Before further flight after incorporating the limitations specified in figure 5 to paragraph (j) of this AD, remove the AFM revision required by paragraph (h) of this AD.

Figure 5 to paragraph (j)—*AFM Revision for Radio Altimeter Tolerant airplanes*

(Required by AD 20-**-**-**)**

Approaches and Landings in the Presence of Radio Altimeter 5G C-Band Interference

Due to the presence of 5G C-Band wireless broadband interference, dispatching or releasing to airports, and approaches or landings on runways, in the contiguous U.S. airspace is prohibited unless operating at a 5G C-Band mitigated airport as identified in an FAA *Domestic Notice*.

(k) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Operational Safety Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or responsible Flight Standards Office, as appropriate. If sending information directly to the manager of the Operational Safety Branch, send it to the attention of the person identified in paragraph (l) of this AD. Information may be emailed to: *AMOC@faa.gov*.

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the responsible Flight Standards Office.

(3) AMOCs approved for AD 2021–23–12, Amendment 39–21810 (86 FR 69984, December 9, 2021) providing relief for specific radio altimeter installations are approved as AMOCs for the requirements specified in paragraph (h) of this AD until June 30, 2023.

(l) Related Information

For more information about this AD, contact Brett Portwood, Continued Operational Safety Technical Advisor, COS Program Management Section, Operational Safety Branch, FAA, 3960 Paramount Boulevard, Lakewood, CA 90712–4137; phone: 817–222–5390; email: *operationalsafety@faa.gov*.

(m) Material Incorporated by Reference

None.

Issued on April 28, 2023.

Michael Linegang,

Acting Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2023–09433 Filed 5–1–23; 4:15 pm]

BILLING CODE 4910–13–C

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

14 CFR Part 1216

[Document Number-23–038; Docket Number-NASA–2022–0005]

RIN 2700–AE56

Procedures for Implementing the National Environmental Policy Act

AGENCY: National Aeronautics and Space Administration.

ACTION: Notice of proposed rulemaking.

SUMMARY: The National Aeronautics and Space Administration (NASA) is proposing to amend and update its regulations for implementing the National Environmental Policy Act of 1969 (NEPA). The proposed amendments would update NASA's regulations to better align with the Agency's current and near future actions, adjust the level of NEPA review and documentation required for certain

actions, and provide more concise descriptions of NASA actions. Additionally, consistent with NASA's requirement to review existing Categorical Exclusions (CatExs) at least every seven years to determine whether modifications, additions, or deletions are appropriate, this proposed rule incorporates updates to NASA's CatExs based on that review.

DATES: Submit comments on or before July 3, 2023.

ADDRESSES: You may send comments, identified by 2700–AE56 to the Federal e-Rulemaking Portal: *https://www.regulations.gov.* Follow the instructions for sending comments. If access to the website is not feasible, NASA welcomes mailed comments to NASA Rulemaking Comments, Environmental Management Division, Suite 2U82, 300 E Street SW, Washington, DC 20546. As the security screening process may delay mail sent through the U.S. Postal Service, NASA encourages electronic submittal. Before including your address, phone number, email address, or other personally identifiable information (PII) in your comment, you should be aware that your entire comment, including your PII, may be made publicly available at any time. While you can request to withhold your PII from public review as part of the overall comment submittal, NASA cannot guarantee the execution of such a request.

FOR FURTHER INFORMATION CONTACT: Tina Norwood, (202) 358–7324, *tina.norwood@nasa.gov.* General information about NASA's NEPA process is available on the NASA NEPA Portal and NEPA Library at *https://www.nasa.gov/emd/nepa.*

SUPPLEMENTARY INFORMATION:

Background

The National Environmental Policy Act, as amended, 42 U.S.C. 4321–4347, requires all Federal agencies to assess the environmental impact of their actions pursuant to 42 U.S.C. 4332(2)(C). The Council on Environmental Quality (CEQ) has issued regulations at 40 CFR parts 1500 through 1508 (CEQ regulations) implementing NEPA that are binding on Federal agencies. On July 16, 2020, CEQ issued a final rule comprehensively updating its regulations implementing NEPA, 85 FR 43304 (July 16, 2020). The CEQ regulations require Federal agencies to develop or revise their procedures for implementing NEPA, as necessary, for consistency with CEQ's regulations or for efficiency (40 CFR 1507.3(b), (c)). However, CEQ has extended the deadline for agencies to propose conforming adjustments to their agency NEPA procedures until September 14, 2023, 86 FR 34154 (June 29, 2021). Moreover, consistent with Executive Orders (E.O.) 13990 of January 20, 2021, Protecting Public Health and the Environment and Restoring Science To Tackle the Climate Crisis, and E.O. 14008 of January 27, 2021, Tackling the Climate Crisis at Home and Abroad, CEQ is conducting a comprehensive review of the 2020 revisions to the CEQ regulations and is taking a phased approach to reconsider the regulations. *See* 86 FR 55757 (Oct. 7, 2021); 87 FR 23453 (Apr. 20, 2022). In this rulemaking, NASA is proposing new and revised CatExs, revising its list of actions normally requiring environmental impact statements or environmental assessments (EA), and making other clarifying non-substantive revisions. NASA will consider whether to propose additional changes to its procedures at the conclusion of CEQ's rulemaking process.

NASA's NEPA regulations are codified in 14 CFR 1216.3 (Procedures for Implementing the National Environmental Policy Act). NASA consulted with CEQ during the development of these proposed updated procedures and prior to their publication in the **Federal Register** (40 CFR 1507.3). These regulations would 1) codify changes to NASA's implementing regulations which reflect lessons learned since NASA last amended its NEPA regulations in 2012 (77 FR 3102 (Jan. 23, 2012)); 2) encourage increased use of programmatic NEPA documents and tiering for routine and repetitive actions for which the environmental impact is well understood; and 3) add several new CatExs for NASA actions that neither individually nor cumulatively have a significant impact on the quality of the human environment.

In addition to NASA's implementing regulations, NASA provides specific instructions pertaining to NEPA program responsibilities internally through NASA Procedural Requirements (NPR) 8580.1, Implementing the National Environmental Policy Act and Executive Order 12114, available at NASA's NEPA website *https://www.nasa.gov/emd/nepa* (under NEPA Process).

Since NASA's last NEPA regulatory revision in 2012, NASA's mission, programs, and strategic goals have evolved with a key focus on leading a new era of human space exploration, performing transformative aeronautics technology research, and continuing to study our planet and the solar system. This proposed rule builds upon decades of NASA's experience and seeks to better align with NASA's evolving technology and mission demands. NASA's NEPA regulations and policy will continue to be available on NASA's Public Portal at *https://www.nasa.gov/emd/nepa/* (under NEPA Process). In addition, NASA NEPA policy (NPR 8580.1) would be updated to reflect the revised updated NASA regulations and posted on the website. Consistent with the coordination requirement of 40 CFR 1507.3, NASA consulted with CEQ throughout the development of this proposed rule.

Introduction

NASA is proposing to amend its regulations for implementing the requirements of NEPA to (1) better align with the Agency's current and near-future actions, (2) adjust the level of NEPA review and documentation required for certain NASA actions that have become routine over the past decade for which NASA has determined they do not have significant environmental effects, (3) provide more concise descriptions of NASA actions and more specific CatExs to ensure appropriate application and tracking by NASA, and 4) ensure consistency with EOs and Presidential Memoranda (*e.g.,* Presidential Memorandum on Launch of Spacecraft Containing Space Nuclear Systems issued August 20, 2019) issued since the last update to NASA's procedures. The proposed amendments are designed to assist decision makers across NASA with a wide array of missions and activities that include space exploration and Earth observation missions, aeronautics research, launch facilities and activities, sounding rocket and balloon campaigns, field campaigns, and facilities construction and maintenance activities.

The proposed amendments would update existing CatExs and add nine new CatExs, amend existing actions normally requiring an EA and add a new action normally requiring an EA, amend existing actions normally requiring an environmental impact statement (EIS), and include other amendments. These changes are described later in this notice.

These proposed amendments to NASA's NEPA procedures incorporate and supplement CEQ's NEPA implementing regulations at 40 CFR parts 1500 through 1508. NASA drafted these procedures to minimize repetition with CEQ regulations and with the understanding that these NASA-specific regulations would be applied in tandem with the CEQ regulations. The terminology used in this Preamble and the proposed amendments include

many words and phrases that are specifically defined in either NEPA or the CEQ regulations found in 40 CFR 1508.1.

Development Process

In 2018, NASA Environmental Management Division (HQ/EMD) formed a working group to review 14 CFR part 1216, subpart 1216.3, including listed CatExs. The members comprising the working group were current NASA professionals with numerous years of NEPA planning and compliance history. Several of the members served on the working group for the 2012 revision of NASA's NEPA regulations. A summary of the working group members' qualifications is available on the NASA NEPA Library website: *https://www.nasa.gov/emd/nepa* (under 2021 NEPA Regulation Update).

In accordance with CEQ's regulations and its 2010 CatEx guidance, ''Establishing, Applying, and Revising Categorical Exclusions under the National Environmental Policy Act,'' the working group reviewed each existing CatEx against NASA's existing policies, procedures, programs, and mission to determine if they were current and appropriate. The working group also reviewed the 2018 CEQ comprehensive list of Federal agencies' CatExs and identified other agencies' CatExs for activities that are similar in nature, scope, and impact on the human environment to those activities conducted by NASA. Based on this benchmarking of other Federal agencies' CatExs and review of their administrative records, the working group recommended NASA add three CatExs to § 1216.304(d). The working group also recommended amending several existing NASA CatExs to clarify and better define the actions and to ensure NASA consistently applies and tracks CatEx use. Concurrently, the working group reviewed NASA's existing extraordinary circumstances to ensure that they adequately account for those situations and settings in which a proposed new or revised CatEx may not be applied, and NASA must prepare an EA or EIS to support Agency action.

In addition to reviewing NASA's CatExs and extraordinary circumstances, the working group reviewed NASA actions normally requiring an EA or EIS to determine if the level of analysis is appropriate and if additional actions should be added. The review considered NASA's current mission and routinely implemented actions, past experiences, and past NEPA reviews (EAs and EISs). The working group recommended adjusting the level of analysis for several actions from EIS to EA and from EA to CatEx because NASA has reviewed the environmental effects of each of the actions and found them not to be significant.

The working group developed a draft proposed rule, then distributed the draft to the NEPA Managers at the ten NASA Centers and component facilities, and to other environmental professionals and stakeholders within NASA, for review and feedback. NASA also consulted with CEQ during the development process to ensure the proposed changes to 14 CFR part 1216, subpart 1216.3, would meet NEPA requirements.

Responsibilities and Implementation Process

NASA proposes to designate the Assistant Administrator, Office of Strategic Infrastructure, within the Mission Support Directorate (MSD), as the NASA Senior Agency Official (SAO). The SAO would be responsible for establishing overall Agency NEPA compliance policy and implementing regulations for NASA, including resolving implementation issues and generally providing oversight of NASA's NEPA program. The proposed updates would incorporate the designation of NASA's SAO and would articulate the SAO's roles and responsibilities.

The NASA Senior Environmental Official (SEO) would be responsible for implementing NASA's NEPA compliance program; including all regulations, policy directives, and procedural requirements; and maintaining up-to-date Agency-wide NEPA program guidance that fully integrates NEPA analysis into Agency planning and decision-making processes. The SEO is the Director, Environmental Management Division, within the Office of Strategic Infrastructure. The NASA NEPA Manager, HQ/EMD would be delegated the responsibility for overseeing the implementation of NEPA by providing guidance and support to the Mission Directorates and NEPA Managers at ten NASA Centers and component facilities that oversee field-level NEPA compliance at their facilities. The responsibility for NEPA compliance resides with the applicable mission's, program's, or project's Responsible Official (decision maker) at NASA who may reside in a Mission Directorate for HQ-led missions/programs or at the Center level for Center-led missions/programs.

Most NASA actions occur at the Center level and the program or project manager (owner of the action requiring NEPA review) coordinates with the respective Center NEPA Manager in completing an environmental checklist for all levels of the NEPA review, reviewing the list of extraordinary circumstances for CatExs, preparing additional NEPA documentation as required, and coordinating with the Responsible Official on planning and decision making. For those actions in which principal responsibility has not been assigned to a Center or Centers (*e.g.,* Agency-wide missions, complex programmatic actions), the NASA NEPA Manager coordinates with the appropriate HQ Mission Directorates and with the Responsible Official for planning and decision making to complete the required NEPA documentation.

For the past 20 years, HQ/EMD has maintained and supplemented the internal NASA Environmental Tracking System (NETS), which contains separate modules for NASA's environmental resource areas (*e.g.,* cultural resources). The HQ and Center NEPA Managers use the NETS NEPA Module as a repository for Center NEPA reviews, EAs, and EISs. The module also auto-populates NASA's NEPA Library public website with EAs and EISs. NETS also includes an annual CatEx reporting feature that allows HQ and Center NEPA Managers to track the application of CatExs on an annual basis. The NETS NEPA Module was upgraded in 2018 to include a multi-Center action component which allows for efficient and consolidated reviews of NASA actions that involve more than one Center. Over the years, the NETS NEPA Module has provided supporting data used in revising NASA's NEPA regulations. Since the last revision of this regulation in 2012, NASA has prepared 35 EAs, four EISs, and, in 2018, applied over 2,400 CatExs.

Projects for which NASA expects to use these NEPA procedures during the upcoming years include airborne science campaigns, construction of facilities projects, International Space Station resupply launches, sample return and other space flight missions, and research field campaigns.

Revised Categorical Exclusions

Section 1216.304 of 14 CFR includes NASA's general provisions for compliance with NEPA through the use of CatExs and identifies actions categorically excluded from EA and EIS review. Within § 1216.304(d), NASA groups similar CatExs under five category headings: Administrative, Operations and Management, Research and Development (R&D), Real and Personal Property, and Aircraft and Airfield Activities. The heading ''Research and Development Activities''

is revised to ''Research, Development, and Science Activities.'' As part of this rulemaking, NASA proposes to amend 16 existing and add nine new categories of actions eligible for categorical exclusion. Many of the changes that NASA is proposing are administrative in nature to clarify application of a particular CatEx. Consistent with CEQ regulations at 40 CFR 1501.4 and 1508.1(d), § 1216.304 of the proposed rule defines ''categorical exclusion'' to mean ''categories of agency actions that normally do not have a significant effect on the human environment.'' The new CatExs reflect NASA's experience with similar factual circumstances, which it has found to have no significant impacts on the ''human environment'' (as that term is broadly defined in CEQ regulations at 40 CFR 1508.1(m)).

The rationale supporting the amended and new CatExs is set forth in NASA's Administrative Record for Updates to the National Aeronautics and Space Administration Categorical Exclusions (administrative record). The administrative record is summarized below and may be accessed in full via the online docket and at *https://www.nasa.gov/emd/nepa*. The CEQ regulations encourage Federal agencies to reduce paperwork and delay when complying with NEPA by using CatExs to define categories of actions that normally do not have a significant effect on the human environment and therefore do not require preparation of an EIS (40 CFR 1500.4(a) and 1500.5(a)). NASA believes that amending current and identifying new CatExs meets this intent. Where CatExs are added, amended, or consolidated, the supporting rationale is explained.

§ 1216.304(a): The proposed edits would incorporate a previously defined acronym, improve grammar, and streamline text. A Record of Environmental Consideration (REC) is required in some cases and text has been added to further clarify that a REC is required to document the application of some NASA CatExs to a proposed action. A REC is a brief document used to describe a proposed action, identify the applicable categorical exclusion, determine whether an extraordinary circumstance exists that may require preparation of an EA or EIS, or explain why further environmental analysis is not required.

§ 1216.304(b): The proposed revisions improve grammar and streamline text.

§ 1216.304(c): This section identifies six extraordinary circumstances that the Agency must consider in determining whether application of the CatEx is appropriate. In considering these extraordinary circumstances, if NASA determines that a significant effect is likely or the effect is unknown, then NASA will prepare an EIS or EA, as appropriate. The update of this section reflects the deletion of one extraordinary circumstance from the original seven and proposed edits to five of the remaining six circumstances to improve grammar and streamline text.

§ 1216.304(d): The proposed edits improve grammar and streamline text. Within the subheadings of this section are the CatEx categories, grouped primarily under activity headings (*i.e.,* (1) Administrative Activities, (2) Operations and Management Activities, (3) Research, Development, and Science Activities, (4) Real and Personal Property Activities, and (5) Aircraft and Airfield Activities). In addition, the proposed edits to § 1216.304(d) include reorganizing and renumbering the paragraph to accommodate new and revised CatExs.

§ 1216.304(d)(1)(ii): The proposed edit incorporates consistent grammar in the section.

§ 1216.304(d)(1)(iv): The proposed edit incorporates consistent grammar in the section.

§ 1216.304(d)(1)(v): The proposed change separates this CatEx into two CatExs with the second becoming a new CatEx in *§ 1216.304(d)(1)(ix).* NASA is making this change to establish a clear distinction between administrative and field activities. The edit retains the text that applies to ''information-gathering exercises'' and updates the sentence to be grammatically correct.

§ 1216.304(d)(1)(vi): The proposed edits incorporate consistent grammar in the section.

§ 1216.304(d)(1)(ix): This proposed new CatEx was previously part of *§ 1216.304(d)(1)(v).* The description was also updated to include monitoring wells as well as temporary equipment into the description of field study examples. The updated text was added to further clarify covered water sampling activities.

§ 1216.304(d)(2)(i): NASA proposed to add examples of routine operations at the end of the CatEx description to further clarify the types of activities addressed with this CatEx.

§ 1216.304(d)(2)(ii): The proposed edits incorporate consistent grammar in the section.

§ 1216.304(d)(2)(iii): The proposed edits incorporate consistent grammar in the section.

§ 1216.304(d)(2)(v): The proposed change clarifies that routine disposal of materials and wastes in accordance with applicable requirements is included in this CatEx. It would also add examples at the end of the CatEx description to further clarify the types of activities addressed with this CatEx.

§ 1216.304(d)(2)(vi): This proposed new CatEx would cover habitat and species management conducted within the boundaries of NASA-controlled properties in accordance with applicable Federal, state, or local requirements. NASA is making this change after reviewing other Federal agency CatExs for similar actions. For example, the U.S. Department of Agriculture, Forest Service's CatExs include similar examples to the proposed new CatEx in 36 CFR 220.6(e)(6)(iv), ''Prescribed burning to reduce natural fuel build-up and improve plant vigor,'' and 36 CFR 220.6(e)(6)(ii), ''Thinning or brush control to improve growth or to reduce fire hazard including the opening of an existing road to a dense timber stand.'' Currently, NASA's habitat and species management is conducted under § 1216.304(d)(2)(i). Establishing a distinct CatEx for these types of activities will permit NASA to specifically track habitat and species management. Based on a review of other agencies' CatExs, NASA has determined that they conduct similar activities, under similar circumstances, and therefore, this proposed new CatEx has been developed to cover these similar habitat and species management activities. The proposed new CatEx would require documentation with a REC.

§ 1216.304(d)(2)(vii): This proposed new CatEx would cover short-term cleanup actions conducted in compliance with the Resource Conservation and Recovery Act or other similar authorities. NASA is making this change after reviewing other Federal agency CatExs for similar actions. NASA is proposing this CatEx based on the Department of Energy's (DOE's) CatEx B6.1 (10 CFR part 1021, appendix B). Examples of actions typically covered under DOE's CatEx that would also be covered by NASA's new proposed CatEx include the following: repair or replacement of leaking containers; perimeter protection if needed to reduce the spread of, or direct contact with, the contamination; segregation of wastes that may react with one another; and installation of fences, warning signs, or other security precautions if humans or animals have access to the release.

§ 1216.304(d)(2)(viii): This proposed new CatEx would cover replacement of existing energy sources with alternative energy sources. NASA is making this change after reviewing other Federal agency CatExs for similar actions. NASA is proposing this CatEx based on the Defense Logistics Agency's (DLA's)

CatEx 37 (DLA Regulation 1000.22, Appendix A). Currently, replacing existing energy sources with alternative energy sources is conducted under *§ 1216.304(d)(2)(i).* Establishing a distinct CatEx for these types of activities will permit NASA to track proactive measures taken as part of sustainability initiatives.

§ 1216.304(d)(2)(ix): This proposed new CatEx would cover routine maintenance, repair, and operation of transportation systems. Currently, these types of activities are conducted under *§ 1216.304(d)(2)(i).* Establishing this distinct CatEx provides clarification between the types of activities covered under each CatEx and creates a more concise description.

§ 1216.304(d)(3): The proposed edit would incorporate the term ''science'' into the heading to clarify applicability.

§ 1216.304(d)(3)(i): NASA proposes to add a sentence with a list of examples at the end of the CatEx to further clarify the types of research, development, testing, and evaluation activities that this CatEx covers.

§ 1216. 304(d)(3)(ii): The proposed change would streamline the description of small quantities of radioactive materials use included in this CatEx. NASA proposes to add a list of examples at the end of the CatEx description to further clarify where radioactive materials may potentially be used.

§ 1216.304(d)(3)(iii): The proposed edits would add examples of laser uses to further clarify the types of activities this CatEx covers.

§ 1216.304(d)(3)(iv): This proposed new CatEx would cover the use of NASA-sponsored payloads as a distinct action separate from the platform on which it is carried. Over the past decade, NASA has launched hundreds of payloads on different platforms. NASA has found the environmental impacts from these activities are not significant. Based on this extensive experience and past analysis, NASA has determined that this type of activity fits the definition of a CatEx under 40 CFR 1501.4 and 1508.1(d), a category of action that normally does not have a significant effect on the human environment.

§ 1216.304(d)(3)(v): This proposed new CatEx category would shift this category of action from ''NASA actions normally requiring an EA'' and would cover the return of samples categorized as an Unrestricted Earth Return (UER). Celestial bodies are classified based on their possibility of containing life as either UER or Restricted Earth Return (RER). The subcategory of solar system bodies identified to have no indigenous life forms (*e.g.,* asteroids, comets, planets, dwarf planets, and planetary moons) are defined as UER by NASA's Planetary Protection Office, within the Office of Safety and Mission Assurance (*https://sma.nasa.gov/sma-disciplines/planetary-protection*). Over the past decades, NASA has been conducting or contributing to UER missions and has found the environmental impacts from these activities not to be significant. Based on this extensive experience and past analysis, NASA has determined that this type of activity fits the definition of a CatEx. RER sample return missions will still be addressed in § 1216.306(b)(2).

§ 1216.304(d)(4)(ii): The proposed edits would incorporate a previously defined acronym, improves grammar, and streamlines text.

§ 1216.304(d)(4)(iii): The proposed edits would streamline text.

§ 1216.304(d)(4)(iv): The proposed edits would incorporate consistent grammar in the section.

§ 1216.304(d)(4)(vi): This proposed new CatEx would cover temporary changes in facility status of real property assets between active and inactive. Inactive status assumes that the asset will be needed in the future and the status change would not pose a significant environmental impact. The proposed CatEx would cover such a temporary status change. Currently, these types of activities are categorically excluded under § 1216.304(d)(2)(i). Establishing this distinct CatEx would improve tracking for NEPA purposes of real property actions.

§ 1216.304(d)(4)(vii): This proposed new CatEx would cover shifting personnel within existing infrastructure at NASA locations. While all actions under the Real and Personal Property Activities include the potential for personnel reductions, realignments, and relocations, they did not specifically identify this aspect in the descriptions. This proposed CatEx would clarify that shifts or reductions in personnel are covered and avoids unnecessary analysis to support previous, repeated conclusions. Based on past experience, such as the examples set forth in the administrative record, NASA has determined that its activities under this proposed CatEx would not result in significant environmental impacts.

§ 1216.304(d)(5)(i): The proposed change would clarify that unmanned aircraft systems are included as aircraft.

§ 1216.304(d)(5)(ii): The proposed change would clarify that unmanned aircraft systems are included as aircraft.

§ 1216.304(e): The proposed edits would incorporate consistent grammar and clarify the Responsible Official's role in determining whether extraordinary circumstances exist that may preclude reliance on a categorical exclusion.

§ 1216.304(f): The proposed edits would delete the previous § 1216.304(f) as unnecessary.

Revisions to NASA Actions Normally Requiring Preparation of an EA

Under paragraph (b), which lists NASA actions normally requiring an EA, NASA is proposing to remove two actions, add one new action, and amend three actions. Where actions normally requiring EAs are removed, added, or amended, the supporting rationale is explained. As noted above, NASA's NEPA procedures incorporate and supplement CEQ's NEPA implementing regulations at 40 CFR parts 1500 through 1508, but do not restate those regulations. NASA relies on the procedural and processing requirements of CEQ's regulations for EAs. To the extent that additional guidance is needed for case-by-case application of a particular requirement, for example selecting the appropriate method of public involvement, NASA will provide specific instructions in NASA NEPA policy (NPR 8580.1). In considering whether a proposed NASA action does, or does not, have significant effects, NASA will consider the effects of connected actions and whether mitigation measures may be implemented which avoid, minimize, or compensate for significant effects caused by a proposed action. If, after consideration of the applicable criteria, NASA determines that a Finding of No Significant Impact (FONSI) cannot be reached, NASA will prepare an EIS using the EA's analysis as a starting point for preparation of the EIS.

§ 1216.305: The proposed edit would align the heading name to be consistent with § 1216.306.

§ 1216.305(a): The proposed edits would incorporate consistent grammar in the section and replace ''The Responsible Official'' with ''NASA'' to be consistent with terminology in § 1216.306.

§ 1216.305(b): The proposed edit would remove ''typical'' from the heading as the term is redundant with ''normally,'' which is the term used in the CEQ regulations and CEQ's 2010 CE guidance.

§ 1216.305(b)(1) (removed): NASA would remove the existing EA category because the launch aspect of the activity is the driver for potential environmental impacts rather than the spacecraft development and space flight projects/programs (*i.e.,* payload systems). Launch environmental impacts are

considered in an EIS under § 1216.306(b)(1) and other Agency launch vehicle NEPA documents. For example, in the *2013 Supplemental Environmental Assessment to the November 2007 Environmental Assessment for the Operation and Launch of the Falcon 1 and Falcon 9 Space Vehicles at Cape Canaveral Air Force Station Florida,* the United States Air Force analyzed potential environmental impacts associated with the operation and launch of a newer version of the Falcon 9 (version 1.1). In addition, a new CatEx, § 1216.304(d)(3)(iv), is proposed to address payload systems.

The proposal would renumber the existing example under paragraph (b)(2) to paragraph (b)(1), incorporate consistent grammar, and streamline the description.

§ 1216.305(b)(2): The proposed edit would expand the description of activities to include some activities previously identified as ''normally requiring an EIS.'' The change would shift the level of environmental analysis associated with major changes of a master plan from an EIS to an EA. This edit clarifies that major changes of a master plan normally do not result in significant environmental impacts. For example, the *2017 Supplemental Environmental Assessment for the NASA Langley Research Center Master Plan, 2016 Programmatic Environmental Assessment for Adoption of JSC's Master Plan, and 2011 Programmatic Environmental Assessment for the NASA Jet Propulsion Laboratory Facility Master Plan Updates* analyzed the potential environmental impacts related to master plan updates and resulted in FONSIs. NASA would tier from a programmatic EA to document the implementation of elements of Center Master Plans that are not adequately addressed in the EA.

Center Master Plans outline NASA's infrastructure plans to support Center operations projected over a 20-year period. An example of a major change would be a proposal for a new facility that was not envisioned in the Center Master Plan. It could also include a new facility that is included in the Center Master Plan that NASA wishes to consider as a new construction site within the Center that could impact natural resources. NASA may determine that the new site would not propose a change in environmental effect, such as construction on a site where a building has recently been demolished. Should NASA determine through EA analysis that a FONSI cannot be reached, NASA will prepare an EIS. This amended EA category also reflects a change in numbering from paragraph (b)(3) to paragraph (b)(2).

§ 1216.305(b)(3): The proposed edit would clarify text associated with the level of analysis to reflect the expectation of no major changes to established land use. This revised EA category also reflects a change in numbering from paragraph (b)(4) to paragraph (b)(3).

§ 1216.305(b)(4): This proposed new EA category would move from ''NASA actions normally requiring an EIS'' to ''NASA actions normally requiring an EA'' for launching a nuclear space system. NASA has prepared one EA (*i.e., 1994 Final Environmental Assessment for the Mars Pathfinder Mission*) and eight EISs over the last three decades for nuclear space system (radioisotope power systems (RPS))-enabled missions listed below:

2014 Final Environmental Impact Statement for the Mars 2020 Mission and 2020 Supplemental Environmental Impact Statement,

2006 Final Environmental Impact Statement for the Mars Science Laboratory Mission,

2005 Final Environmental Impact Statement for the New Horizons Mission,

2002 Final Environmental Impact Statement for the Mars Exploration Rover,

1995 Cassini Final Environmental Impact Statement,

1990 Final Environmental Impact Statement for the Ulysses Mission (Tier 2),

1989 Final Environmental Impact Statement for the Galileo Mission (Tier 2), and

1988 Final (Tier 1) Environmental Impact Statement for the Galileo and Ulysses Missions.

The DOE served as a cooperating agency in the preparation of each EIS because of its technical expertise and jurisdiction by law over the special nuclear material used in the spacecraft. In addition to extensive study of the safety features of the RPS, the DOE conducted radiological consequence analyses for each mission. This analysis has consistently demonstrated the low probabilities of a launch or post-launch mishap that would result in damage to the nuclear material's containment systems that would result in a release into the human environment with associated environmental impacts. None of the safety consequences and environmental analyses prepared over the 30-year span of these EISs conclude a significant environmental effect would be likely.

To date, all NASA nuclear-enabled missions have launched from Kennedy Space Center (KSC) in Cape Canaveral, FL. Prior to the launch of the Mars 2020 mission in August 2020, the NASA–KSC completed consultation with the United States Fish and Wildlife Service (USFWS) under Section 7 of the Endangered Species Act. The USFWS concurred with NASA's determination that the proposed action (Mars 2020 launch) may affect, but is not likely to adversely affect, threatened or endangered species or result in the destruction of designated critical habitat. In its consultation, NASA and USFWS agreed that in the event of a launch mishap, NASA would enter into emergency consultation to assess and remediate potential effects, if any, on listed species located in the affected area. NASA's long history in evaluating the safety, reliability, and potential environmental impacts of the use of nuclear-enabled spacecraft leads the Agency to conclude that the environmental effects of the use of nuclear-enabled spacecraft, even in the highly unlikely event of a launch or post-launch mishap, would not be significant. This conclusion leads the Agency to propose that for future nuclear-enabled missions, the appropriate starting level of its NEPA analysis is an EA, which, as is required by NEPA, would allow for the preparation of an EIS if the environmental effects were assessed to be significant. This change in the starting level of the NEPA analysis does not change NASA's long-standing commitment to conduct a rigorous, risk-informed safety analysis and launch authorization process as detailed in the new Presidential Memorandum signed August 20, 2019, *Launch of Spacecraft Containing Space Nuclear Systems.* Additional information on NASA's RPS-enabled missions is available at *https://www.nasa.gov/emd/nepa/rps.*

§ 1216.305(b)(5) (removed): As previously discussed, NASA is proposing to establish a CatEx at § 1216.304(d)(3)(v) for UER missions. As noted in the description that supports the proposed new CatEx, NASA has been conducting or contributing to UER missions over the past decades and has found the environmental impacts from these activities normally are not significant.

Revisions to NASA Actions Normally Requiring Preparation of an EIS

Under the heading ''NASA actions normally requiring an environmental impact statement (EIS),'' NASA is proposing to amend the headings to reflect categories under § 1216.306(b) that were identified as § 1216.306(c), (d), (e), and (f) (*i.e.,* the activities should

have been under the heading ''NASA actions normally requiring an EIS). In addition, NASA is proposing to remove two (existing *§ 1216.306(c) and (e)*) and amend three EIS categories. The two removed categories have been modified and incorporated into NASA actions normally requiring an EA as discussed in the previous section. As noted above, NASA's NEPA procedures incorporate and supplement CEQ's NEPA implementing regulations at 40 CFR parts 1500 through 1508, but do not restate those regulations. NASA relies on the procedural and processing requirements of CEQ's regulations for NASA EISs. To the extent that additional guidance is needed for case-by-case application of a particular requirement, such as selecting the appropriate method of public involvement as required by 40 CFR 1506.6, NASA will provide specific instructions in the NASA NEPA Policy (NPR 8580.1).

§ 1216.306: The heading title would include the acronym definition.

§ 1216.306(a): The proposed edits would improve grammar and streamline text while also incorporating a cross reference to CEQ's regulation.

§ 1216.306(b): The proposed edit would remove ''typical'' from the heading as the term is redundant with ''normally,'' which is the term used in the CEQ regulations.

§ 1216.306(b)(1): The edit adds ''NASA-developed'' to clarify that an EIS will be prepared when NASA proposes to develop a new space launch system, such as the EIS prepared (*https://www.nasa.gov/directorates/heo/library/nepa/orion_sls.html*) for the new launch vehicle that NASA is currently developing (*https://www.nasa.gov/exploration/systems/sls/indix.html*).

§ 1216.306(b)(2): This proposed revised category of NASA actions normally requiring preparation of an EIS would replace the parenthetical reference to appendix A with the definition from appendix A, remove reference to a subcommittee that is no longer active, and restructure the description to clarify the aspect of NASA activities that would potentially result in environmental impacts necessitating an EIS level of analysis. For example, it is the management of restricted Earth return samples from solar system bodies and not the development of the space flight program for those returned samples that potentially result in environmental impacts. This revision also expands the description to include ground systems that will be needed to process and manage an RER sample such as recovery, transport, and curation. This revised category of actions normally requiring preparation of an EIS also reflects a change in numbering from paragraph (d) to paragraph (b)(2).

§ 1216.306(b)(3): This proposed revised category of NASA actions normally requiring preparation of an EIS would add ''and natural'' to clarify that effects are potentially on the human and natural environment and remove text that is repetitive as it is not necessary to indicate that if an existing EIS covered the scope of the master plan, another EIS would not be required. This revised category of actions normally requiring preparation of an EIS also reflects a change in numbering from paragraph (f) to paragraph (b)(3).

Other Amendments

Additional amendments are proposed in sections of the rule, other than §§ 1216.304, 1216.305, and 1216.306. These proposed edits are described below.

§ 1216.300(b): The proposed edits would streamline text.

§ 1216.302(a): The proposed edit adds the name and responsibilities of the SAO.

§ 1216.302(a)(1): The proposed edits would shift the definition of SEO from § 1216.302(a), incorporate consistent grammar, and streamline the description.

§ 1216.302(a)(2): The proposed edits would shift numbering due to the insert of § 1216.302(a)(1) and streamline the description.

§ 1216.302(a)(3): The proposed edits would shift numbering due to the insert of § 1216.302(a)(1) and streamline the description.

§ 1216.302(b): The proposed edits would simplify and clarify identification of decision makers as the NASA official with authority to commit the Agency to take the proposed action.

§ 1216.302(c): The proposed edits would remove unnecessary text.

§ 1216.303(a): The proposed edits would update text.

§ 1216.303(a)(1): The proposed edits would incorporate consistent grammar.

§ 1216.303(a)(2): The proposed edits would update NASA's policy on NEPA and public involvement.

§ 1216.303(a)(3): The proposed edits would clarify text and incorporate consistent grammar.

§ 1216.303(b): The proposed edits streamline text.

§ 1216.303(c): The proposed edits would incorporate consistent grammar and add ''public health and safety'' and ''security'' as factors to be considered for a NASA proposed action. In addition, a cross reference to CEQ's regulation would be incorporated.

§ 1216.303(d): This proposed new description under the *NEPA process in NASA planning and decision making* identifies when NASA uses a REC. For example, RECs are used to document: application of a specific Categorical Exclusion (CatEx); adoption of a draft or final EIS, EA, or portion thereof; reevaluation of an existing NEPA document; and determination on whether an action fits within an existing NEPA document, including a programmatic NEPA document. Adoption of the proposed new description would avoid unnecessary analysis to support previous, repeated conclusions.

§ 1216.307: The proposed edits would add two paragraphs, § 1216.307(a) and (b), to clarify the conditions for tiering within NASA's process and incorporate consistent grammar. This change is intended to improve NASA efficiency and maximize the use of programmatic documents to streamline NASA's NEPA process.

§ 1216.308: The proposed edits would clarify NASA's process for preparing supplemental NEPA documents. The proposed edits would also incorporate text to be consistent with CEQ regulations. The proposed edits also include incorporation of paragraphs (*§ 1216.308(a) through (d)*) and add text that identifies NASA's process for completion of Supplement Analysis. A Supplement Analysis is a NASA document used to determine whether a new or supplemental EA or EIS should be prepared or to support a decision to prepare a new EA or EIS.

§ 1216.309: The proposed edit would incorporate consistent grammar.

§ 1216.310(a): The proposed edit would incorporate consistent grammar.

§ 1216.311(a): The proposed revisions would incorporate edits for consistency with the CEQ guidance memorandum ''Emergencies and the National Environmental Policy Act Guidance'' (85 FR 60137 (Sept. 14, 2020)), and incorporate consistent grammar. The proposed revision also would remove ''in accordance with the provisions in sections 305 and 307 of this subpart,'' as it duplicates text that refers to completion of NEPA analysis.

§ 1216.311(a)(1): The proposed revisions incorporate edits for consistency with CEQ's updated emergencies guidance, incorporate consistent grammar, and streamline text.

§ 1216.311(a)(2): The proposed revision shifts § 1216.311(b) to the previously reserved § 1216.311(a)(2). The proposed revisions would incorporate edits for consistency with CEQ's updated emergencies guidance, incorporate consistent grammar,

streamline text, and incorporate elevation of oversight of compliance with NEPA in an emergency to the SAO rather than the SEO.

§ 1216.311(b): The proposed revision would reflect a shift in subparagraph numbering and incorporate edits for consistency with CEQ's updated emergencies guidance, incorporate consistent grammar, streamline text, and incorporate elevation of oversight of compliance with NEPA in an emergency to the SAO rather than the SEO.

Appendix A to Subpart 1216.3: The proposed edit removes definitions and incorporates new acronyms.

Regulatory Analysis

A. Executive Order (E.O.) 12866—Regulatory Planning and Review

E.O.s 13563 and 12866 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. This proposed rule has been designated a ''significant regulatory action'' although not economically significant, under section 3(f) of E.O. 12866. Accordingly, the proposed rule has been reviewed by the Office of Management and Budget.

B. Review Under the Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) requires an agency to prepare an initial regulatory flexibility analysis to be published at the time the proposed rule is published. This requirement does not apply if the agency ''certifies that the rule will not, if promulgated, have a significant economic impact on a substantial number of small entities'' (5 U.S.C. 603). This proposed rule modifies existing policies and procedural requirements for NASA compliance with NEPA. The proposed rule makes no substantive changes to requirements imposed on applicants for licenses, permits, financial assistance, and similar actions as related to NEPA compliance. Therefore, NASA certifies this proposed rule would not have a ''significant economic impact on a substantial number of small entities.''

C. Review Under the Paperwork Reduction Act

This proposed rule does not contain any information collection requirements subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

D. Environmental Review Under the National Environmental Policy Act

The proposed rule would revise agency procedures and guidance for implementing NEPA. NASA NEPA procedures are procedural guidance to assist in the fulfillment of agency responsibilities under NEPA but are not the agency's final determination of what level of NEPA analysis is required for a particular proposed action. The CEQ sets forth the requirements for establishing agency NEPA procedures in its regulations at 40 CFR 1507.3. The CEQ regulations do not require agencies to conduct NEPA analyses or prepare NEPA documentation when establishing their NEPA procedures. The determination that establishing agency NEPA procedures does not require supporting NEPA analysis and documentation has been upheld in *Heartwood, Inc.* v. *U.S. Forest Service,* 73 F. Supp. 2d 962, 972–73 (S.D. Ill 1999), *aff'd,* 230 F.3d 947, 954–55 (7th Cir. 2000).

E. Review Under Executive Order 13132

NASA has considered this proposed rule under the requirements of E.O. 13132, Federalism. The Agency has concluded that the rule conforms with the federalism principles set out in this E.O. will not impose any compliance costs on the states and will not have substantial direct effects on the states or the relationship between the National Government and the states or on the distribution of power and responsibilities among the various levels of government. Therefore, the Agency has determined that no further assessment of federalism implications is necessary.

F. Review Under the Unfunded Mandates Reform Act

Pursuant to Title II of the Unfunded Mandates Reform Act (UMRA) of 1995 (2 U.S.C. 1531–1538), NASA has assessed the effects of the proposed rule on state, local, and Tribal governments, and the private sector. This proposed rule would not compel the expenditure of $100 million or more by any state, local, or Tribal government, or anyone in the private sector. Therefore, this proposed rule is not subject to the requirements of section 202 and 205 of the UMRA.

G. Expected Impact of the Proposed Rule

NASA does not expect this proposed rule to have any economic impact on the overall economy of the United States; state, local, or Tribal governments or communities; or any private party involved in commercial space launch activities at NASA facilities. Given the most recent data NASA has available, most NASA actions fall within the scope of a CatEx (98 percent categorically excluded, 1.4 percent had an EA/Finding of No Significant Impact, and 0.16 percent had an EIS/Record of Decision). By expanding the list of actions covered by a CatEx, NASA would promote more efficient NEPA compliance without sacrificing the integrity of the environmental impact review process for those actions which may require an EA or EIS.

The proposed updates to several existing NASA CatExs and the addition of nine new CatExs are intended to further streamline NASA NEPA compliance for actions that, individually or cumulatively, do not have a significant impact on the quality of the human environment. The proposed rule does not materially alter the budgetary impact of entitlements, grants, NASA loan programs, or the rights and obligations of recipients thereof. The proposed rule does not raise novel legal or policy issues; rather it promotes consistency with the CEQ's NEPA implementing regulations, thereby providing more regulatory certainty concerning NEPA compliance obligations to both NASA programs and commercial space operators who may propose actions that would occur on NASA jurisdictional facilities. Therefore, this proposed rule is not expected to have any adverse effect, economically or otherwise, on NASA, any other Federal, state, local, or Tribal entity or any private party who may propose an action that would occur at a NASA jurisdictional facility.

List of Subjects in 14 CFR Part 1216

Environmental impact statements, Flood plains, Foreign relations.

For the reasons given in the preamble, NASA proposes to amend 14 CFR part 1216 as follows:

PART 1216—ENVIRONMENTAL QUALITY

■ 1. Add an authority citation for part 1216 to read as follows:

Authority: 51 U.S.C. 20101 *et seq.;* 42 U.S.C. 4321 *et seq.;* 40 CFR parts 1500 through 1508.

Subpart 1216.3—Procedures for Implementing the National Environmental Policy Act (NEPA)

■ 2. The authority citation for subpart 1216.3 is revised to read as follows:

Authority: 42 U.S.C. 2451 *et seq.;* 42 U.S.C. 4321 *et seq.;* 42 U.S.C. 4371 *et seq.;* 42 U.S.C. 7609; E.O. 11514, 35 FR 4247, 3 CFR, 1966–1970, Comp., p. 902, as amended by E.O. 11991, 42 FR 26967, 3 CFR, 1977 Comp., p. 123; E.O. 12114, 44 FR 1957, 3 CFR, 1979 Comp., p. 356; and 40 CFR parts 1500 through 1508.

■ 3. Amend § 1216.300 by revising paragraph (b) to read as follows:

§ 1216.300 Scope.

* * * * *

(b) Through this subpart, NASA adopts the Council on Environmental Quality (CEQ regulations implementing NEPA (40 CFR parts 1500 through 1508) and supplements those regulations with this subpart, for actions proposed by NASA that are subject to NEPA. This subpart and NASA's NEPA policy are available on NASA's Public Portal at *https://www.nasa.gov/emd/nepa.*

■ 4. Revise § 1216.302 to read as follows:

§ 1216.302 Responsibilities.

(a) The NASA Senior Agency Official (SAO), is the Associate Administrator, Mission Support Directorate. The SAO is responsible for overall Agency NEPA compliance, including integration of NEPA into the Agency's planning and decision making and resolving implementation issues.

(1) The NASA Senior Environmental Official (SEO) is the Assistant Administrator, Office of Strategic Infrastructure (OSI). The SEO, in consultation with the SAO, is responsible for development and implementation of NASA NEPA policy requirements and guidance which fully integrate NEPA compliance into Agency planning and decision-making processes. To the extent the CEQ's implementing regulations at 40 CFR parts 1500 through 1508 reserve a specific authority to the SAO, the SAO is the responsible NASA official for resolving matters related to that specific authority.

(2) The NASA Headquarters/Environmental Management Division (HQ/EMD), in consultation with the SEO, is responsible for implementing NEPA functions and guiding NASA's integration of NEPA into the Agency's planning and decision making. HQ/EMD provides oversight of all NASA entities in implementing their assigned responsibilities under NEPA. HQ/EMD, in coordination with the Center Environmental Management Office, is responsible for determining the appropriate level of NEPA documentation and maintaining a publicly accessible internet portal which includes information on the status of environmental impact statements (EISs) and other elements of NASA's NEPA program (*https://www.nasa.gov/emd/nepa*).

(3) Each NASA Center has an environmental management office that directs and implements the NEPA process, such as evaluating proposed actions; developing, reviewing, and approving required documentation; and advising Center-level program and project managers.

(b) The ''Responsible Official'' is the NASA official who will ensure that planning and decision making for each proposed Agency action complies with the regulations in this subpart and with Agency NEPA policy and guidance provided by the SAO, SEO, HQ/EMD, and the Center's environmental management office as applicable.

(c) NASA must comply with this subpart when considering issuance of a permit, lease, easement, or grant to a non-Federal party and may seek such non-Federal party's assistance in obtaining necessary information and completing the NEPA process.

■ 5. Revise § 1216.303 to read as follows:

§ 1216.303 NEPA process in NASA planning and decision making.

(a) NEPA is a procedural statute intended to ensure Federal agencies consider the environmental impacts of their proposed actions in the decision-making process. Full integration of the NEPA process with NASA project and program planning improves Agency decisions and ensures:

(1) Consideration of sustainability, environmental stewardship, and compliance with applicable environmental statutes, regulations, and policies.

(2) NASA's analyses and documentation are prepared using a process that is transparent to the public, including opportunities for receipt and consideration of public comment, when appropriate.

(3) Potential program and project risks and delays are minimized.

(b) In considering whether the effects of a proposed action are significant and determining the appropriate level of NEPA review and documentation (*i.e.,* EIS, environmental assessments (EA), categorical exclusions (CatEx)), NASA shall consider and analyze the potentially affected environment (*i.e.,* affected area [national, regional, or local] and resources located therein) and the degree of the effects of the proposed action (*e.g.,* short- and long-term effects, effects both beneficial and adverse, effects on public health and safety, effects that would violate Federal, state, Tribal, or local law protecting the environment).

(c) NASA shall consider the reasonably foreseeable environmental impacts of a proposed Agency action, along with technical, economic, public health and safety, security, and other factors that are reasonably foreseeable, beginning in the early planning stage of a proposed action. NASA will not take any action that would have an adverse environmental impact or limit the choice of reasonable alternatives prior to completing NEPA review except as provided in 40 CFR 1506.1.

(d) Records of Environmental Consideration (RECs) will be used to document:

(1) Application of specific categorical exclusions to proposed actions;

(2) Adoption of a Federal draft or final NEPA documents;

(3) Reevaluation of an existing NEPA document; and

(4) Determination of whether an action fits within an existing NEPA document, including a programmatic NEPA document.

■ 6. Amend § 1216.304 by:

■ a. Revising paragraphs (a), (b), (c) introductory text, (c)(1), and (c)(3) through (6);

■ b. Removing paragraph (c)(7);

■ c. Revising paragraphs (d) introductory text and (d)(1)(ii) and (iv) through (vi);

■ d. Adding paragraph (d)(1)(ix);

■ e. Revising paragraphs (d)(2)(i) through (iii) and (v);

■ f. Adding paragraphs (d)(2)(vi) through (ix);

■ g. Revising paragraphs (d)(3) and (d)(4)(ii) through (iv);

■ h. Adding paragraphs (d)(4)(vi) and (vii);

■ i. Revising paragraphs (d)(5)(i) and (ii) and (e); and

■ j. Removing paragraph (f).

The revisions and additions read as follows:

§ 1216.304 Categorical exclusions.

(a) Categorical exclusions (CatExs) are categories of Agency actions that normally do not have a significant effect on the human environment and therefore do not require preparation of an EA or EIS. CatExs reduce paperwork, improve Government efficiency, and eliminate delays in initiating and completing proposed actions having no significant environmental impact. For some CatExs, as indicated in paragraph (d) of this section, a REC is required.

(b) Application of CatExs and presence of extraordinary circumstances:

(1) A proposed action may be categorically excluded if the action fits

within the categories listed in paragraph (d) of this section and it does not involve any extraordinary circumstances in which a normally excluded action may have a significant effect.

(2) If an extraordinary circumstance as described in paragraph (c) of this section is present, NASA may nevertheless categorically exclude the proposed action if the action fits within the categories listed in paragraph (d) of this section and NASA determines that implementation of mitigation measures, such as relocation of the proposed action to an alternative site or limiting construction activities to certain seasonal periods of the year to avoid the extraordinary circumstance(s) in question, are sufficient to allow the proposed action to be categorically excluded.

(c) Extraordinary circumstances include situations where the proposed action:

(1) Has a reasonable likelihood of having a significant effect on public health and safety or the human environment.

* * * * *

(3) Is of significantly greater scope or size than is normal for the particular category of action.

(4) Has a reasonable likelihood of having effects that would violate Federal, state, Tribal, or local laws, or other enforceable requirements applicable to environmental protection.

(5) May adversely affect sensitive resources, such as, but not limited to, federally listed threatened or endangered species, their designated critical habitat, wilderness areas, floodplains, wetlands, aquifer recharge areas, coastal zones, wild and scenic rivers, and significant fish or wildlife habitat, unless the impact has been resolved through another environmental review process; *e.g.,* the Clean Water Act (CWA) or the Coastal Zone Management Act (CZMA).

(6) May adversely affect national natural landmarks or cultural or historic resources, including, but not limited to, property listed on or eligible for listing on the National Register of Historic Places, unless the impact has been resolved through another review process; *e.g.,* the National Historic Preservation Act (NHPA).

(d) The following actions normally do not have a significant effect on the human environment and are categorically excluded from the requirement to prepare an EA or EIS:

(1) * * *

(ii) Issuing procedural rules, manuals, directives, and requirements.

* * * * *

(iv) Preparing documents, including design and feasibility studies, analytical supply and demand studies, reports and recommendations, master and strategic plans, and other advisory documents.

(v) Information-gathering exercises, such as inventories, audits, and studies.

(vi) Preparing and disseminating information, including document mailings, publications, classroom materials, conferences, speaking engagements, websites, and other educational/informational activities.

* * * * *

(ix) Field studies, including water sampling, monitoring wells, cultural resources surveys, biological surveys, geologic surveys, modeling or simulations, routine data collection and analysis, and/or temporary equipment.

(2) * * *

(i) Routine maintenance, minor construction or rehabilitation, minor demolition, minor modification, minor repair, and continuing or altered operations at, or of, existing NASA or NASA-funded or -approved facilities and equipment, such as buildings, roads, grounds, utilities, communication systems, and ground support systems (*e.g.,* space tracking and data systems). This includes routine operations such as security, public health and safety, and environmental services.

(ii) Installing or removing equipment, including component parts, at existing Government or private facilities.

(iii) Contributing equipment, software, technical advice, exchanging data, and consulting with other agencies and public and private entities.

* * * * *

(v) Routine packaging, labeling, storage, transportation, and disposal of materials and wastes, in accordance with applicable Federal, state, Tribal, or local laws or requirements. Examples include but are not limited to hazardous, non-hazardous, and other regulated materials and wastes.

(vi) Habitat and species management activities conducted within the boundaries of NASA-controlled properties in accordance with applicable Federal, state, or local requirements. Examples include but are not limited to restoration of unique or critical habitat; thinning or brush control to improve growth of natural habitat, reduce invasive species, or reduce fire hazard; prescribed burning to reduce natural fuel build-up, reduce invasive species, or improve native plant vigor; planting appropriate vegetation that does not include noxious weeds or invasive plants; or wildlife management activities (REC required).

(vii) Small-scale, short-term cleanup actions under the Resource Conservation and Recovery Act or other authorities to reduce risk to human health or the environment from the release or imminent and substantial threat of release of a hazardous substance other than high-level radioactive waste and spent nuclear fuel, including treatment (such as incineration, encapsulation, physical or chemical separation, and compaction), recovery, storage, or disposal of wastes at existing facilities currently handling the type of waste involved in the action.

(viii) Replacement of existing energy sources with alternative or renewable energy sources that comply with existing permit conditions.

(ix) Routine maintenance, repair, and operation of vessels (including unmanned autonomous surface vessels), aircraft (including unmanned aircraft systems), overland/surface transportation vehicles, and other transportation systems as applicable. Examples include but are not limited to transportation or relocation of NASA equipment and hardware by barge, aircraft, or surface transportation system (*e.g.,* tractor trailer or railroad); retrieval of spent solid rocket boosters by vessel; repair or overhaul of vessel, aircraft, or surface transportation systems that do not result in a change in the environmental impacts of their normal operation.

(3) Research, Development, and Science Activities including:

(i) Research, development, testing, and evaluation in compliance with all applicable Federal, state, Tribal, or local laws or requirements and Executive orders. This includes the research, development, testing, and evaluation of scientific instruments proposed for use on spacecraft, aircraft (including unmanned aircraft systems), sounding rockets, balloons, laboratories, watercraft, or other outdoor activities.

(ii) Use of small quantities of radioactive materials used for instrument detectors, calibration, and other purposes. Materials may be associated with the proposed use on spacecraft, aircraft (including unmanned aircraft systems), sounding rockets, balloons, laboratories, watercraft, or other outdoor activities.

(iii) Use of lasers for research and development, scientific instruments and measurements, and distance and ranging, where such use meets all applicable Federal, state, Tribal, or local laws or requirements and Executive orders. This includes lasers associated with spacecraft, aircraft (including unmanned aircraft systems), sounding rockets, balloons, laboratories, watercraft, or other outdoor activities.

(iv) Use of non-space nuclear system payloads on various platforms (*e.g.,* launch vehicle, sounding rocket, scientific balloon, and aircraft) (REC required).

(v) Return of samples from solar system bodies (*e.g.,* asteroids, comets, planets, dwarf planets, and planetary moons) to Earth when categorized as an Unrestricted Earth Return. NASA defines this activity as collecting extraterrestrial materials from solar system bodies, deemed by scientific opinion to have no indigenous life forms, and returning those samples to Earth (REC required).

(4) * * *

(ii) Granting or accepting easements, leases, licenses, rights-of-entry, and permits to use NASA property, or any non-NASA property, for activities that would be categorically excluded in accordance with this section (REC required).

(iii) Transfer or disposal of real property, property rights, or interests if a resulting change in use is a use that would be categorically excluded under this section (REC required).

(iv) Transferring real property administrative control to another Federal agency, including the return of public domain lands to the Department of the Interior (DoI) or other Federal agencies, and reporting of property as excess and surplus to the General Services Administration (GSA) for disposal, when the agency receiving administrative control (or GSA, following receipt of a report of excess) shall complete any necessary NEPA review prior to any change in land use (REC required).

* * * * *

(vi) Change in the facility status of real property assets (*e.g.,* active or inactive).

(vii) Reductions, realignments, or relocation of personnel into existing federally owned or commercially leased space that does not involve a substantial change affecting the supporting infrastructure (*e.g.,* no increase in vehicular traffic beyond the capacity of the supporting road network to accommodate such an increase).

(5) * * *

(i) Periodic aircraft (including unmanned aircraft systems) flight activities, including training and research and development, which are routine and comply with applicable Federal, state, Tribal, or local laws or requirements, and Executive orders.

(ii) Relocation of similar aircraft (including unmanned aircraft systems) not resulting in a substantial increase in total flying hours, number of aircraft operations, operational parameters (*e.g.,* noise), or permanent personnel or logistics support requirements at the receiving installation (REC required).

(e) The Responsible Official shall review the proposed action in its early planning stage and consider the scope of the action, the potentially affected environment, and the degree of the reasonably foreseeable effects of the action to determine whether extraordinary circumstances exist that could result, either individually or cumulatively, in significant environmental impacts. If extraordinary circumstances exist, the Responsible Official must determine whether application of the categorical exclusion to the proposed action is appropriate or whether preparation of an EA or EIS is required.

■ 7. Revise § 1216.305 to read as follows:

§ 1216.305 Actions normally requiring an environmental assessment (EA).

(a) NASA shall prepare an EA, which complies with 40 CFR 1501.5, when a proposed action is not categorically excluded and is not likely to have significant effects or when the significance of the effects is unknown. NASA shall consider the potentially affected environment and degree of the effects of the action when determining whether to prepare an EA.

(b) NASA actions normally requiring an EA include:

(1) Altering the ongoing operations at a NASA Center where the significance of the environmental effect(s) is unknown.

(2) Construction or modifications of facilities that represent a major change to an existing master plan and could result in a change in the environmental effect(s).

(3) Actions that are expected to result in major changes to established land use.

(4) Launching a spacecraft containing a space nuclear system. Space nuclear systems include radioisotope power systems, such as radioisotope thermoelectric generators and radioisotope heater units, and fission systems used for surface power and spacecraft propulsion.

■ 8. Revise § 1216.306 to read as follows:

§ 1216.306 Actions normally requiring an environmental impact statement (EIS).

(a) NASA shall prepare an EIS for actions that are likely to significantly impact the quality of the human environment, including actions for which an EA demonstrates that significant environmental impacts will potentially occur which will not be reduced or eliminated by changes to the proposed action or mitigation of its potentially significant environmental impacts. An EIS shall be prepared and published in accordance with CEQ's implementing regulations (40 CFR part 1502).

(b) NASA actions normally requiring an EIS include:

(1) Development and operation of new NASA-developed launch vehicles or space transportation systems.

(2) Management, including recovery, transport, and curation, of sample returns to Earth from solar system bodies (such as asteroids, comets, planets, dwarf planets, and planetary moons) that would receive a Restricted Earth Return categorization. NASA requires such a mission to include additional measures to ensure any potential indigenous life form would be contained so it could not adversely impact humans or Earth's environment.

(3) Substantial construction projects expected to result in significant effect(s) on the quality of the human and natural environment, when such construction and its effects are not within the scope of an existing master plan.

■ 9. Revise § 1216.307 to read as follows:

§ 1216.307 Programmatic documents and tiering.

(a) For actions that require EAs or EISs, NASA encourages programmatic-level analysis for actions that are similar in nature, broad in scope, or likely to have similar environmental effects. Programmatic NEPA analyses may take place in the form of an EA or EIS.

(b) Tiering from previously prepared EISs or EAs is appropriate when it would eliminate repetitive discussions of the same issues and exclude from consideration issues already decided. Tiering from a programmatic-level NEPA document is appropriate for site- or project-specific actions that are included within the scope of the programmatic-level analysis.

■ 10. Revise § 1216.308 to read as follows:

§ 1216.308 Supplemental EAs and EISs.

(a) In cases where a major Federal action remains to occur, supplemental documentation may be required for previously prepared EAs or EISs under the following circumstances:

(1) If substantial changes are made to the proposed action that are relevant to environmental concerns; or

(2) There are significant new circumstances or information relevant to environmental concerns and bearing on the proposed action and its impacts; or

(3) NASA determines that the purposes of NEPA will be furthered by doing so.

(b) The preparation of a supplemental EA or EIS shall be undertaken using the same procedural requirements set forth in 40 CFR 1501.5 or 40 CFR part 1502, as applicable; however, in the event a supplement to an EIS is required, scoping shall not be required unless, at NASA's discretion and in consideration of the factors and requirements of 40 CFR 1501.9, it is determined to be necessary or would otherwise further the purposes of NEPA.

(c) When it is unclear if an EA or EIS supplement is required, NASA may prepare a Supplement Analysis.

(1) The Supplement Analysis will discuss the circumstances that are pertinent to deciding whether to prepare a supplemental EA or EIS.

(2) The Supplement Analysis will contain sufficient information for NASA to determine whether:

(i) An existing EA or EIS should be supplemented;

(ii) A new EA or EIS should be prepared; or

(iii) No further NEPA documentation is required.

(3) NASA shall make the determination and the related Supplement Analysis available to the public for information.

(d) When applicable, NASA shall incorporate the determination and supporting Supplement Analysis made under paragraph (b) of this section, into the administrative record related to the action that is the subject of the EA or EIS supplement or determination.

■ 11. Revise § 1216.309 to read as follows:

§ 1216.309 Mitigation and monitoring.

When the analysis proceeds to an EA or EIS and mitigation measures are adopted for the purpose of avoiding or reducing the significance of environmental impacts, such mitigation measures will be identified in the EA Finding of No Significant Impact (FONSI) or the EIS Record of Decision (ROD). NASA shall implement mitigation measures (including adaptive management strategies, where appropriate) consistent with applicable FONSIs and/or RODs and shall monitor their implementation and effectiveness. The Responsible Official shall ensure that funding for such mitigation measures is included in the program or project budget.

■ 12. Amend § 1216.310 by revising paragraph (a) to read as follows:

§ 1216.310 Classified actions.

(a) The classified status of a proposed action does not relieve NASA of the requirement to assess, document, and consider the environmental impacts of a proposed action.

* * * * *

■ 13. Revise § 1216.311 to read as follows:

§ 1216.311 Emergency responses.

(a) When the Responsible Official determines that emergency circumstances exist which make it necessary to take immediate response and/or recovery action(s) before preparing a NEPA analysis, then the following provisions apply:

(1) The Responsible Official may undertake immediate emergency response and/or recovery action(s) necessary to protect life, property, or valuable resources. When taking such action(s), the Responsible Official shall, to the extent practicable, mitigate foreseeable adverse environmental impacts.

(2) At the earliest practicable time, the Responsible Official shall notify the SAO of the emergency and any past, ongoing, or future NASA emergency response and/or recovery action(s). The SAO shall determine if NEPA applies and the appropriate level of NEPA analysis to document the emergency. If the emergency response and/or recovery action(s) will reasonably result in significant environmental impacts, the SAO shall consult with the CEQ about alternative arrangements for compliance with NEPA.

(b) If the Responsible Official proposes emergency response and/or recovery actions that will continue beyond those needed to immediately protect life, property, and valuable resources, the Responsible Official shall consult with the SAO to determine the appropriate level of NEPA compliance. If continuation of the emergency actions will reasonably result in significant environmental impacts, the SAO shall consult with the CEQ about alternative arrangements for compliance.

■ 14. Revise appendix A to subpart 1216.3 to read as follows:

Appendix A to Subpart 1216.3 of Part 1216—Acronyms

CatEx Categorical Exclusion
CEQ Council on Environmental Quality
CFR Code of Federal Regulations
CWA Clean Water Act
CZMA Coastal Zone Management Act
DoI (U.S.) Department of the Interior
EA Environmental Assessment
EMD Environmental Management Division
EIS Environmental Impact Statement
FONSI Finding of No Significant Impact
FR Federal Register
GSA General Services Administration
HQ Headquarters
NASA National Aeronautics and Space Administration
NEPA National Environmental Policy Act
NHPA National Historic Preservation Act
REC Record of Environmental Consideration
RHU Radioisotope Heater Unit
RPS Radioisotope Power Systems
SAO Senior Agency Official
SEO Senior Environmental Official
OGC Office of the General Counsel
ROD Record of Decision
U.S.C. United States Code

Nanette Smith,

Team Lead, NASA Directive and Regulations.

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BILLING CODE 7510–13–P

DEPARTMENT OF COMMERCE

Census Bureau

15 CFR Part 30

[DOCKET NO. 230421–0109]

RIN 0607–AA61

Foreign Trade Regulations (FTR): State Department Directorate of Defense Trade Controls Filing Requirement and Clarifications to Current Requirements

AGENCY: Census Bureau, Commerce Department.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Census Bureau is proposing to amend its regulations to reflect new export reporting requirements related to the State Department, Directorate of Defense Trade Controls (DDTC) Category XXI Determination Number. Specifically, the Census Bureau is proposing to add a conditional data element, DDTC Category XXI Determination Number, when ''21'' is selected in the DDTC USML Category Code field in the Automated Export System (AES) to represent United States Munitions List (USML) Category XXI. In addition to the new export reporting requirement, the proposed rule would make remedial changes to the Foreign Trade Regulations (FTR) to update International Traffic in Arms Regulations (ITAR) references in existing data elements: DDTC Significant Military Equipment Indicator and DDTC Eligible Party Certification Indicator. The proposed rule also makes remedial changes to the FTR that were proposed in the Notice of Proposed Rulemaking published December 15, 2021.

DATES: Written comments must be received on or before July 3, 2023.

ADDRESSES: You may submit comments by any of the following methods:

• *Federal eRulemaking Portal: https://www.regulations.gov.* The identification number for this rulemaking is identified by RIN 0607–AA61; or

• By email directly to *gtmd.ftrnotices@census.gov.* Include RIN 0607–AA61 in the subject line.

All comments received are part of the public record. No comments will be posted to *https://www.regulations.gov* for public viewing until after the comment period has closed. Comments will generally be posted without change. All Personally Identifiable Information (for example, name and address) voluntarily submitted by the commenter may be publicly accessible. Do not submit confidential business information or otherwise sensitive or protected information.

FOR FURTHER INFORMATION CONTACT: Lisa E. Donaldson, Chief, Economic Management Division, Census Bureau by phone (301) 763–7296 or by email *lisa.e.donaldson@census.gov.*

SUPPLEMENTARY INFORMATION:

Background

The Census Bureau is responsible for collecting, compiling, and publishing export trade statistics for the United States under the provisions of title 13, United States Code (U.S.C.), chapter 9, section 301. Additionally, the Census Bureau is responsible for publishing the Foreign Trade Regulations (FTR) that set the export reporting requirements for Electronic Export Information (EEI). The EEI is made up of mandatory, conditional, and optional data elements. The purpose of this rulemaking is to add a conditional data element, Directorate of Defense Trade Controls (DDTC) Category XXI Determination Number, when ''21'' (see Appendix L of the Automated Export System Trade Interface Requirements (AESTIR)) is selected in the DDTC United States Munitions List (USML) Category Code field in the EEI. The FTR defines the DDTC USML Category Code as the USML category of the article being exported (22 CFR part 121).

The Congressional mandate in Public Law 106–113 that amended section 301, of title 13 of the U.S. Code authorized the Secretary of Commerce to require the mandatory electronic filing of export information through the Automated Export System (AES) for items identified in the Commerce Control List (CCL) and the USML. Under the authorities in chapter 9 of title 13, the Secretary of Commerce proposes to collect additional data on the export of items under DDTC USML Category Code ''21'' to identify and validate which commodities DDTC USML Category Code ''21'' was cited for.

The DDTC Category XXI Determination Number is a unique number issued by DDTC in conjunction with a notification that a specific commodity is described in USML Category XXI. Information on valid USML Category XXI determinations and the prospective AES error code may be found in the Frequently Asked Questions section of DDTC's website (*www.pmddtc.state.gov*).

The Census Bureau is seeking public comments from data users, businesses and others to assess this proposed change. Below are considerations when providing feedback to this proposed rule; however, any pertinent feedback not captured by these considerations is welcome.

1. Describe the potential value of adding the DDTC Category XXI Determination Number to the EEI.

2. How long would a company that utilizes or manages proprietary software need to make programming changes to potentially add the DDTC Category XXI Determination Number field to its interface to the AES?

3. Are there business practices that a company would need to implement in order to come into compliance with the reporting of the DDTC Category XXI Determination Number field? If so, how long would a company need to implement new business practices?

The proposed rule also makes remedial changes to the FTR that were proposed in the Notice of Proposed Rulemaking published December 15, 2021 in the **Federal Register**, Volume 86, No. 238 (2021–26874.pdf (*census.gov*), and comments to these changes were favorable.

Finally, the U.S. Department of Homeland Security and the U.S. Department of State concur with the revisions to the FTR as required by 13 U.S.C. 302, and Public Law 107–228, division B, title XIV, section 1404.

Program Requirements

Pursuant to the Foreign Relations Act, Public Law 107–228 and 13 U.S.C. 301 302, the Census Bureau is amending relevant sections of the FTR to revise or clarify export reporting requirements. Therefore, the Census Bureau is proposing to amend 15 CFR part 30 by making the following amendments:

• Revise § 30.2(d)(3) to remove the language, ''(See subpart B of this part for export control requirements for these types of transactions.),'' as the exclusion overrides the export control requirements.

• Revise § 30.6(a)(1)(iii) to clarify that when the Dun and Bradstreet Number (DUNS) is reported as the U.S. Principal Party in Interest (USPPI) Identification Number, the Employer Identification Number (EIN) of the USPPI also is required to be reported in the Automated Export System.

• Revise § 30.6(b)(3) to amend the Foreign Trade Zone (FTZ) identifier to allow for 9-digits. The increased number of digits is required because of the increase in the number of subzones.

• Revise § 30.6(b)(16)(ii) to amend the DDTC Significant Military Equipment (SME) indicator by updating the ITAR references as a result of DDTC relocating certain ITAR provisions to improve the overall structure of the ITAR.

• Revise § 30.6(b)(16)(iii) to amend the DDTC eligible party certification indicator by updating the ITAR references as a result of DDTC relocating certain ITAR provisions to improve the overall structure of the ITAR.

• Revise § 30.6(b)(16)(ix) to add the conditional data element ''DDTC Category XXI Determination Number.'' The ''DDTC Category XXI Determination Number'' will be the unique number issued by DDTC to a member of the regulated community (usually the original equipment manufacturer) in conjunction with a notification that a specific commodity is described in USML Category XXI. This number is required only when citing Category XXI as an export classification and is used to confirm that an authoritative DDTC USML Category XXI determination is being referenced to do so.

• Revise § 30.37(u) to remove and reserve the exemption for technical data. This exemption is covered under § 30.2(d)(3), making the exemption redundant.

• Revise § 30.55 to remove the citation ''19 CFR 103.5'' and add in its place ''19 CFR part 103.''

• Revise § 30.71 to amend the Note to paragraph (b) to address the yearly adjustments for civil penalties as a result of inflation.

• Revise § 30.74 to amend paragraph (c)(5) to remove information that may become outdated and referencing the Census Bureau website to obtain the most current method for submitting a Voluntary Self-Disclosure.

Rulemaking Requirements

Regulatory Flexibility Act

The Chief Council for Regulation of the Department of Commerce has certified to the Chief Counsel for Advocacy, Small Business Administration that this proposed rule will not have a significant economic impact on a substantial number of small entities.

In the current Foreign Trade Regulations, the Electronic Export Information (EEI) shall be filed through the Automated Export System (AES) for all exports of physical goods. The AES is the electronic system for collecting Shipper's Export Declaration (SED) (or any successor document) information from persons exporting goods from the United States, Puerto Rico, Foreign Trade Zones located in the United States and Puerto Rico, the U.S. Virgin Islands, between the U.S. and Puerto Rico, and to the U.S. Virgin Islands from the United States or Puerto Rico. In the proposed revisions, export shipments with ''21'' in the DDTC USML Category Code field will be required to report the DDTC Category XXI Determination Number.

In calendar year 2022, authorized agents and U.S. Principal Parties in Interest reported the DDTC USML Category Code of ''21'' on 0.6% of EEI records. A large majority of the EEI records involved export shipments of defense articles from branches of the Department of Defense. Based on these statistics, the Census Bureau believes this proposed rule will not create any economic impact on all companies including a substantial number of small entities.

Executive Orders

This proposed rule has been determined to not be significant for purposes of Executive Order 12866. This proposed rule does not contain policies with federalism implications sufficient to warrant preparation of a federalism assessment under Executive Order 13132.

Paperwork Reduction Act

Notwithstanding any other provisions of law, no person is required to respond to, nor shall a person be subject to, a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act (PRA) unless that collection of information displays a valid Office of Management and Budget (OMB) control number.

This proposed rule covers collections of information subject to the provisions of the PRA, which are cleared by OMB under OMB Control Number 0607–0152—AES Program.

This proposed rule will not impact the current reporting-hour burden requirements as approved under OMB Control Number 0607–0152 under provisions of the PRA. The proposed rule will not require any revisions to the information sought under OMB Control Number 0607–0152. Robert L. Santos, Director, Census Bureau, approved the publication of this notification in the **Federal Register**.

List of Subjects in 15 CFR Part 30

Economic statistics, Exports, Foreign trade, Reporting and recordkeeping requirements.

For the reasons set out in the preamble, the Census Bureau is proposing to amend 15 CFR part 30 as follows:

PART 30—FOREIGN TRADE REGULATIONS

■ 1. The authority citation for 15 CFR part 30 continues to read as follows:

Authority: 5 U.S.C. 301; 13 U.S.C. 301–307; Reorganization plan No. 5 of 1990 (3 CFR 1949–1953 Comp., p.1004); Department of Commerce Organization Order No. 35–2A, July 22, 1987, as amended, and No. 35–2B, December 20, 1996, as amended; Public Law 107–228, 116 Stat. 1350.

■ 2. Amend § 30.2 by revising paragraph (d)(3) to read as follows:

§ 30.2 General requirements for filing Electronic Export Information (EEI).

* * * * *

(d) * * *

(3) Electronic transmissions and intangible transfers.

* * * * *

■ 3. Amend § 30.3 by revising paragraphs (e)(1)(ii) to read as follows:

§ 30.3 Electronic Export Information filer requirements, parties to export transactions, and responsibilities of parties to export transactions.

* * * * *

(e) * * *

(1) * * *

(ii) USPPI's EIN or DUNS.

* * * * *

■ 4. Amend § 30.6 by revising paragraphs (a)(1)(iii), (b)(3), (b)(16)(ii) and (iii), and adding paragraph (b)(16)(ix) to read as follows:

§ 30.6 Electronic Export Information data elements.

* * * * *

(a) * * *

(1) * * *

(iii) *USPPI identification number.* Report the Employer Identification Number (EIN) of the USPPI. If the USPPI has only one EIN, report that EIN. If the USPPI has more than one EIN, report the EIN that the USPPI uses to report employee wages and withholdings, and not the EIN used to report only company earnings or receipts. Use of another company's EIN is prohibited. If a USPPI reports a DUNS, the EIN is also required to be reported. If a foreign entity is in the United States at the time goods are purchased or obtained for export, the foreign entity is the USPPI. In such situations, when the foreign entity does not have an EIN, the authorized agent shall report a border crossing number, passport number, or any number assigned by CBP on behalf of the foreign entity.

* * * * *

(b) * * *

(3) *FTZ identifier.* If goods are removed from a FTZ and not entered for consumption, report the FTZ identifier. This is the unique 9-digit alphanumeric identifier assigned by the Foreign Trade Zone Board that identifies the FTZ, subzone or site from which goods are withdrawn for export.

* * * * *

(16) * * *

(ii) *DDTC Significant Military Equipment (SME) indicator.* A term used to designate articles on the USML (22 CFR part 121) for which special export controls are warranted because of their capacity for substantial military utility or capability. See sections 120.36 and 120.10(c) of the ITAR (22 CFR parts 120 through 130) for a definition of SME and for items designated as SME articles, respectively.

(iii) *DDTC eligible party certification indicator.* Certification by the U.S. exporter that the exporter is an eligible party to participate in defense trade. See 22 CFR 120.16(c). This certification is required only when an exemption is claimed.

* * * * *

(ix) *DDTC Category XXI Determination Number.* The unique number issued by DDTC to a member of the regulated community (usually the original equipment manufacturer) in conjunction with a notification that a specific commodity is described in USML Category XXI. This number is required only when citing USML Category XXI as an export classification and is used to confirm that an authoritative USML Category XXI determination is being referenced to do so.

* * * * *

§ 30.37 [Amended]

■ 5. Amend § 30.37 by removing and reserving paragraph (u).

■ 6. Amend § 30.55 by revising the introductory text to read as follows:

§ 30.55 Confidential information, import entries, and withdrawals.

The contents of the statistical copies of import entries and withdrawals on file with the Census Bureau are treated as confidential and will not be released without authorization by CBP, in accordance with 19 CFR part 103

relating to the copies on file in CBP offices. The importer or import broker must provide the Census Bureau with information or documentation necessary to verify the accuracy or resolve problems regarding the reported import transaction.

* * * * *

■ 7. Amend § 30.71 by revising the note to paragraph (b) to read as follows:

§ 30.71 False or fraudulent reporting on or misuse of the Automated Export System.

* * * * *

Note 1 to paragraph (b): The civil monetary penalties are adjusted for inflation annually based on The Federal Civil Penalties Inflation Adjustment Act of 1990 (Pub. L. 101–410; 28 U.S.C. 2461), as amended by the Debt Collection Improvement Act of 1996 (Pub. L. 104–134) and the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (Section 701 of Pub. L. 114–74). In accordance with this Act, as amended, the penalties in title 13, chapter 9, sections 304 and 305(b), United States Code are adjusted and published each year in the **Federal Register** no later than January 15th.

■ 8. Amend § 30.74 by revising paragraph (c)(5) to read as follows:

§ 30.74 Voluntary self-disclosure.

* * * * *

(c) * * *

(5) *Where to make voluntary self-disclosures.* The information constituting a Voluntary Self-Disclosure or any other correspondence pertaining to a Voluntary Self-Disclosure may be submitted to the U.S. Census Bureau, Branch Chief, Trade Regulations Branch by methods permitted by the Census Bureau. See *www.census.gov/trade* for more details.

* * * * *

Dated: April 25, 2023.

Shannon Wink,

Program Analyst, Policy Coordination Office, U.S. Census Bureau.

[FR Doc. 2023–09322 Filed 5–2–23; 8:45 am]

BILLING CODE 3510–07–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 73

[Docket No. FDA–2023–C–1487]

Filing of Color Additive Petition From Environmental Defense Fund, et al.; Request To Revoke Color Additive Listing for Use of Titanium Dioxide in Food

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of petition.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing that we have filed a color additive petition, submitted by Environmental Defense Fund, et al., proposing that FDA repeal the color additive regulation providing for the use of titanium dioxide in foods.

DATES: The color additive petition was filed on April 14, 2023. Either electronic or written comments must be submitted by July 3, 2023.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of July 3, 2023. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comment, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper instructions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions)*: Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your objection, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2023–C–1487 for ''Filing of Color Additive Petition from Environmental Defense Fund, et al.; Request To Revoke Color Additive Listing for Use of Titanium Dioxide in Food.'' Received comments, those filed in a timely manner (see **DATES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comment only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' We will review this copy, including the claimed confidential information, in our consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80

FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts, and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Paulette M. Gaynor, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–1192.

SUPPLEMENTARY INFORMATION:

I. Background

Under section 721(d)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 379e(d)(1)), we are giving notice that we have filed a color additive petition (CAP 3C0325), submitted by Environmental Defense Fund, Center for Environmental Health, Center for Food Safety, Center for Science in the Public Interest, and Environmental Working Group, c/o Tom Neltner, 1875 Connecticut Ave. NW, Washington, DC 20009. The petition proposes that we repeal the color additive regulation for titanium dioxide in § 73.575 (21 CFR 73.575), which permits the use of titanium dioxide in foods.

II. Request To Repeal Section 73.575

In accordance with the procedure in section 721(d) of the FD&C Act for issuance, amendment, or repeal of regulations, the petition asks us to repeal section 73.575 to no longer provide for the use of titanium dioxide in foods. The petitioners assert that the intended use of this color additive no longer meets the safety standard under 21 CFR 70.3(i), and cite, as evidence, an opinion by the European Food Safety Authority (EFSA) entitled ''Safety assessment of titanium dioxide (E171) as a food additive'' that was published in May 2021 (we are using EFSA's title for this document, rather than the one cited by the petitioners), and other publications.

We invite comments, additional scientific data, and other information related to the issues raised by this petition. If we determine that the available data justify repealing section 73.575 to no longer provide for the safe use of titanium dioxide in foods, we will publish our decision in the **Federal Register** in accordance with 21 CFR 71.20.

The petitioners have claimed that this action is categorically excluded under 21 CFR 25.32(m), which applies to an action to prohibit or otherwise restrict or reduce the use of a substance in food, food packaging, or cosmetics. In addition, the petitioners have stated that, to their knowledge, no extraordinary circumstances exist (see 21 CFR 25.21). If FDA determines a categorical exclusion applies, neither an environmental assessment nor an environmental impact statement is required. If FDA determines a categorical exclusion does not apply, we will request an environmental assessment and make it available for public inspection.

Dated: April 28, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–09366 Filed 5–2–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[REG–124064–19]

RIN 1545–BP55

Section 367(d) Rules for Certain Repatriations of Intangible Property

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking.

SUMMARY: This document contains proposed regulations that, in certain cases, would terminate the continued application of certain tax provisions arising from a previous transfer of intangible property to a foreign corporation when the intangible property is repatriated to certain United States persons. The proposed regulations would affect certain United States persons that previously transferred intangible property to a foreign corporation.

DATES: Written or electronic comments and requests for a public hearing must be received by July 3, 2023. Requests for a public hearing must be submitted as prescribed in the ''Comments and Requests for a Public Hearing'' section.

ADDRESSES: Commenters are strongly encouraged to submit public comments electronically. Submit electronic submissions via the Federal eRulemaking Portal at *https://www.regulations.gov* (indicate IRS and REG–124064–19) by following the online instructions for submitting comments. Once submitted to the Federal eRulemaking Portal, comments cannot be edited or withdrawn. The Department of the Treasury (the ''Treasury Department'') and the IRS will publish for public availability any comments submitted electronically or on paper to its public docket.

Send paper submissions to: CC:PA:LPD:PR (REG–124064–19), Room 5203, Internal Revenue Service, P.O. Box 7604, Ben Franklin Station, Washington, DC 20044.

FOR FURTHER INFORMATION CONTACT: Concerning the proposed regulations other than § 1.904–4, Chadwick Rowland and L. Ulysses Chatman, (202) 317–6937; concerning § 1.904–4, Jeffrey L. Parry, (202) 317–6936; concerning submissions of comments and requests for a public hearing, Vivian Hayes at (202) 317–6901 (not toll-free numbers) or by sending an email to *publichearings@irs.gov* (preferred).

SUPPLEMENTARY INFORMATION:

Background

I. Sections 367(d) and 6038B

A. Statute

Section 367(d) of the Internal Revenue Code (the ''Code'') provides rules for outbound transfers of intangible property (as defined in section 367(d)(4)) by a United States person (a ''U.S. person'') to a foreign corporation.[1] Section 367(d)(1) provides that, except as provided in regulations, if a U.S. person (a ''U.S. transferor'') transfers any intangible property to a foreign corporation (the ''transferee foreign corporation'') in an exchange described in section 351 or 361, section 367(d) (and not section 367(a)) applies to the transfer. Section 367(d)(2)(A) provides that a U.S. transferor that transfers intangible property subject to section 367(d) is treated as having sold the intangible property in exchange for payments that are contingent upon the productivity, use, or disposition of the intangible property.

Specifically, the U.S. transferor is treated as receiving amounts that reasonably reflect the amounts that would have been received annually in the form of such payments over the useful life of the intangible property (an ''annual inclusion''), or, in the case of a

[1] For purposes of these regulations, a U.S. person is defined in § 1.367(a)–1(d)(1), which defines a U.S. person, in part, by reference to persons described in section 7701(a)(30). Section 7701(a)(30) defines a U.S. person as a citizen or resident of the United States, a domestic partnership, a domestic corporation, and certain estates and trusts.

direct or indirect disposition of the intangible property following the transfer, at the time of the disposition (a ''lump-sum inclusion,'' and each inclusion, a ''section 367(d) inclusion''). *See* section 367(d)(2)(A)(ii)(I) and (II). The amounts taken into account by the U.S. transferor must be commensurate with the income attributable to the transferred intangible property. *See* section 367(d)(2)(A) (flush language). Section 367(d)(2)(B) provides that, for purposes of chapter 1 of subtitle A of the Code, the earnings and profits (''E&P'') of the transferee foreign corporation are reduced by the amount required to be included in the income of the U.S. transferor as a section 367(d) inclusion.

Section 6038B(a)(1)(A) grants the Secretary regulatory authority to require information reporting related to certain outbound transfers of property by a U.S. person to a foreign corporation, including rules related to outbound transfers of intangible property. Section 6038B(c) generally provides rules for failures to furnish the required information.

B. Legislative History

Congress enacted section 367(d) in substantially its present form to address ''specific and unique problems'' that exist with respect to outbound transfers of intangible property. *See* S. Rep. No 169, 98th Cong., 2d Sess., at 360 (1984); H.R. Rept. No. 432, 98th Cong., 2d Sess., at 1315 (1984). Congress generally identified the cause of such problems as follows:

> [T]ransferor U.S. companies hope to reduce their U.S. taxable income by deducting substantial research and experimentation expenses associated with the development of the transferred intangible and, by transferring the intangible to a foreign corporation at the point of profitability, to ensure deferral of U.S. tax on the profits generated by the intangible.

Id.

Congress also explained that, after the initial outbound transfer of intangible property, these problems could arise by reason of certain subsequent direct or indirect dispositions of the intangible property. *See* S. Rept. No 169, 98th Cong., 2d Sess., at 368 (1984) (''[G]ain on a disposition of stock in a [transferee foreign corporation] will be treated as being attributable, in part, to the transferred intangible . . . ; similarly, upon a disposition of the intangible by the [transferee foreign corporation], the U.S. transferor will be treated as receiving a payment [with respect to that intangible]'').

C. Regulations

1. In General

Temporary regulations were published under sections 367(d) and 6038B(a)(1)(A) on May 16, 1986 (51 FR 17936). Proposed regulations were also published under these sections on September 16, 2015 (80 FR 55568), and the related final regulations were published on December 16, 2016 (81 FR 91012) (these final regulations and the temporary regulations, together, the ''section 367(d) regulations'').

Consistent with section 367(d) and its legislative history, the section 367(d) regulations provide rules for determining a U.S. transferor's section 367(d) inclusion and a transferee foreign corporation's required adjustments for its deemed payment to the U.S. transferor. In general, the U.S. transferor takes into account an annual inclusion over the useful life of the intangible property, as determined in accordance with the provisions of section 482 and regulations thereunder. *See* § 1.367(d)–1T(c)(1). For this purpose, the useful life is the entire period during which exploitation of the intangible property is reasonably anticipated to affect the determination of taxable income, as of the time of transfer. *See* § 1.367(d)–1(c)(3)(i).

Additionally, for purposes of chapter 1 of subtitle A of the Code, the transferee foreign corporation reduces its E&P by the amount of the deemed payment to the U.S. transferor, and, for purposes of subpart F of part III of subchapter N of chapter 1 (''subpart F''), the transferee foreign corporation may treat the deemed payment as, in relevant part, an expense properly allocated and apportioned to gross income subject to subpart F in accordance with the provisions of §§ 1.954–1(c) and 1.861–8. *See* § 1.367(d)–1T(c)(2); *see also* § 1.951A–2(c)(2)(ii) (providing similar treatment for purposes of determining tested income or tested loss of a controlled foreign corporation (as defined in section 957, a ''CFC'')).

2. Subsequent Transfer Rules

If the U.S. transferor subsequently transfers the stock of the transferee foreign corporation it received in exchange for the intangible property, or if the transferee foreign corporation subsequently transfers the intangible property it received in exchange for its stock, the section 367(d) regulations provide different rules based on whether the transferee in the subsequent transfer is a U.S. person or a foreign person and whether the transferee is a related person or an unrelated person as to the U.S. transferor. *See* § 1.367(d)–1T(d), (e), and (f); *see also* Notice 2012–39, 2012–31 I.R.B. 95 (describing regulations that would apply in lieu of § 1.367(d)–1T(c), (d), (e), and (g) with respect to certain outbound transfers of intangible property by a domestic corporation to a foreign corporation in an exchange described in section 361(a) or (b)). These subsequent transfer rules treat certain subsequent transfers of the stock of the transferee foreign corporation or the intangible property as a disposition of the intangible property (within the meaning of section 367(d)(2)(A)(ii)(II)) that can accelerate a section 367(d) inclusion, and corresponding adjustments, by reason of the deemed payment. *See,* for example, § 1.367(d)–1T(d).

If the U.S. transferor subsequently transfers stock of the transferee foreign corporation to a related U.S. person (a ''successor U.S. transferor''), the transfer is not treated as a disposition of the intangible property, and the successor U.S. transferor is treated as receiving a right to receive a proportionate share (determined under § 1.367(d)–1T(e)(4)) of the annual inclusion that would otherwise be taken into account by the U.S. transferor under § 1.367(d)–1T(c). Therefore, the successor U.S. transferor is required to take into account that proportionate share of the annual section 367(d) inclusion over the remaining useful life of the intangible property, and the transferee foreign corporation takes into account any adjustments from the successor U.S. transferor's annual section 367(d) inclusion. *See* § 1.367(d)–1T(e)(1) and (2). If the U.S. transferor transfers a portion of the stock of the transferee foreign corporation to one or more successor U.S. transferors and retains a portion of the stock of the transferee foreign corporation, the U.S. transferor continues to take into account the portion of the annual section 367(d) inclusion that is not taken into account by a successor U.S. transferor.[2] *See* § 1.367(d)–1T(c)(1).

Alternatively, if a U.S. transferor subsequently transfers stock of the transferee foreign corporation to an unrelated person (U.S. or foreign), the transfer is treated as an indirect disposition of the transferred intangible property that triggers a lump-sum section 367(d) inclusion. As a result, the U.S. transferor recognizes gain immediately (determined based on the fair market value of the intangible

[2] The section 367(d) regulations apply separately as to each U.S. person treated as a U.S. transferor. Any reference to a ''U.S. transferor'' in the remainder of this Preamble includes a reference to a ''successor U.S. transferor'' unless otherwise noted.

property at the time of the indirect disposition and the U.S. transferor's adjusted basis in the intangible property at the time of the initial section 367(d) transfer), as if the U.S. transferor had sold the intangible property to the unrelated person, and the transferee foreign corporation makes corresponding adjustments. *See* § 1.367(d)–1T(d); *see also* § 1.367(d)–1T(e)(1)(iii) and (e)(2) (providing pro rata rules for cases in which there is a subsequent transfer of stock of the transferee foreign corporation to both an unrelated person(s) and a successor U.S. transferor(s)).

If the transferee foreign corporation subsequently transfers the intangible property to a related person, notwithstanding that such subsequent transfer is a direct disposition of the intangible property, the section 367(d) regulations do not trigger a lump-sum inclusion but rather provide that ''the requirement that the U.S. transferor recognize gain under [§ 1.367(d)–1T(c)(1) or (e)(1)] shall not be affected'' by such transfer. *See* § 1.367(d)–1T(f)(3). The regulation does not distinguish between a related U.S. or foreign person and provides further that ''for purposes of any required adjustments, and of any accounts receivable created under [§ 1.367(d)–1T(g)] the related person that receives the intangible property shall be treated as the transferee foreign corporation.'' *See* § 1.367(d)–1T(f)(3).

Conversely, if the transferee foreign corporation subsequently transfers the intangible property to an unrelated person (U.S. or foreign), the U.S. transferor recognizes gain immediately (in the form of a lump-sum inclusion determined using the U.S. transferor's former adjusted basis in the intangible property immediately before the transfer to the transferee foreign corporation and a partial annual inclusion), and the transferee foreign corporation makes corresponding adjustments. *See* § 1.367(d)–1T(f)(1) and (2).

As described in the preceding paragraphs of this part I.C.2 of the Background, the consequences of a direct or indirect transfer of the intangible property following an initial outbound transfer of that property depend, in relevant part, on whether the transferee in the subsequent transfer is a related or unrelated person. In determining relatedness, the section 367(d) regulations lower certain thresholds that normally apply in determining whether persons are related, to preserve the application of section 367(d) for cases in which a U.S. transferor retains a sufficient nexus to the intangible property after the subsequent transfer. *See* § 1.367(d)–1T(h)(2). Thus, the section 367(d) regulations generally preserve the application of the annual inclusion stream upon a subsequent transfer, but if the transfer sufficiently severs the U.S. transferor's nexus to the intangible property, the transfer is treated as a direct or indirect disposition of the intangible property, as applicable, and the section 367(d) regulations provide that the U.S. transferor has a lump-sum inclusion and a partial annual inclusion.

II. Application of Section 367(d) to Repatriations of Intangible Property

The Treasury Department and the IRS are aware that some taxpayers are evaluating whether to repatriate to the United States intangible property that was previously transferred to a foreign corporation in a transaction subject to section 367(d).

Because, in relevant part, the section 367(d) regulations do not distinguish between subsequent transfers of intangible property made to a related U.S. or foreign person, as described in part I.C.2 of this Background, there is a concern that, in certain cases, the section 367(d) regulations can inappropriately require the U.S. transferor to continue recognizing an annual section 367(d) inclusion even if the subsequent transfer is to a related U.S. person that will recognize the income derived from the intangible property. Specifically, the section 367(d) regulations do not terminate the required annual section 367(d) inclusion even if the intangible property is transferred to a related U.S. person that is subject to U.S. taxation on income earned from the intangible property. As a result, if the section 367(d) inclusion stream continues, the income earned from the intangible property would be subject to excessive U.S. taxation. Because the continued application of section 367(d) in these situations could result in excessive U.S. taxation and may disincentivize certain repatriations of intangible property, the Treasury Department and the IRS are proposing, in certain cases, to terminate the application of section 367(d) if the intangible property is repatriated to certain U.S. persons that are subject to U.S. taxation with respect to the income derived from the intangible property. The term ''repatriation'' is, unless otherwise noted, used in this Preamble to generally denote a subsequent transfer of the intangible property to the U.S. transferor or a U.S. person related to the U.S. transferor.

Where the U.S. transferor is a member of a consolidated group, and the intangible property is repatriated to another member of the same consolidated group (''transferee member''), some taxpayers have asked whether the U.S. transferor's annual inclusions could be redetermined to be excluded from gross income under § 1.1502–13(c)(6)(ii)(A) (the ''Automatic Relief Rule''). For that to occur, the transferee member's corresponding item must be a deduction or loss that is ''permanently and explicitly disallowed'' under another provision of the Code or regulations. *See* § 1.1502–13(c)(6)(ii)(A). However, the U.S. transferor's annual inclusions may not be excluded under the Automatic Relief Rule, because § 1.367(d)–1T(c)(2) does not explicitly disallow the transferee member's deduction for its expense tied to its deemed payment. Rather, in appropriate factual situations, the IRS has ruled that the U.S. transferor's annual inclusions may be excluded from income under the Commissioner's discretionary rule of § 1.1502–13(c)(6)(ii)(D).

To address repatriations of intangible property more generally, and not just those where the related U.S. person is a member of the same consolidated group as the U.S. transferor (and to avoid the need to obtain a ruling in such a case), these proposed regulations provide rules that more broadly apply section 367(d) to the repatriation of intangible property, including the circumstances in which the application of section 367(d) is terminated (these rules, collectively, the ''section 367(d) repatriation rules'').

III. Section 904(d) Foreign Branch Income

Section 904 provides for the application of separate foreign tax credit limitations to certain categories of income under section 904(d). One of those categories is the separate category for foreign branch income under section 904(d)(1)(B). Section 1.904–4(f)(1)(i) provides that foreign branch category income means the gross income of a United States person (as defined in section 7701(a)(30), other than a pass-through entity) that is attributable to foreign branches (as defined in § 1.904–4(f)(3)(vii)) held directly or indirectly through disregarded entities by the United States person.

In general, § 1.904–4(f)(2)(vi)(A) adjusts the attribution of gross income when disregarded payments are made between a foreign branch and a foreign branch owner, or between foreign branches. Disregarded remittances or contributions, however, do not result in the reattribution of gross income. Accordingly, when a disregarded transaction with a foreign branch may

be structured as either a remittance or contribution, on the one hand, or as a sale, exchange, or license, on the other hand, the amount of gross income attributed to a foreign branch could be manipulated. This concern is heightened when the property in question is highly mobile and highly valuable, as is generally true of intangible property (and less frequently true of tangible property).

To address these concerns § 1.904–4(f)(2)(vi)(D) provides that the amount of gross income attributable to a foreign branch (and the amount of gross income attributable to its foreign branch owner) that is not passive category income must be adjusted to reflect all transactions that are disregarded for U.S. tax purposes in which property described in section 367(d)(4) is transferred to or from a foreign branch or between foreign branches, whether or not a disregarded payment is made in connection with the transfer. In determining the amount of gross income that is attributable to a foreign branch that must be adjusted, the principles of sections 367(d) and 482 apply. For example, if a foreign branch owner transfers property described in section 367(d)(4) to a foreign branch, the principles of section 367(d) are applied by treating the foreign branch as a separate foreign corporation to which the property is transferred in exchange for stock of the corporation in a transaction described in section 351. Similarly, if a foreign branch remits property described in section 367(d)(4) to its foreign branch owner, the foreign branch is treated as having sold the transferred property to the foreign branch owner in exchange for annual payments contingent on the productivity or use of the property, the amounts of which are determined under the principles of sections 367(d) and 482.

Explanation of Provisions

I. Section 367(d) Repatriation Rules

A. In General

As described in part II of the Background of this Preamble, § 1.367(d)–1T(f)(3) provides that a subsequent disposition of intangible property by the transferee foreign corporation to a related person does not affect a U.S. transferor's annual inclusion under § 1.367(d)–1T(c) or (e). This provision further provides that the related person that receives the intangible property is treated as the new transferee foreign corporation for purposes of any required adjustments and any accounts receivable created under § 1.367(d)–1T(g). Accordingly, the section 367(d) regulations require the U.S. transferor to recognize annual inclusions even if the income earned from the intangible property is subject to current U.S. taxation in the hands of the U.S. person holding the intangible property. In addition, the deemed (substituted) transferee foreign corporation is not allowed a deduction that could reduce taxable income, even though that deemed transferee foreign corporation is the U.S. transferor or a related U.S. person.

Continuing to apply section 367(d) in such cases could give rise to excessive U.S. taxation and disincentivize taxpayers from repatriating that property. To address these concerns, proposed § 1.367(d)–1(f)(4) generally terminates the application of section 367(d) if the transferee foreign corporation repatriates the intangible property to a ''qualified domestic person'' and certain reporting requirements are satisfied. *See* proposed § 1.367(d)–1(f)(4)(i). *See* part I.C of this Explanation of Provisions for a discussion of the definition of a qualified domestic person and part III of this Explanation of Provisions for a discussion of the reporting requirements.

B. Consequences of Repatriating Intangible Property

1. In General

As noted in part I.A of this Explanation of Provisions, the proposed regulations terminate the continued application of section 367(d) when a transferee foreign corporation repatriates intangible property to a qualified domestic person and the U.S. transferor provides the relevant information described in proposed § 1.6038B–1(d)(2) and, when those requirements are met, the proposed regulations require the U.S. transferor to include in gross income a partial annual inclusion attributable to the part of its taxable year that the transferee foreign corporation held the intangible property, after which the intangible property is no longer subject to section 367(d) (thus, for example, the annual inclusion stream terminates). *See* proposed § 1.367(d)–1(f)(4)(i). The proposed regulations also require the U.S. transferor to recognize gain (which amount may be zero in certain cases) as a result of the repatriation. *See Id.* Additionally, the proposed regulations provide a special rule (discussed in part I.D of this Explanation of Provisions) to determine the qualified domestic person's basis in the repatriated intangible property. The transferee foreign corporation, on the other hand, makes the required adjustments currently described in § 1.367(d)–1T(c)(2), with minor clarifications, for cases in which the section 367(d) repatriation rules apply (that is, the adjustments with respect to the U.S. transferor's partial annual inclusion for the year of the repatriation). *See* part I.E of this Explanation of Provisions for a discussion of the modifications made with respect to the required adjustments described in current § 1.367(d)–1T(c)(2)(ii) and (e)(2)(ii).

The manner in which the repatriation occurs will determine whether the U.S. transferor must recognize gain in connection with the repatriation transaction, with corresponding adjustments being made as to the transferee foreign corporation. For example, the U.S. transferor would not recognize gain in the case of a repatriation occurring by reason of a nonrecognition transaction pursuant to which no gain or loss is recognized as to the transferee foreign corporation. *See* part I.B.2 of this Explanation of Provisions for a discussion of the rules that apply based on the form of the transaction by which the intangible property is repatriated. The proposed regulations, therefore, address the tax consequences under section 367(d) as to the intangible property, but do not otherwise alter the tax treatment of the transaction by which the intangible property is repatriated.

2. Gain Recognition as to the U.S. Transferor

Consistent with section 367(d)(2)(A)(ii)(II), proposed § 1.367(d)–1(f)(4)(i)(A) (the ''gain recognition rule'') requires the U.S. transferor to recognize gain equal to the amount described in proposed § 1.367(d)–1(f)(4)(ii). The gain recognition rule, in conjunction with the rules described in parts I.B.3 (Required adjustments for certain gain recognized) and I.D (Qualified domestic person's adjusted basis in repatriated intangible property) of this Explanation of Provisions, generally ensures that a qualified domestic person does not receive a tax-free increase to the adjusted basis in the repatriated intangible property.

Thus, as noted in part I.B.1 of this Explanation of Provisions, whether the U.S. transferor recognizes gain under the gain recognition rule depends on the form of the repatriation transaction. Specifically, the gain recognition rule focuses on whether the intangible property is transferred basis property (as defined in section 7701(a)(43)) by reason of the repatriation, without regard to the application of section 367(d) and the section 367(d)

regulations. *See* proposed § 1.367(d)–1(f)(4)(ii). The proposed regulations incorporate the definition of transferred basis property for this purpose, as opposed to other approaches for distinguishing the form of the repatriation transaction, to ensure the appropriate application of these proposed rules in all circumstances.[3]

If the intangible property is transferred basis property as described in the preceding paragraph, the amount of gain the U.S. transferor will recognize pursuant to the gain recognition rule is the amount of gain the transferee foreign corporation would recognize, if any, upon the repatriation under general subchapter C rules if its adjusted basis in the intangible property were equal to the U.S. transferor's former adjusted basis in the property. *See* proposed § 1.367(d)–1(f)(4)(ii)(A). This amount may be zero in the case of certain repatriations, for example, a repatriation by a transferee foreign corporation of intangible property to the U.S. transferor in a complete liquidation described in sections 332 and 337, in which case the U.S. transferor will not recognize any gain under the gain recognition rule. Alternatively, if, for example, the repatriation occurs in an exchange described in section 351(b) in which the transferee in the exchange is a qualified domestic person (as defined in proposed § 1.367(d)–1(f)(4)(iii)), the amount of gain determined under this rule may be greater than zero, even though the intangible property is transferred basis property, because the amount of gain is determined by reference to the gain the transferee foreign corporation would recognize upon the transaction if the adjusted basis in the intangible property were equal to the U.S. transferor's former adjusted basis in the intangible property.

If the intangible property is not transferred basis property by reason of the repatriation, the amount of gain a U.S. transferor will recognize pursuant to the gain recognition rule is the excess, if any, of the fair market value of the intangible property on the date of the repatriation over the U.S. transferor's former adjusted basis in the property. *See* proposed § 1.367(d)–1(f)(2)(ii)(B). For example, if the transferee foreign corporation repatriates the intangible property to the U.S. transferor in a distribution described in section 311, the intangible property is not transferred basis property, and therefore the rule described in this paragraph applies to determine the amount of gain recognized by the U.S. transferor under the gain recognition rule.

3. Required Adjustments Related to Certain Gain Recognized

Current § 1.367(d)–1T(f)(2)(i) provides that a transferee foreign corporation's E&P are reduced, in relevant part, by the amount of gain recognized by a U.S. transferor under § 1.367(d)–1T(f)(1). Because a U.S. transferor recognizes gain in these cases in the form of a lump-sum inclusion, the corresponding adjustment to the transferee foreign corporation's E&P is generally intended to reduce the E&P that arises for the transferee foreign corporation by reason of the disposition (and, in so doing, the adjustment prevents potential excessive E&P arising from that disposition). To achieve this goal, § 1.367(d)–1T(f)(2) necessarily implies a preceding increase to the transferee foreign corporation's E&P by reason of the disposition that is then offset by the corresponding reduction. For example, consider a case in which a U.S. transferor contributed intangible property with an adjusted basis of $0 to a wholly owned transferee foreign corporation in an exchange described in section 351(a) that was subject to section 367(d). In a later year, the transferee foreign corporation disposes of the intangible property to an unrelated person when the fair market value of the intangible property is $100x, which causes the U.S. transferor to recognize $100x of gain under § 1.367(d)–1T(f)(1); also, assume the transferee foreign corporation has $50x of other E&P unrelated to the subsequent disposition of the intangible property. Section 1.367(d)–1T(f)(2) does not simply reduce the transferee foreign corporation's E&P by $100x, but rather the corresponding reduction would offset the $100x of E&P that arises as to the transferee foreign corporation by reason of the disposition, thereby preventing potential excessive E&P and leaving the transferee foreign corporation's other E&P unaffected.

Similarly, and in order to prevent excessive E&P and gross income as to the transferee foreign corporation because of the gain recognition rule or § 1.367(d)–1T(f)(1), proposed § 1.367(d)–1(f)(2)(i) provides certain adjustments to the transferee foreign corporation's E&P and gross income that arise by reason of any gain the U.S. transferor recognizes under the gain recognition rule or § 1.367(d)–1T(f)(1). Specifically, for purposes of chapter 1 of the Code—that is, chapter 1 (relating to normal taxes and surtaxes) of subtitle A (relating to income taxes) of the Code—the transferee foreign corporation reduces (but not below zero) the portion of its E&P and gross income arising from the transaction to take into account the gain recognized by the U.S. transferor. *See* proposed § 1.367(d)–1(f)(2)(i). And, as provided currently under the section 367(d) regulations, any gain so recognized can be received by the U.S. transferor without further U.S. tax consequences pursuant to the account receivable mechanism provided in § 1.367(d)–1T(g)(1). *See* proposed § 1.367(d)–1(f)(2)(ii).

Because section 367(d) effectively shifts certain gain a transferee foreign corporation would recognize as to intangible property directly to a U.S. transferor under the gain recognition rule or § 1.367(d)–1T(f)(1) (as applicable), these rules are intended to provide appropriate reductions to offset, as to the transferee foreign corporation, the impact of a U.S. transferor's recognition of gain under section 367(d). In most cases, the proper reduction described in proposed § 1.367(d)–1(f)(2)(i) will equal the amount of gain recognized by the U.S. transferor under the provisions described in the preceding sentence. But the proper reduction may diverge from the amount of gain recognized by the U.S. transferor in certain cases, depending on the position taken with respect to the transferee foreign corporation's basis in the intangible property during the time the intangible property is subject to section 367(d). *See* part I.D of this Explanation of Provisions for additional discussion of this issue.

4. Special Rule for Related Transactions

Proposed § 1.367(d)–1(f)(4)(v) provides a special rule that applies if the intangible property is transferred in two or more related transactions. If this special rule applies, whether and how the proposed regulations apply depends on the ultimate recipient of the intangible property. *See* proposed § 1.367(d)–1(f)(6)(ii)(D) and (E) (*Examples 4* and *5*) for illustrations of this rule.

C. Qualified Domestic Person

Proposed § 1.367(d)–1(f)(4)(iii) defines a qualified domestic person for purposes of the proposed regulations. First, a qualified domestic person includes the U.S. transferor that initially transferred the intangible property subject to section 367(d) that is

[3] For example, if the form of the repatriation transaction were distinguished by reference to whether the repatriation occurred pursuant to a nonrecognition transaction (as described in section 7701(a)(45)), uncertainty could arise in certain cases, such as repatriations that occur pursuant to exchanges involving boot (such as cash). This uncertainty would impact the proposed rules for determining a qualified domestic person's adjusted basis in the repatriated intangible property, which relies on the form of the repatriation as described in this paragraph.

repatriated (an ''initial U.S. transferor'') and a U.S. person treated as the U.S. transferor pursuant to § 1.367(d)1T(e)(1) as applied with certain limitations (a ''qualified successor''). *See* proposed § 1.367(d)–1(f)(4)(iii)(A) and (B). Specifically, these limitations require that a qualified successor must be either an individual or a corporation other than a corporation exempt from tax under section 501(a), a regulated investment company (as defined in section 851(a)), a real estate investment trust (as defined in section 856(a)), a domestic international sales corporation (DISC) (as defined in section 992(a)(1)), or an S corporation (as defined in section 1361(a)) (a domestic corporation meeting these requirements, a ''qualified corporation''). Second, a qualified domestic person also includes a U.S. person that is an individual or a qualified corporation related to the U.S. transferor within the meaning of § 1.367(d)–1T(h). *See* proposed § 1.367(d)–1(f)(4)(iii)(C) and (D).

The proposed regulations define a qualified domestic person in this manner based on the principle that it is generally appropriate to terminate the continued application of section 367(d) only when all the income produced by the intangible property, as well as gain recognized on a disposition of the intangible property, will be subject to current tax in the United States as to the qualified domestic person while that person holds the property. It is also appropriate to terminate the continued application of section 367(d) for a repatriation to an initial U.S. transferor because such a transfer merely restores the circumstances that existed at the time of the original outbound transfer subject to section 367(d).

A qualified domestic person, as noted above, also includes certain U.S. persons (individuals and qualified corporations) related to either the initial U.S. transferor or qualified successor, as applicable. *See* proposed § 1.367(d)–1(f)(4)(iii)(C) and (D). This aspect of the definition of qualified domestic person implements the same principle described in the preceding paragraph; that is, to terminate the continued application of section 367(d), all of the income or gain from the intangible property must be subject to current tax in the United States as to the qualified domestic person after the repatriation or the repatriation must restore the circumstances that existed at the time of the original outbound transfer subject to section 367(d).

In the case of a domestic partnership, § 1.367(d)–1T(h) defines a related person for purposes of the section 367(d) regulations by reference to certain relationships described in section 267 or 707(b)(1). Thus, if a U.S. transferor owns more than 50 percent of the capital or profits interest in a domestic partnership, the U.S. transferor and the domestic partnership are related within the meaning of section 707(b)(1) and, therefore, the U.S. transferor and the domestic partnership are related for purposes of § 1.367(d)–1T(h), even if the domestic partnership has one or more foreign partners. The proposed regulations, however, do not treat the domestic partnership as a qualified domestic person. The Treasury Department and the IRS considered addressing such cases by including rules in the proposed regulations treating a partnership as an aggregate of its partners (an ''aggregate approach''), with the analysis for qualified domestic person status occurring under such an aggregate approach. *See, for example,* §§ 1.367(a)–1T(c)(3)(i) and 1.367(d)–1T(a) for similar rules that apply to certain transfers of intangible property by a partnership to a foreign corporation. The proposed regulations do not adopt an aggregate approach because that approach could allow taxpayers to circumvent the purposes of these proposed regulations and other related regulations following a repatriation to a domestic partnership. This could occur if, for example, partnership allocations are changed after the repatriation or if the transferee foreign corporation (or a related foreign corporation) has liquidation rights to the intangible property following the transfer. Additionally, in the case of a partnership with one or more partners that are qualified domestic persons and one or more partners that are not, an aggregate approach would necessitate rules to measure the extent to which proposed § 1.367(d)–1(f)(4)(i) applies by reason of a repatriation (and, by extension, the extent to which the annual inclusion stream under section 367(d) should continue to apply after the repatriation). To address this concern, the Treasury Department and the IRS also considered including, as part of an aggregate approach in the proposed regulations, rules like those provided in §§ 1.367(a)–3 and 1.367(a)–8 regarding gain recognition agreements to ensure that, to the extent the relief provided in proposed § 1.367(d)–1(f)(4)(i) applies as to a repatriation, a corresponding amount of income from the intangible property would be, and would continue to be, subject to tax in the United States. After consideration, however, the Treasury Department and the IRS are not proposing such an approach, because it would be unworkable due to the compliance and administrative burden.

D. Qualified Domestic Person's Adjusted Basis in Repatriated Intangible Property

Proposed § 1.367(d)–1(f)(4)(iv) provides rules regarding a qualified domestic person's basis in the intangible property it receives in a repatriation. Specifically, the proposed regulations provide that, in the case of repatriation pursuant to which the intangible property qualifies as transferred basis property, a qualified domestic person's adjusted basis in the intangible property will equal, subject to any applicable limitations that may apply under the Code, the lesser of the U.S. transferor's former adjusted basis in the intangible property or the transferee foreign corporation's adjusted basis in that property (immediately before the repatriation), increased by the greater of the amount of gain recognized by the U.S. transferor under the proposed regulations upon the repatriation (if any) or the amount of gain recognized by the transferee foreign corporation upon the repatriation (if any). *See* § 1.367(d)–1(f)(4)(v)(A). The result in most cases will track the result that would occur under generally applicable rules, like section 334(b) or 362, while appropriately accounting for situations in which the gain a U.S. transferor recognizes under the gain recognition rule differs from the gain the transferee foreign corporation recognizes by reason of the repatriation. Alternatively, if the intangible property does not qualify as transferred basis property, a qualified domestic person's adjusted basis in the intangible property will equal the fair market value of the intangible property as of the date of the subsequent disposition. *See* proposed § 1.367(d)–1(f)(4)(iv)(B).

The Treasury Department and the IRS are aware of the uncertainty regarding the treatment of adjusted basis in intangible property subject to section 367(d) while section 367(d) applies, particularly when the U.S. transferor's former adjusted basis is greater than zero. The proposed regulations are intended to address basis consequences solely when intangible property is repatriated in a transaction that eliminates the continued application of section 367(d). In this manner, the effect of proposed § 1.367(d)–1(f)(4)(iv) is prospective insofar as it provides for a qualified domestic person's adjusted basis in the intangible property after the property is no longer subject to section 367(d). Thus, the proposed regulations do not address, nor is any implication intended as to, the appropriate treatment of adjusted basis as to the

transferee foreign corporation in intangible property subject to section 367(d) while section 367(d) applies; instead, the Treasury Department and the IRS will address general basis rules under section 367(d) in future rulemaking. Until such general rules are issued, proposed § 1.367(d)–1(f)(4)(iv) would operate in a manner intended to reach an appropriate result regarding a qualified domestic person's basis in repatriated intangible property. *See* proposed § 1.367(d)–1(f)(6)(ii)(C) (*Example 3*) for an illustration of this rule.

E. Required Adjustments Related to an Annual Section 367(d) Inclusion

As noted in part I.A of this Explanation of Provisions, the transferee foreign corporation makes the required adjustments currently described in § 1.367(d)–1T(c)(2) for cases in which the section 367(d) repatriation rules apply (that is, the adjustments with respect to the U.S. transferor's partial annual inclusion for the year of the repatriation). Current § 1.367(d)–1T(c)(2)(ii) provides that, as to a U.S. transferor's annual inclusion, the transferee foreign corporation may treat that deemed payment as an expense (whether or not paid) properly allocated and apportioned against gross income subject to subpart F, in accordance with §§ 1.954–1(c) and 1.861–8.

The proposed regulations provide that the deemed payment by the transferee foreign corporation is treated as an allowable deduction that must be allocated and apportioned to such corporation's classes of gross income in accordance with §§ 1.882–4(b)(1), 1.954–1(c), and 1.960–1(c) and (d) (as appropriate). *See* proposed § 1.367(d)–1(c)(2)(ii). Proposed § 1.367(d)–1(c)(2)(ii) thus clarifies that the allowable deduction is allocated and apportioned under the provisions cited in the previous sentence potentially to any class (or classes) of gross income (as appropriate) rather than solely to gross income subject to subpart F in all circumstances. The proposed regulations make identical clarifications in proposed § 1.367(d)–1(e)(2)(ii) (required adjustments in the case of a subsequent transfer of stock of the transferee foreign corporation to a successor U.S. transferor). The proposed regulations change the reference to ''expense'' in the current regulations to ''allowable deduction'' for clarity; this modification is not intended to be a substantive change.

F. Multiple U.S. Transferors

As noted in part I.C of the Background section of this Preamble, there may be multiple U.S. transferors with respect to the same intangible property, which may occur, for example, if a U.S. transferor subsequently transfers a portion of its stock in the transferee foreign corporation to a successor U.S. transferor. In these cases, because the section 367(d) regulations apply separately as to each U.S. transferor, the requirements of proposed § 1.367(d)–1(f)(4)(i) also apply separately with respect to each U.S. transferor. That is, to terminate the continued application of section 367(d) with respect to a particular U.S. transferor, the recipient of the transferred intangible property must be a qualified domestic person with respect to that U.S. transferor and the information described in proposed § 1.6038B–1(d)(2)(iv) must be provided.

To illustrate, assume that a transferee foreign corporation (''TFC'') holds intangible property that is subject to section 367(d), and TFC repatriates that intangible property on date X. Also assume that two domestic corporations (''US1'' and ''US2'') are treated as U.S. transferors under the section 367(d) regulations by reason of owning stock of TFC (US1 was the original U.S. transferor and US2 is a successor U.S. transferor by reason of its acquisition of a portion of the stock of TFC from US1). Therefore, if the recipient of the transferred intangible property on date X is a qualified domestic person (for example, a related domestic corporation) with respect to US1, but is an unrelated person with respect to US2, the following occurs: proposed § 1.367(d)–1(f)(4)(i) would apply with respect to US1, if the information described in proposed § 1.6038B–1(d)(2)(iv) is provided, and US2 would recognize gain under § 1.367(d)–1T(f)(1) by reason of the transaction.

G. Other Modifications

The proposed regulations update the references to section 936(h)(3)(B) that appear in the applicable regulations under section 367 with references to section 367(d)(4), which was added as part of the Consolidated Appropriations Act in 2018. *See* Public Law 115–141 and §§ 1.367(a)–1(d)(5) and (6) and 1.367(e)–2(b)(2)(i)(B). The proposed regulations do not update all references to section 936(h)(3)(B) that appear in regulations issued under other sections of the Code, but such an update will be included as part of future rulemaking.

The proposed regulations provide that proposed § 1.367(d)–1(f)(3) would not apply as to a repatriation meeting the requirements of proposed § 1.367(d)–1(f)(4)(i)(B); instead, proposed § 1.367(d)–1(f)(4)(i) applies, and, thereafter, the intangible property is no longer subject to section 367(d). The language in proposed § 1.367(d)–1(f)(3) also reflects minor editorial differences from the language currently in § 1.367(d)–1T(f)(3) that are not intended to be substantive. See proposed § 1.367(d)–1(f)(3).

The proposed regulations fix a longstanding typographical error by replacing the reference to ''section 267(d)'' in current § 1.367(d)–1T(h)(2)(ii) with a reference to ''267(f).''

Finally, the proposed regulations eliminate § 1.951A–2(c)(2)(ii), which provides that deductions taken into account in determining a CFC's tested income and tested loss under section 951A include the amount of a deemed payment under section 367(d)(2)(A). This rule is no longer necessary because the proposed regulations provide that such deemed payments are treated as allowable deductions in accordance with, in relevant part, § 1.951A–2(c)(3). *See* proposed § 1.367(d)–1(c)(2)(ii) and (e)(2)(i).

II. Section 904(d) Foreign Branch Income Rules

As noted in part III of the Background section of this Preamble, the provisions in § 1.904–4(f)(2)(vi)(D) provide that, in relevant part, the principles of section 367(d) apply for determining the amount of gross income that is attributable to a foreign branch that must be adjusted under § 1.904–4(f)(2)(vi)(D). But those provisions do not elaborate on how the principles of section 367(d) apply for that purpose; in particular, there is no mention of how or whether current § 1.367(d)–1T(f) applies in the foreign branch income context.

The Treasury Department and the IRS believe that due to the differing scopes and purposes of section 367(d) and § 1.904–4(f)(2)(vi)(D), the consequences of a subsequent transfer for purposes of determining a U.S. transferor's section 367(d) inclusion do not necessarily inform the appropriate treatment for purposes of the section 904(d) branch income rules. Section 367(d), as a threshold matter, applies only in the case of certain outbound transfers of intangible property by a U.S. person to a foreign corporation, whereas § 1.904–4(f)(2)(vi)(D) applies to outbound transfers by a U.S. foreign branch owner to a foreign branch, inbound transfers by a foreign branch to a U.S. foreign branch owner, as well as transfers between foreign branches with the same U.S. foreign branch owner. If there are multiple transfers of an item of intangible property over time, each transfer must be separately evaluated and could result in differing amounts of

deemed annual payments depending on any interim changes in the value of the intangible property between successive transfers. Accordingly, these proposed regulations provide that each successive transfer to which § 1.904–4(f)(2)(vi)(D) applies is considered independently from any other preceding or subsequent transfers. *See* proposed § 1.904–(f)(2)(vi)(D)(*4*). Therefore, the subsequent transfer rules in the regulations under section 367(d), including the rule for repatriations provided in these proposed regulations, do not apply in the context of determining gross income attributable to the foreign branch income category and each successive transfer is separately subject to the provisions of § 1.904–(f)(2)(vi)(D)(*1*) and will not terminate or otherwise impact the application of § 1.904–(f)(2)(vi)(D)(*1*) to a prior transfer described in that paragraph.

III. Reporting

A. Reporting Requirements for Subsequent Transfers of Intangible Property

As described in part I.A of this Explanation of Provisions, proposed § 1.367(d)–1(f)(4)(i) requires a U.S. transferor to provide the information described in proposed § 1.6038B–1(d)(2)(iv) with respect to the repatriation. In general, §§ 1.6038B–1 and 1.6038B–1T provide information reporting rules that apply with respect to transfers of property to foreign corporations, including transfers of property described in sections 367(a) and (d). *See* § 1.6038B–1(c) and (d). Section 1.6038B–1T(d) provides specific information reporting rules for transfers subject to section 367(d), including rules that apply to subsequent transfers. *See* § 1.6038B–1T(d)(2).

These proposed regulations make two conforming changes to the reporting requirements for subsequent transfers under § 1.6038B–1T(d)(2) (the ''proposed information reporting rules''). The first change provides that, to the extent a qualified domestic person receives intangible property in a subsequent transfer, the subsequent transfer information described in proposed § 1.6038B–1(d)(2)(iv) instead of the subsequent transfer information described in § 1.6038B–1T(d)(2)(iii) must be provided.

The second change adds information reporting requirements for a subsequent transfer of intangible property to a qualified domestic person. *See* proposed § 1.6038B–1(d)(2)(iv). These reporting rules request information that is necessary to ensure that proposed § 1.367(d)–1(f)(4) is appropriately applied to the subsequent transfer.

B. Relief for Certain Failures To Provide Required Information

In general, as a condition for terminating the application of section 367(d) with respect to the transferred intangible property, proposed § 1.367(d)–1(f)(4)(i)(B) requires a U.S. transferor to provide the information described in proposed § 1.6038B–1(d)(2)(iv). If a U.S. transferor fails to provide that information, the repatriation is subject to proposed § 1.367(d)–1(f)(3) such that the section 367(d) regulations, including the requirement to take an annual inclusion into account over the useful life of the intangible property, continue to apply. However, a U.S. transferor is eligible for relief under the proposed regulations if proposed § 1.367(d)–1(f)(4)(i)(B) would have applied to the subsequent transfer of intangible property but for the fact that the required information was not provided and the U.S. transferor, upon becoming aware of the failure, promptly provides the required information and explains its failure to comply. *See* proposed § 1.367(d)–1(f)(5). When it applies, proposed § 1.367(d)–1(f)(5) treats the requirements of proposed § 1.367(d)–1(f)(4)(i)(B) as satisfied as of the date of the transfer of intangible property to the qualified domestic person.

IV. Applicability Dates

The proposed regulations generally apply to subsequent dispositions of intangible property occurring on or after the date of publication of the Treasury decision adopting these rules as final regulations in the **Federal Register**. *See* proposed §§ 1.367(d)–1(j)(2)), 1.904–4(q)(3), and 1.6038B–1(g). Proposed § 1.951A–2(c)(2) applies to taxable years of foreign corporations ending on or after the date of publication of the Treasury decision adopting these rules as final regulations in the **Federal Register**, and to taxable years of United States shareholders in which or with which such taxable years end. *See* proposed § 1.951A–7(e).

Special Analyses

I. Regulatory Planning and Review—Economic Analysis

The Administrator of the Office of Information and Regulatory Affairs (''OIRA''), Office of Management and Budget (''OMB''), has determined that this proposed rule is not a significant regulatory action, as that term is defined in section 3(f) of Executive Order 12866. Therefore, OIRA has not reviewed this proposed rule pursuant to section 6(a)(3)(A) of Executive Order 12866 and the April 11, 2018, Memorandum of Agreement between the Treasury Department and OMB.

II. Paperwork Reduction Act

The collection of information contained in this notice of proposed rulemaking has been submitted to OMB for review in accordance with the Paperwork Reduction Act under control number 1545–0026. Commenters are strongly encouraged to submit public comments electronically. Written comments and recommendations for the proposed information collection should be sent to *https://www.reginfo.gov/public/do/PRAMain,* with copies to the Internal Revenue Service. Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' then by using the search function. Submit electronic submissions for the proposed information collection to the IRS via email at *omb.unit@irs.gov* (indicate ''REG–124064–19 (1545–0026)'' on the Subject line). Comments on the collection of information should be received by July 3, 2023. Comments are specifically requested concerning:

Whether the proposed collection of information is necessary for the proper performance of the functions of the IRS, including whether the information will have practical utility;

The accuracy of the estimated burden associated with the proposed collection of information;

How the quality, utility, and clarity of the information to be collected may be enhanced;

How the burden of complying with the proposed collection of information may be minimized, including through the application of automated collection techniques or other forms of information technology; and

Estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

The collection of information in this proposed regulation is in § 1.6038B–1(d)(2)(iv). This information is necessary to ensure that proposed § 1.367(d)–1(f)(4) is appropriately applied to the subsequent transfer.

The collection of information is required to comply with section 367(d). The likely respondents are domestic corporations. Burdens associated with these requirements will be reflected in the burden for Form 926, *Return by a U.S. Transferor of Property to a Foreign Corporation.*

Estimated change in annual reporting burden: 1601 hours.

Estimated increase in annual burden per respondent: 2.4 hours.

Estimated number of respondents: 667.

Estimated frequency of responses: annually.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid control number assigned by the Office of Management and Budget.

III. Regulatory Flexibility Act

When an agency issues a rulemaking proposal, the Regulatory Flexibility Act (5 U.S.C. chapter 6) (''RFA'') requires the agency ''to prepare and make available for public comment an initial regulatory flexibility analysis'' that will ''describe the impact of the proposed rule on small entities.'' *See* 5 U.S.C. 603(a). Section 605 of the RFA provides an exception to this requirement if the agency certifies that the proposed rulemaking will not have a significant economic impact on a substantial number of small entities. A small entity is defined as a small business, small nonprofit organization, or small governmental jurisdiction. *See* 5 U.S.C. 601(3) through (6).

The Treasury Department and the IRS do not have detailed data readily available to assess the exact number of small entities potentially affected by the proposed regulations. Based on the limited data available, it is estimated that there will be less than 700 taxpayers potentially affected by the proposed regulations. But, among those taxpayers, an even smaller portion will likely be affected by the proposed regulations as these rules apply to a specific type of transaction—repatriations of intangible property subject to section 367(d). Moreover, the entities potentially affected by these proposed regulations are generally not small entities, because of the resources and investment necessary to develop intangible property and, once so developed, transfer the intangible property to a foreign corporation. Therefore, the Treasury Department and the IRS certify that the proposed regulations will not have a significant economic impact on a substantial number of small entities. The IRS invites the public to comment on the impact of these regulations on small entities.

IV. Section 7805(f)

Pursuant to section 7805(f), this notice of proposed rulemaking has been submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small business.

V. Unfunded Mandates Reform Act

Section 202 of the Unfunded Mandates Reform Act of 1995 requires that agencies assess anticipated costs and benefits and take certain other actions before issuing a final rule that includes any Federal mandate that may result in expenditures in any one year by a State, local, or Tribal government, in the aggregate, or by the private sector, of $100 million in 1995 dollars, updated annually for inflation. This rule does not include any Federal mandate that may result in expenditures by State, local, or Tribal governments, or by the private sector in excess of that threshold.

VI. Executive Order 13132: Federalism

Executive Order 13132 (entitled ''Federalism'') prohibits an agency from publishing any rule that has federalism implications if the rule either imposes substantial, direct compliance costs on State and local governments, and is not required by statute, or preempts State law, unless the agency meets the consultation and funding requirements of section 6 of the Executive order. This proposed rule does not have federalism implications, does not impose substantial direct compliance costs on State and local governments, and does not preempt State law within the meaning of the Executive order.

Comments and Requests for Public Hearing

Before these proposed amendments to the regulations are adopted as final regulations, consideration will be given to comments that are submitted timely to the IRS as prescribed in the Preamble under the **ADDRESSES** section. The Treasury Department and the IRS request comments on all aspects of the proposed regulations.

A public hearing will be scheduled if requested in writing by any person who timely submits electronic or written comments. Requests for a public hearing are encouraged to be made electronically. If a public hearing is scheduled, notice of the date and time for the public hearing will be published in the **Federal Register**. Announcement 2020–4, 2020–17 IRB 1, provides that until further notice, public hearings conducted by the IRS will be held telephonically. Any telephonic hearing will be made accessible to people with disabilities.

Statement of Availability of IRS Documents

IRS Revenue Procedures, Revenue Rulings, and Notices cited in this Preamble are published in the Internal Revenue Bulletin (or Cumulative Bulletin) and are available from the Superintendent of Documents, U.S. Government Publishing Office, Washington, DC 20402, or by visiting the IRS website at *https://www.irs.gov.*

Drafting Information

The principal authors of these regulations are Chadwick Rowland and L. Ulysses Chatman, Office of Associate Chief Counsel (International). However, other personnel from the Treasury Department and the IRS participated in their development.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Proposed Amendments to the Regulations

Accordingly, the Treasury Department and the IRS propose to amend 26 CFR part 1 as follows:

PART 1—INCOME TAXES

■ **Paragraph 1.** The authority citation for part 1 continues to read in part as follows:

Authority: 6 U.S.C. 7805 * * *

Section 1.367(d)–1 also issued under 26 U.S.C. 367(d).

* * * * *

§ 1.367(a)–1 [Amended]

■ **Par. 2.** Section 1.367(a)–1 is amended by removing the language ''section 936(h)(3)(B)'' in paragraphs (d)(5) and (6) and adding the language ''section 367(d)(4)'' in its place.

■ **Par. 3.** Section 1.367(d)–1 is amended by:

■ 1. Removing reserved paragraphs (c)(1) through (2).

■ 2. Adding a heading to paragraph (c) and adding paragraphs (c)(1) and (2).

■ 3. Removing reserved paragraphs (c)(4) through (g)(2) (introductory text).

■ 4. Adding paragraphs (c)(4), (d), (e), and (f).

■ 5. Adding a heading to paragraph (g) and adding paragraphs (g)(1) and (g)(2) introductory text.

■ 6. Removing reserved paragraphs (g)(2)(ii) through (g)(2)(iii)(D).

■ 7. Adding paragraph (g)(2)(ii) and reserved paragraphs (g)(2)(iii) introductory text and (g)(2)(iii)(A) through (D).

■ 8. Removing reserved paragraphs (g)(4) through (i).

■ 9. Adding paragraphs (g)(4), (h), and (i).

■ 10. Revising paragraph (j).

The additions and revision read as follows:

§ 1.367(d)–1 Transfers of intangible property to foreign corporations.

* * * * *

(c) *Deemed payments upon transfer of intangible property to foreign corporation*—(1) *In general.* For further guidance, see § 1.367(d)–1T(c)(1).

(2) *Required adjustments.* For further guidance, see § 1.367(d)–1T(c)(2) introductory text and (c)(2)(i).

(i) [Reserved]

(ii) The deemed payment is treated as an allowable deduction (whether or not that amount is paid) of the transferee foreign corporation properly allocated and apportioned to the appropriate classes of gross income in accordance with §§ 1.882–4(b)(1), 1.951A–2(c)(3), 1.954–1(c), 1.960–1(c), and 1.960–1(d), as applicable.

* * * * *

(4) *Blocked income.* For further guidance, see § 1.367(d)–1T(c)(4).

(d) *Subsequent transfer of stock of transferee corporation to unrelated person.* For further guidance, see § 1.367(d)–1T(d).

(e) *Subsequent transfer of stock of transferee foreign corporation to related person*—(1) *Transfer to related U.S. person treated as disposition of intangible property.* For further guidance, see § 1. 367(d)–1T(e)(1).

(2) *Required adjustments.* For further guidance, see § 1.367(d)–1T(e)(2) introductory text and (e)(2)(i).

(i) [Reserved]

(ii) The deemed payment is treated as an allowable deduction (whether or not that amount is paid) of the transferee foreign corporation properly allocated and apportioned to the appropriate classes of gross income in accordance with §§ 1.882–4(b)(1), 1.951A–2(c)(3), 1.954–1(c), 1.960–1(c), and 1.960–1(d), as applicable.

(iii) For further guidance, see § 1.367(d)–1T(e)(2)(iii) through (e)(4).

(iv) [Reserved]

(3) through (4) [Reserved]

(f) *Subsequent disposition of transferred intangible property by transferee foreign corporation—(1) In general.* For further guidance, see § 1.367(d)–1T(f)(1).

(2) *Required adjustments.* If a U.S. transferor is required to recognize gain under paragraph (f)(4)(i)(A) of this section or § 1.367(d)–1T(f)(1), then, in addition to the adjustments described in paragraph (c)(2)(ii) of this section and § 1.367(d)–1T(c)(2) with respect to the deemed payment described in § 1.367(d)–1T(f)(1)(ii)—

(i) For purposes of chapter 1 of the Code, the transferee foreign corporation reduces (but not below zero) the portion of its earnings and profits and gross income arising by reason of the subsequent disposition of the intangible property by the amount of gain recognized by the U.S. transferor under paragraph (f)(4)(i)(A) of this section or § 1.367(d)–1T(f)(1); and

(ii) The U.S. transferor may establish an account receivable from the transferee foreign corporation equal to the amount of gain recognized under paragraph (f)(4)(i)(A) of this section or § 1.367(d)–1T(f)(1) in accordance with § 1.367(d)–1T(g)(1).

(3) Subsequent transfer of intangible property to related person. Except as provided in paragraph (f)(4)(i)(B) of this section, a U.S. person's requirement to recognize income under § 1.367(d)–1T(c) or (e) is not affected by the transferee foreign corporation's subsequent disposition of the transferred intangible property to a related person. For purposes of any required adjustments, and of any accounts receivable created under § 1.367(d)–1T(g)(1), the related person that receives the intangible property is treated as the transferee foreign corporation.

(4) Subsequent transfer of intangible property to qualified domestic person—(i) In general. Except as provided in paragraph (f)(4)(v) of this section, if a U.S. person transfers intangible property subject to section 367(d) and the rules of this section and § 1.367(d)–1T to a foreign corporation in an exchange described in section 351 or 361 and, within the useful life of the intangible property, that transferee foreign corporation subsequently disposes of the intangible property to a qualified domestic person, then—

(A) The U.S. transferor of the intangible property (or any person treated as such pursuant to § 1.367(d)–1T(e)(1)) is required to recognize gain, as applicable, equal to the amount described in paragraph (f)(4)(ii) of this section; and

(B) If the U.S. transferor provides the information described in § 1.6038B–1(d)(2)(iv), then—

(*1*) The U.S. transferor is required to recognize a deemed payment as provided in § 1.367(d)–1T(f)(1)(ii); and

(*2*) The intangible property is no longer subject to section 367(d), this section, and § 1.367(d)–1T after applying paragraphs (f)(4)(i)(A) and (f)(4)(i)(B)(1) of this section.

(ii) *Gain recognition for U.S. transferor.* The amount of gain a U.S. transferor must recognize under paragraph (f)(4)(i)(A) of this section is determined as follows—

(A) If the intangible property is transferred basis property (as defined in section 7701(a)(43)) by reason of the subsequent disposition (determined without regard to section 367(d), this section, and § 1.367(d)–1T), the amount of gain, if any, the transferee foreign corporation would recognize if its adjusted basis in the intangible property were equal to the U.S. transferor's former adjusted basis in the property; or

(B) If the intangible property is not transferred basis property by reason of the subsequent disposition (determined without regard to section 367(d), this section, and § 1.367(d)–1T), the excess, if any, of the fair market value of the intangible property on the date of the subsequent disposition and the U.S. transferor's former adjusted basis in that property.

(iii) *Qualified domestic person.* For purposes of paragraph (f)(4) of this section, a qualified domestic person means—

(A) The U.S. transferor that initially transferred intangible property subject to section 367(d);

(B) A U.S. person treated as a U.S. transferor under § 1.367(d)–1T(e)(1), provided such person is an individual or a corporation other than a corporation exempt from tax under section 501(a), a regulated investment company (as defined in section 851(a)), a real estate investment trust (as defined in section 856(a)), a domestic international sales corporation (DISC) (as defined in section 992(a)(1)), or an S corporation (as defined in section 1361(a));

(C) A U.S. person that is an individual related, within the meaning of paragraph (h)(2)(ii) of this section and § 1.367(d)–1T(h), to the person described in paragraph (f)(4)(iii)(A) or (B) of this section; or

(D) A U.S. person that is a corporation related, within the meaning of paragraph (h)(2)(ii) of this section and § 1.367(d)–1T(h), to the person described in paragraph (f)(4)(iii)(A) or (B) of this section, other than a corporation exempt from tax under section 501(a), a regulated investment company (as defined in section 851(a)), a real estate investment trust (as defined in section 856(a)), a DISC (as defined in section 992(a)(1)), or an S corporation (as defined in section 1361(a)).

(iv) *Qualified domestic person's basis in the intangible property.* The qualified domestic person's adjusted basis in the intangible property is—

(A) In the case of a subsequent disposition of intangible property described in paragraph (f)(4)(ii)(A) of this section, and subject to any applicable limitations that may apply

under the Code, the lesser of the U.S. transferor's former adjusted basis in the intangible property or the transferee foreign corporation's adjusted basis in the intangible property (as determined immediately before the subsequent disposition), in each case increased by the greater of the amount of gain (if any) described in paragraph (f)(4)(ii)(A) of this section and recognized by the U.S. transferor or the amount of gain (if any) recognized by the transferee foreign corporation as to the intangible property by reason of the subsequent disposition; or

(B) In the case of a subsequent disposition of intangible property described in paragraph (f)(4)(ii)(B) of this section, the fair market value of the intangible property (as determined on the date of the subsequent disposition).

(v) *Special rule for related transactions.* If the transferee foreign corporation subsequently disposes of the transferred intangible property to a person that would, absent this paragraph (f)(4)(v), be a qualified domestic person (initial transferee) and, as part of a series of related transactions, the intangible property is subsequently disposed of to any other person, including by reason of multiple dispositions, then the initial transferee is treated as a qualified domestic person only if the ultimate recipient of the intangible property is a qualified domestic person. See paragraphs (f)(6)(ii)(D) and (E) of this section (*Examples 4* and *5*), for illustrations of the application of this paragraph (f)(4)(v).

(5) *Relief for certain failures to comply.* This paragraph (f)(5) provides relief if paragraph (f)(4)(i)(B)(2) of this section would apply but for the U.S. transferor's failure to provide the information required by paragraph (f)(4)(i)(B) of this section (a ''failure to comply''). When a failure to comply occurs, the subsequent disposition of the transferred intangible property is generally subject to paragraphs (f)(3) and (f)(4)(i)(A) of this section, and not paragraph (f)(4)(i)(B)(2) of this section. Nevertheless, a failure to comply is deemed not to have occurred (regardless of whether the U.S. transferor continued to include amounts in gross income under § 1.367(d)–1T(c) or (e) after the subsequent disposition), and the requirements of paragraph (f)(4)(i)(B) of this section are treated as satisfied as of the date of the subsequent disposition if, promptly after the U.S. transferor becomes aware of the failure, the U.S. transferor provides such information and provides a reasonable explanation for its failure to comply to the Director of Field Operations, Cross Border Activities Practice Area of Large Business & International (or any successor to the roles and responsibilities of such position, as appropriate). Additionally, the U.S. transferor must timely file an amended return for the taxable year in which the subsequent disposition occurred (and, if applicable, for each taxable year starting with the taxable year immediately after the taxable year in which the subsequent disposition occurred and ending with the taxable year in which the U.S. transferor seeks relief under this paragraph (f)(5)) that includes the information required by paragraph (f)(4)(i)(B) of this section. If any taxable year of the U.S. transferor is under examination when an amended return is filed, a copy of the amended return (or, if applicable, amended returns) must be provided to the Internal Revenue Service personnel conducting the examination.

(6) *Examples*—(i) *Assumed facts.* For purposes of the examples in paragraph (f)(6)(ii) of this section, and except where otherwise indicated, the following facts are assumed.

(A) USP and USS are domestic corporations that each use a calendar taxable year.

(B) TFC is a foreign corporation whose functional currency is the U.S. dollar.

(C) In year 1, USP transfers intangible property, as defined in section 367(d)(4), with a $0 adjusted basis, to TFC in a section 351 exchange (the ''transferred IP''), and such transfer is subject to section 367(d).

(D) Each annual inclusion (including any amount described in § 1.367(d)–1T(f)(1)(ii)) is taken into account under section 367(d)(2)(A)(ii)(I) and § 1.367(d)–1T(c)(1).

(E) Any subsequent transfer or disposition of stock of TFC or the transferred IP occurs within the useful life of the transferred IP.

(F) All transactions are respected under general principles of tax law.

(ii) *Examples.* The following examples illustrate the application of paragraph (f)(4) of this section and other paragraphs of this section that relate to paragraph (f)(4).

(A) *Example 1: Complete liquidation of transferee foreign corporation into a qualified domestic person*—(*1*) *Facts.* In year 2, USP transfers all the stock of TFC to USS, a related person within the meaning of § 1.367(d)–1T(h) and paragraph (h)(2)(ii) of this section, in a section 351 exchange to which § 1.367(d)–1T(e)(1) applies (the ''year 2 transfer''). In year 3, TFC distributes all its property (including the transferred IP) to USS pursuant to a complete liquidation to which sections 332 and 337 apply (the ''year 3 liquidation''). The all earnings and profits amount determined under § 1.367(b)–2(d) with respect to the stock of TFC held by USS is $0. The information described in § 1.6038B–1(d)(2) is provided by USS for the taxable year in which the year 3 liquidation occurs.

(*2*) *Analysis*—(*i*) *The year 2 transfer.* Because the year 2 transfer involves a transfer of all the stock of TFC by USP (the initial U.S. transferor) to a related U.S. person (USS), under § 1.367(d)–1T(e)(1)(i) USS (a successor U.S. transferor) is treated as receiving the right to receive a proportionate share of the contingent annual payments that USP would have otherwise taken into account under § 1.367(d)–1T(c). As determined under § 1.367(d)–1T(e)(4), USS's proportionate share of such payments is 100 percent. Accordingly, USS will annually include in its gross income the full amount of each of the annual payments that USP would otherwise have taken into account under § 1.367(d)–1T(c) over the useful life of the transferred IP, and USP will not recognize any gain upon the year 2 transfer. See § 1.367(d)–1T(e)(1)(ii) and (iii).

(*ii*) *The year 3 liquidation.* The year 3 liquidation results in a subsequent disposition of the transferred IP to USS. USS, a U.S. person treated as the U.S. transferor pursuant to § 1.367(d)–1T(e)(1), is a qualified domestic person within the meaning of paragraph (f)(4)(iii) of this section. Pursuant to paragraph (f)(4)(i)(A) of this section, USS must recognize the amount of gain described in paragraph (f)(4)(ii) of this section. Because the year 3 liquidation is a complete liquidation to which sections 332 and 337 apply, the intangible property is transferred basis property (as defined in section 7701(a)(43) and determined without regard to section 367(d), this section, and § 1.367(d)–1T), and therefore paragraph (f)(4)(ii)(A) applies to determine the amount of any gain USS must recognize. Because TFC does not recognize gain with respect to the transferred IP (regardless of the adjusted basis in the intangible property) by reason of the year 3 liquidation, the amount of gain described in paragraph (f)(4)(ii)(A) of this section is $0. Accordingly, USS does not recognize gain pursuant to paragraph (f)(4)(i)(A) of this section by reason of the year 3 liquidation. Additionally, because USS provides the information described in § 1.6038B–1(d)(2), paragraph (f)(4)(i)(B) of this section applies to the year 3 liquidation. USS therefore recognizes a deemed payment representing the part of USS's taxable year during which TFC held the transferred IP pursuant to paragraph (f)(4)(i)(B)(*1*) of this section, and the required adjustments described in paragraph (c)(2)(ii) of this section and § 1.367(d)–1T(c)(2)(i) apply as to the deemed payment. Also, because USS does not recognize gain pursuant to paragraph (f)(4)(i)(A) of this section, the required adjustments described in paragraph (f)(2) of this section do not apply. Pursuant to paragraph (f)(4)(i)(B)(*2*) of this section, after taking the deemed payment into account, the transferred IP is no longer subject to section 367(d), this section, and § 1.367(d)–1T. Finally, pursuant to paragraph (f)(4)(iv)(A) of this section, USS's adjusted basis in the

transferred IP is $0, which is equal to USP's former adjusted basis in the transferred IP ($0), increased by the greater of the amount of gain recognized by USS under paragraph (f)(4)(i)(A) of this section ($0) or the amount of gain recognized by TFC upon the year 3 distribution ($0).

(B) *Example 2: Taxable distribution of the transferred intangible property to a qualified domestic person*—(*1*) *Facts.* The facts are the same as in paragraph (f)(6)(ii)(A) of this section (Example 1), except that, instead of in year 3 TFC distributing all its property to USS pursuant to a complete liquidation, in year 3 TFC distributes the transferred IP to USS in a distribution described in section 311(b) when the fair market value of the transferred IP is $100x (the ''year 3 distribution''). TFC's adjusted basis in the transferred IP immediately before the distribution is $0.

(*2*) *Analysis.* The consequence of the year 2 transfer is the same as described in paragraph (f)(6)(ii)(A)(*2*)(*i*) of this section (*Example 1*). Like the consequences described in paragraph (f)(6)(ii)(A)(*2*) of this section (*Example 1*), the year 3 distribution is a subsequent disposition of the transferred IP to USS, a qualified domestic person. Pursuant to paragraph (f)(4)(i)(A) of this section, USS must recognize the amount of gain described in paragraph (f)(4)(ii) of this section. Because the year 3 distribution is described in section 311(b) the intangible property is not transferred basis property (as defined in section 7701(a)(43) and determined without regard to section 367(d), this section, and § 1.367(d)–1T), and therefore USS must recognize $100x gain under paragraph (f)(4)(ii)(B) of this section. The $100x gain amount equals the excess of the fair market value of the transferred IP on the date of the year 3 distribution ($100x) over USP's former adjusted basis in the property ($0). TFC, because of USS's gain recognition under paragraph (f)(4)(i)(A) of this section, reduces (but not below zero) the portion of its earnings and profits and gross income arising by reason of the year 3 distribution by the amount of such gain under paragraph (f)(2)(i) of this section. Specifically, because the year 3 distribution requires USS to recognize $100x of gain, TFC reduces the portion of its earnings and profits and gross income that arise by reason of the year 3 distribution, which is $100x (the excess of the fair market value of the transferred IP ($100x) over TFC's adjusted basis in the transferred IP ($0)), by $100x (the amount of gain USS recognizes pursuant to paragraph (f)(4)(i)(A) of this section). As a result, after taking into account the reduction, TFC has no earnings and profits or gross income that arise by reason of the year 3 distribution. Furthermore, USS may establish an account receivable from TFC equal to $100x under paragraph (f)(2)(ii) of this section. Additionally, and as described in paragraph (f)(6)(ii)(A)(2) of this section (*Example 1*), pursuant to paragraph (f)(4)(i)(B)(*1*) of this section, USS recognizes a deemed payment for the portion of USS's taxable year during which TFC held the transferred IP, and the required adjustments described in paragraph (c)(2)(ii) of this section and § 1.367(d)–1T(c)(2) apply to this deemed payment. After taking these consequences into account, pursuant to paragraph (f)(4)(i)(B)(*2*) of this section, the transferred IP is no longer subject to section 367(d), this section, and § 1.367(d)–1T. Finally, pursuant to paragraph (f)(4)(iv)(B) of this section, USS's adjusted basis in the transferred IP is $100x, which is the fair market value of the transferred IP on the date of the year 3 distribution.

(C) *Example 3: Qualified domestic person's basis in intangible property when intangible property is repatriated in an exchange described in section 351*(*b*)—(*1*) *Facts.* The facts are the same as in paragraph (f)(6)(ii)(A) of this section (*Example 1*), except that the transfer of stock of TFC to USS in year 2 does not occur and instead of the year 3 liquidation, in year 3 TFC transfers the intangible property to USS (a qualified domestic person as defined in paragraph (f)(4)(iii) of this section) in an exchange described in section 351(b) pursuant to which TFC recognizes $50x of gain and USP recognizes $50x of gain under paragraph (f)(4)(i)(A) of this section (the ''year 3 exchange'').

(*2*) *Analysis.* Pursuant to paragraph (f)(4)(iv)(A) of this section, USS's adjusted basis in the intangible property is $50x, which is the amount equal to the lesser of USP's former adjusted basis in the property ($0) or TFC's adjusted basis in the property ($0), increased by the greater of the amount of gain recognized by USP under paragraph (f)(4)(i)(A) of this section ($50x) or the amount of gain recognized by TFC upon the year 3 exchange ($50x).

(D) *Example 4: Repatriation as part of a series of related transactions culminating in transfer to a foreign corporation*—(*1*) *Facts.* The facts are the same as in paragraph (f)(6)(ii)(A)(1) of this section (*Example 1*), except that the year 3 liquidation occurs as part of a series of related transactions pursuant to which USS transfers the transferred IP that it receives from TFC to a related foreign corporation (FC1) in exchange for stock in FC1.

(*2*) *Analysis.* Because the year 3 liquidation occurs as part of a series of related transactions pursuant to which the transferred IP is ultimately contributed to a FC1, a foreign corporation, and because a foreign corporation is not a qualified domestic person pursuant to paragraph (f)(4)(iii) of this section, then, under paragraph (f)(4)(v) of this section, the year 3 liquidation is not treated as a subsequent disposition described in paragraph (f)(4)(i) of this section, but is instead treated as a subsequent disposition described in paragraph (f)(3) of this section.

(E) *Example 5: Repatriation as part of a series of related transactions culminating in transfer to a qualified domestic person*—(*1*) *Facts.* The facts are the same as in paragraph (f)(6)(ii)(B)(1) of this section (*Example 2*), except that the year 3 distribution occurs as part of a series of related transactions pursuant to which USS disposes of the transferred IP that it receives from TFC to USP.

(*2*) *Analysis.* Because the year 3 distribution occurs as part of a series of related transactions pursuant to which the transferred IP is distributed to USP, and because USP is a qualified domestic person pursuant to paragraph (f)(4)(iii) of this section, paragraph (f)(4)(v) of this section does not prevent paragraph (f)(4)(i) of this section from applying to the year 3 distribution. Accordingly, the consequences under section 367(d) of the year 3 distribution are the same as those described in paragraph (f)(6)(ii)(B)(2) of this section (Example 2), and the consequences of the subsequent disposition of the transferred IP by USS to USP are determined after applying paragraph (f)(4) of this section to the transfer of the transferred IP by TFC to USS.

(g) *Special rules*—(1) *Establishment of accounts receivable.* For further guidance, see § 1.367(d)–1T(g)(1).

(2) *Election to treat transfer as sale.* For further guidance, see § 1.367(d)–1T(g)(2) introductory text.

* * * * *

(ii) For further guidance, see § 1.367–1T(g)(2)(ii) through (g)(2)(iii)(D).

(iii) [Reserved]

(A) through (D) [Reserved]

* * * * *

(4) *Coordination with section 482.* For further guidance, see § 1.367(d)–1T(g)(4).

(5) *Determination of fair market value.* For further guidance, see § 1.367(d)–1T(g)(5).

(6) *Anti-abuse rule.* For further guidance, see § 1.367(d)–1T(g)(6).

(h) *Related person.* For further guidance, see § 1.367(d)–1T(h) introductory text and (h)(1).

(1) [Reserved]

(2) For further guidance, see § 1.367(d)–1T(h)(2) introductory text and (h)(2)(i).

(i) [Reserved]

(ii) Section 1563 applies (for purposes of section 267(f)) without regard to section 1563(b)(2).

(i) *Effective date.* For further guidance, see § 1.367(d)–1T(i).

(j) *Applicability dates*—(1) *In general.* This section applies to transfers occurring on or after September 14, 2015, and to transfers occurring before September 14, 2015, resulting from entity classification elections made under § 301.7701–3 of this chapter that are filed on or after September 14, 2015. For transfers occurring before this section is applicable, see § 1.367(d)–1T as contained in 26 CFR part 1 revised as of April 1, 2016.

(2) *Certain subsequent dispositions of intangible property.* Paragraphs (c)(2)(ii), (e)(2)(ii), (f)(2) through (5), and (h)(2)(ii) of this section apply to subsequent dispositions of intangible property occurring on or after [date of publication of final regulations in the **Federal Register**]. For subsequent dispositions of intangible property occurring before

[date of publication of final regulations in the **Federal Register**], see § 1.367(d)–1T (as contained in 26 CFR part 1, revised as of April 1, 2022).

§ 1.367(d)–1T [Amended]

■ **Par. 4.** Section 1.367(d)–1T is amended by:
■ 1. Removing ''; and'' at the end of paragraph (c)(2)(i) and adding a period in its place.
■ 2. Removing and reserving paragraphs (c)(2)(ii), (e)(2)(ii), and (f)(2) and (3).
■ 3. Removing ''; and'' at the end of paragraph (h)(2)(i) and adding a period in its place.
■ 4. Removing and reserving paragraph (h)(2)(ii).

§ 1.367(e)–2 [Amended]

■ **Par. 5.** Section 1.367(e)–2 is amended by removing the language ''section 936(h)(3)(B)'' in the last sentence of paragraph (b)(2)(i)(B) and adding the language ''section 367(d)(4)'' in its place.

■ **Par. 6.** Section 1.904–4 is amended by adding paragraph (f)(2)(vi)(D)(*4*) and revising paragraph (q)(3) to read as follows:

§ 1.904–4 Separate application of section 904 with respect to certain categories of income.

* * * * *

(f) * * *

(2) * * *

(vi) * * *

(D) * * *

(4) *Multiple transfers of intangible property.* If the same intangible property is transferred in a series of transfers described in paragraph (f)(2)(vi)(D)(*1*) of this section, each successive transfer is separately subject to the provisions of paragraph (f)(2)(vi)(D)(*1*) and will not terminate or otherwise affect the application of paragraph (f)(2)(vi)(D)(*1*) to a prior transfer described in paragraph (f)(2)(vi)(D)(*1*).

* * * * *

(q) * * *

(3) Except as provided in the following sentence, paragraph (f) of this section applies to taxable years that begin after December 31, 2019, and end on or after November 2, 2020. Paragraph (f)(vi)(D)(*4*) of this section applies to taxable years that begin on or after [date of publication of final regulations in the **Federal Register**].

■ **Par. 7.** Section 1.951A–2 is amended by revising paragraph (c)(2) to read as follows:

§ 1.951A–2 Tested income and tested loss.

* * * * *

(c) * * *

(2) *Determination of gross income and allowable deductions.* For purposes of determining tested income and tested loss, the gross income and allowable deductions of a controlled foreign corporation for a CFC inclusion year are determined under the rules of § 1.952–2 for determining the subpart F income of the controlled foreign corporation, except, for a controlled foreign corporation which is engaged in the business of reinsuring or issuing insurance or annuity contracts and which, if it were a domestic corporation engaged only in such business, would be taxable as an insurance company to which subchapter L of chapter 1 of the Code applies, substituting ''the rules of sections 953 and 954(i)'' for ''the principles of §§ 1.953–4 and 1.953–5'' in § 1.952–2(b)(2).

* * * * *

■ **Par. 8.** Section 1.951A–7 is amended by adding paragraph (e) to read as follows:

§ 1.951A–7 Applicability dates.

* * * * *

(e) *Determination of gross income and allowable deductions.* Section 1.951A–2(c)(2) applies to taxable years of foreign corporations ending on or after [date of publication of final regulations in the **Federal Register**], and to taxable years of United States shareholders in which or with which such taxable years end. For taxable years of foreign corporations ending before [date of publication of final regulations in the **Federal Register**], and to taxable years of United States shareholders in which or with which such taxable years end, see § 1.951A–2(c)(2)(i) and (ii) as contained in 26 CFR part 1, revised as of April 1, 2022.

■ **Par. 9.** Section 1.6038B–1 is amended by:
■ 1. Removing reserved paragraphs (d)(1) through (1)(iii).
■ 2. Adding paragraphs (d) heading and (d)(1) introductory text and reserved paragraphs (d)(1)(i) through (iii).
■ 3. Removing reserved paragraphs (d)(1)(viii) through (d)(2).
■ 4. Adding paragraphs (d)(1)(viii), (d)(2), and (g)(8).

The additions read as follows:

§ 1.6038B–1 Reporting of certain transfers to foreign corporations.

* * * * *

(d) *Transfers subject to section 367 (d)*—(1) *Initial transfer.* For further guidance, see § 1.6038B–1T(d)(1) introductory text through (d)(1)(iii).

(i) through (iii) [Reserved]

* * * * *

(viii) *Other intangibles.* For further guidance, see § 1.6038B–1T(d)(1)(viii).

(2) *Subsequent transfers.* For additional, see § 1.6038B–1T(d)(2) introductory text through (d)(2)(ii).

(i) through (ii) [Reserved]

(iii) *Subsequent transfer.* Except for a subsequent transfer described in paragraph (d)(2)(iv) of this section, provide the following information concerning the subsequent transfer:

(A) For further guidance, see § 1.6038B–1T(d)(2)(iii)(A) through (C).

(B) through (C) [Reserved]

(iv) *Subsequent transfer of intangible property to a qualified domestic person.* Provide the following information concerning a subsequent transfer of intangible property described in § 1.367(d)–1(f)(4)(i):

(A) A statement providing that § 1.367(d)–1(f)(4)(i)(B) applies to the subsequent transfer;

(B) A general description of the subsequent transfer and any wider transaction of which it forms a part, including the U.S. transferor's former adjusted basis in the intangible property and the transferee foreign corporation's adjusted basis in the intangible property (as determined immediately before the subsequent transfer), the amount and computation of any gain recognized by the U.S. transferor under § 1.367(d)–1(f)(4)(i)(A), and a description of whether the intangible property was, or is expected to be, subsequently transferred to one or more other persons (as described in § 1.367(d)–1(f)(4)(v));

(C) A description of the intangible property;

(D) A copy of the Form 926 with respect to the original transfer of the intangible property and any attachments identifying the intangible property as within the scope of section 367(d);

(E) The name, address, and taxpayer identification number of the qualified domestic person that receives the intangible property, including a statement describing the relationship between the U.S. transferor and the qualified domestic person, and, if applicable, such information regarding any other persons described in § 1.367(d)–1(f)(4)(v); and

(F) Any other information as may be prescribed by the Commissioner in publications, forms, instructions, or other guidance.

* * * * *

(g) * * *

(8) Paragraphs (d)(2)(iii) introductory text and (d)(2)(iv) of this section apply to transfers occurring on or after [date of publication of final regulations in the **Federal Register**].

■ **Par. 10.** Section 1.6038B–1T is amended by revising paragraph (d)(2)(iii) introductory text to read as follows:

§ 1.6038B–1T Reporting of certain transactions to foreign corporations (temporary).

* * * * *

(d) * * *

(2) * * *

(iii) *Subsequent transfer.* For further guidance, see § 1.6038B–1(d)(2)(iii) introductory text:

* * * * *

Douglas W. O'Donnell,

Deputy Commissioner for Services and Enforcement.

[FR Doc. 2023–08843 Filed 5–2–23; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 236

[Docket ID: DOD–2019–OS–0112]

RIN 0790–AK86

Department of Defense (DoD) Defense Industrial Base (DIB) Cybersecurity (CS) Activities

AGENCY: Office of the DoD Chief Information Officer, Department of Defense (DoD).

ACTION: Proposed rule.

SUMMARY: The DoD is proposing revisions to the eligibility criteria for the voluntary Defense Industrial Base (DIB) Cybersecurity (CS) Program. These revisions will allow a broader community of defense contractors to benefit from bilateral information sharing as when this proposed rule is finalized all defense contractors who are subject to mandatory cyber incident reporting will be able to participate. DoD is also proposing changes to definitions and some technical corrections for readability.

DATES: Comments must be received by June 20, 2023.

ADDRESSES: Please submit comments on this proposed rule, identified by 32 CFR part 236, Docket ID: DOD–2019–OS–0112 and/or by Regulatory Information Number (RIN) 0790–AK86, by any of the following methods:

- *Federal Rulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Department of Defense, Office of the Assistant to the Secretary of Defense for Privacy, Civil Liberties, and Transparency, Regulatory Directorate, 4800 Mark Center Drive, Mailbox #24, Suite 08D09, Alexandria, VA 22350–1700.

Instructions: The general policy for comments is to make these submissions available for public viewing as they are received without change, including any personal identifiers or contact information provided by the commenter.

FOR FURTHER INFORMATION CONTACT:

- Stacy Bostjanick, Chief Defense Industrial Base Cybersecurity, Office: 703–604–3167.
- *DIB CS Program Management Office: OSD.DIBCSIA@mail.mil.*

Instructions: DO NOT submit comments to this email address.

SUPPLEMENTARY INFORMATION:

Background and Authority

The Defense Industrial Base (DIB) means the Department of Defense, Government, and private sector worldwide industrial complex with capabilities to perform research and development, design, produce, and maintain military weapon systems, subsystems, components, or parts to satisfy military requirements. The DIB Cybersecurity Program is a voluntary program to enhance and supplement participants' capabilities to safeguard DoD information that resides on, or transits, DIB unclassified information systems. The program encourages greater threat information sharing to complement mandatory aspects of DoD's DIB cybersecurity activities which are contractually mandated through Defense Federal Acquisition Regulation Supplement (DFARS) 252.204–7012, Safeguarding Covered Defense Information and Cyber Incident Reporting.[1] This program supports and complements DoD-specific authorities at 10 U.S.C. 2224 and the Federal Information Security Management Act (FISMA) (44 U.S.C. 3541 *et seq.*). Cyber threat information sharing activities under this proposed rule also fulfill important elements of DoD's critical infrastructure protection responsibilities, as the sector risk management agency for the DIB (see Presidential Policy Directive 21 (PPD–21),[2] ''Critical Infrastructure Security and Resilience''). Expanding eligibility requirements for the DIB CS Program will augment DoD's information sharing activities with the DIB.

Currently, the DIB CS Program has the following objectives:

- Establish a voluntary, mutually acceptable framework to protect information from unauthorized access.
- Protect the confidentiality of information exchanged to the maximum extent authorized by law.
- Create a trusted environment to maximize network defense and remediation efforts by:

1. Sharing cyber threat information and incident reports.
2. Providing mitigation/remediation strategies and malware analysis.

This program is part of DoD's larger portfolio of work to protect DoD information handled by the DIB by understanding and sharing information, building security partnerships, implementing long-term risk management programs, and maximizing efficient use of resources. It supports two-way information sharing and maintains meaningful relationships and frequent dialogue across the diverse array of eligible defense contractors. For eligible defense contractors, the program maintains a capability for companies to access classified government cyber threat information providing additional context to better understand the cyber threats targeting their networks and information systems.

In May 2012, DoD published an interim final rule establishing the voluntary DIB CS Program and the bilateral information sharing model still used today.[3] The 2012 rule established a voluntary cyber threat information sharing program for cleared defense contractors (CDC) with the ability to safeguard classified information, estimated at 2,650 in 2012. Under the rule cleared defense contractor is defined as a private entity granted clearance by DoD to access, receive, or store classified information for the purpose of bidding for a contract or conducting activities in support of any program of DoD. The 2012 rule stated DoD would maintain a website to facilitate the following aspects of program participation: (1) sharing information regarding eligibility and participation in the program with potential participants, (2) applying to the program online, and (3) executing the necessary agreements with the Government. DoD has established this capability as an online portal referred to as ''DIBNet,'' located at *https://dibnet.dod.mil.* A final rule responding to public comments was published in October 2013.[4] In October 2015, responding to new statutory requirements for cyber incident reporting for DoD contractors,

[1] *https://www.ecfr.gov/current/title-48/chapter-2/subchapter-H/part-252/subpart-252.2/section-252.204-7012.*

[2] *https://obamawhitehouse.archives.gov/the-press-office/2013/02/12/presidential-policy-directive-critical-infrastructure-security-and-resil.*

[3] 77 FR 27615, May 11, 2012 (*https://www.govinfo.gov/content/pkg/FR-2012-05-11/pdf/2012-10651.pdf*).

[4] 78 FR 62430, October 22, 2013 (*https://www.govinfo.gov/content/pkg/FR-2013-10-22/pdf/2013-24256.pdf*).

subcontractors, and those providing operationally critical support, DoD published another interim final rule [5] to expand eligibility to all cleared defense contractors (estimated at 8,500 in 2015 and 12,000 in 2022), subject to program eligibility requirements. The 2015 rule removed the safeguarding requirement to participate in the program. The rule also removed the mandatory program eligibility requirement to have or acquire a Communications Security (COMSEC) account [6] and obtain access to DoD's secure voice and data transmission systems, although participants still have to fulfill these requirements to receive classified cyber threat information electronically. A final rule responding to public comments was published in October 2016.[7]

Discussion of the Proposed Rule

With this rule, the Department proposes to expand eligibility requirements to allow greater program participation and increase the benefits of bilateral information sharing, which helps protect DoD controlled unclassified information from cyberattack, as well as to better align the voluntary DIB CS Program with DoD's mandatory cyber incident reporting requirements. The current eligibility requirements, based on the October 2016 rule, requires a company to be a cleared defense contractor [8] who:

- Has DoD-approved medium assurance certificates; [9]
- Has an existing facility clearance [10] to at least the Secret level;
- Can execute the standardized Framework Agreement [11] provided to interested contractors after the Department has verified the DIB company is eligible.

The program has experienced steady growth, with the annual number of applications tripling since 2016 (80 total applications received in 2016, 266 total applications received in 2022). It has also seen a steady increase in the percentage of defense contractors who are interested in participating but do not meet current eligibility requirements. The percentage of applications received from ineligible defense contractors has risen at an average rate of 5% per year since 2016; 10% of applications received in 2016 were from ineligible defense contractors, while 45% of applicants in 2022 were ineligible. This steady increase in ineligible applicants indicates an increasing desire amongst defense contractors to participate in a cyber threat information sharing program.

In addition, the Department has actively engaged defense associations, universities, and companies in the DIB, as well as participated in many public forums discussing cyber threats and the way forward. The overwhelming feedback was for the Department to facilitate engagement with the broader community of defense contractors beyond just the cleared defense community. In general, smaller defense contractors have fewer resources to devote to cybersecurity, which may provide a vector for adversaries to access information critical to national security. In addition, the Department is working on providing more tailored threat information to support the needs of a broader community of defense contractors with varying cybersecurity capabilities. The gap in eligibility in the current program, feedback from interested but ineligible contractors, a vulnerable DoD supply chain, and a pervasive cyber threat have prompted DoD to propose revising the eligibility requirements of the DIB CS Program to allow participation by non-cleared defense contractors.

The maximum number of defense contractors estimated to be subject to mandatory cyber incident reporting under DFARS clause 252.204–7012 is 80,000. The presence of the clause in a contract does not establish that covered defense information is shared. DoD is working on reporting mechanisms to better assess contractors managing covered defense information. The population of defense contractors in possession of covered defense information and subject to mandatory incident reporting requirements far exceeds the population of defense contractors currently eligible to participate in the voluntary DIB CS Program. With the proposed changes to the eligibility criteria, an estimated additional 68,000 defense contractors will be eligible to participate in the voluntary DIB CS Program. Based on prior participation statistics, it is estimated that about 10% of the eligible contractors (12,000 + 68,000 = 80,000) will actually apply to join the voluntary DIB CS Program ($80{,}000 \times 0.10 = 8{,}000$).

Currently, the DIB CS Program has approximately 1,000 cleared defense contractors participating in the program. Program participants have access to technical exchange meetings, a collaborative web platform (DIBNet-U), and threat products and services through the DoD Cyber Crime Center (DC3). DC3 implements the program's operations by sharing cyber threat information and intelligence with the DIB, and offering a variety of products, tools, services, and events. DC3 serves as the single clearinghouse for unclassified Mandatory Incident Reports (MIRs) and voluntary threat information sharing reports.

Changes to Definitions

In addition to the program eligibility changes described above, DoD is also proposing the following changes.

§ 236.2 Definitions

1. Access to media—This definition is being removed as it is no longer used in the rule text.

3. DIB CS Program participant—This definition has been revised to align with the revised eligibility requirements set forth in this proposed rule.

4. Government furnished information (GFI)—This definition was revised to adopt the convention of referring to the DIB CS Program with a capital 'P'.

Other Proposed Changes

DoD is amending § 236.5 (DoD's DIB CS program) in order to align the program description with the revised eligibility requirements. As a result, references to cleared defense contractors have been replaced with contractors that own or operate a covered contractor information system. Security clearance information is only collected, when applicable, if a company elects to participate in classified information sharing. In addition, the language stating participation is typically three to ten company-designated points of contact (POC) has been removed, to avoid confusion regarding the number of POCs, as some larger companies may wish to nominate a larger number of

[5] 80 FR 59581, October 2, 2015 (*https://www.govinfo.gov/content/pkg/FR-2015-10-02/pdf/2015-24296.pdf*).

[6] The National Security Agency administers COMSEC accounts.

[7] 81 FR 68312, October 4, 2016 (*https://www.govinfo.gov/content/pkg/FR-2016-10-04/pdf/2016-23968.pdf*).

[8] 32 CFR 236.2 defines cleared defense contractor to mean a subset of contractors cleared under the National Industrial Security Program (NISP) who have classified contracts with the DoD.

[9] The DoD has established the External Certification Authority (ECA) program to support the issuance of DoD-approved certificates to industry partners and other external entities and organizations. The ECA program is designed to provide the mechanism for these entities to securely communicate with the DoD and authenticate to DoD Information Systems. [*https://public.cyber.mil/eca/*].

[10] Entities (including companies and academic institutions) engaged in providing goods or services to the U.S. Government involving access to or creation of classified information may be granted a Facility Clearance (FCL). The Defense Counterintelligence and Security Agency (DCSA) processes, issues, and monitors the continued eligibility of entities for an FCL. [*https://www.dcsa.mil/mc/isd/fc/*].

[11] Applicants to the DIB CS Program submit an application from *https://dibnet.dod.mil*. Once a company has been verified, the Framework Agreement is made available for review.

POCs and smaller companies may wish to nominate fewer.

DoD is amending § 236.7 (DoD's DIB CS program requirements) to remove the requirement that a company have an existing active facility clearance (FCL) to at least the Secret level granted under 32 CFR part 117, National Industrial Security Program Operating Manual (NISPOM),[12] to be eligible to participate in the DIB CS Program. In addition, references to cleared defense contractors have been replaced with contractors that own or operate a covered contractor information system.

A foundational element of the activities described in this part is the recognition that the information shared between DoD and DIB CS Program participants pursuant to the DIB CS Program includes extremely sensitive information that requires protection. For additional information regarding the Government's safeguarding of information received from contractors that requires protection, see the Privacy Impact Assessment (PIA) for the DIB Cybersecurity Activities located at: *https://dodcio.defense.gov/Portals/0/Documents/DIB_PIA.pdf.* The PIA provides detailed procedures for handling personally identifiable information (PII), attributional information about the strengths or vulnerabilities of specific covered contractor information systems, information providing a perceived or real competitive advantage on future procurement action, and contractor information marked as proprietary or commercial or financial information. In addition, personnel information is covered by Office of the Secretary of Defense (OSD) System of Records Notice (SORN) DCIO 01 (*https://dpcld.defense.gov/Portals/49/Documents/Privacy/SORNs/OSDJS/DCIO-01.pdf*). No changes to the PIA or SORN are being proposed in conjunction with this proposed rule.

Expected Impact of the Proposed Rule

Costs

DoD believes the cost impact of the proposed changes to this proposed rule is not significant, as the changes primarily expand the availability of the established DIB CS Program to additional defense contractors. The newly eligible population of defense contractors may incur costs to familiarize themselves with the rule and those who elect to participate in the program will incur costs related to program participation. The Government will continue to incur costs related to operating the program. The DIB CS Program conducts outreach activities to defense contractors through press releases, participation in defense-oriented conferences, speaking engagements, and through digital media. The program will leverage pre-established channels to message changes to the program and engage with the eligible population of defense contractors. Based on the program growth experienced that during the last phase of program expansion the program is forecasting annual growth at just over 1% of the eligible population. At a growth rate of 1% per year it will take the program approximately 10 years to achieve the estimated 10% participation rate of the eligible DIB.

Costs to DIB Participants

In order to join the DIB CS Program there is an initial labor burden for a defense contractor to familiarize themselves with the rule and subsequently apply to the program and provide POC information. In total, if it takes each contractor 30 minutes to read and familiarize him/herself with the rule, it will take contractors 4,000 hours to familiarize themselves with the rule (8,000 participants × .5 = 4,000 hours). At an hourly wage of $108.92, the total cost incurred by contractors for rule familiarization will amount to $108,920 dollars ($108.92 × .5 hours = $54.46 × 4,000 hours = $217,840). The hourly labor cost is based on the mean wage estimate from the Bureau of Labor Statistics for an Information Security Analysts, Occupational Employment and Wages, May 2021 and is covered under information collection 0704–0490. This hourly wage is adjusted upward by 100% to account for overhead and benefits, which implies a value of $108.92 per hour.

The estimated annual burden for a company to apply to the program or for a participating company to update POC information is $36.31, with a total annual cost to all participants of $319,498.67 at peak program participation. This calculation is based on 8,000 participants submitting an average of one application per year and 10% of the population (800 participants) submitting an update each year, with 20 minutes of labor per submission, at a cost of $108.92 per hour ($36.31 ($108.92 × ⅓ hours) × 8,800 events = $319,498.67).

There is an estimated annual burden projected at $544.60 for defense contractors voluntarily sharing cyber threat information. This is based on a defense contractor electing to submit an average of five informational reports per year with two hours of labor per voluntary submission, at a cost of $108.92 per hour ($108.92 × 2 hours each = $217.84 × 5 reports = $1,089.20). It is estimated that 1% of the newly eligible population will elect to join the DIB CS Program annually, which currently has approximately 1,000 participants, with program growth plateauing at 10% of the population by Year 9. The table below shows the costs to industry to voluntarily sharing cyber threat information over a 9-year period. If, in the first year of the program expanding there are 980 participants and 800 new participants join the program, there will be a total of 1,780 participants. Assuming each participant responds five times, this totals 8,900 annual responses times $217.84 per response and will equal $1,938,776 in total annual cost to participants, which is covered in information collection 0704–0489.

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9
DIB CS Participants	1,780	2,580	3,380	4,180	4,980	5,780	6,580	7,380	8,000
Voluntary Reports Received	8,900	12,900	16,900	20,900	24,900	28,900	32,900	36,900	40,000
Annual Cost	$1,938,776	$2,810,136	$3,681,496	$4,552,856	$5,424,216	$6,295,576	$7,166,936	$8,038,296	$8,713,600

In addition, DIB CS Program participants may choose to attend meetings in conjunction with the DIB CS Program. All new participants are invited to attend an orientation session and all existing participants are invited to attend meetings on a quarterly basis. If a defense contractor chooses to send an employee to a day-long meeting each quarter, the defense contractor would incur a cost of $1,742 ($108.92 × 8 hours = $871.36 × 4 meetings = $3,485.44).

[12] *https://www.ecfr.gov/current/title-32/subtitle-A/chapter-I/subchapter-D/part-117.*

Costs to the Government

The DoD has identified general areas of costs related to the operation of this program. First, DoD incurs costs to implement this program operationally by responding to inquiries, processing application submissions and collecting, sharing, and managing POC information for program administration and management purposes. Second, DoD incurs costs to collect, analyze, and disseminate threat information.

DoD responds to an average of 2,000 questions each year and these responses are estimated to take 20 minutes per response. If it takes 20 minutes to respond to each question, it will take 667 hours to respond to questions. At an hourly wage of $51.16,[13] it will cost the DoD $34,107 dollars to respond to questions ($51.16 × (.333 × 2,000) = $34,107). Costs to the government are incurred when a company applies to the DIB CS Program to validate and store POC information and to perform follow-up activities with a company when the information is outdated. The processing time for these activities is estimated to be one hour per company. If 8,000 companies participate in the program and 10% of the companies update information with the program annually the labor cost to the government is expected to be $450,208 = (8,800 × $51.16).

In addition, there is a cost incurred by the DoD to receive cyber threat information submitted by defense contractors to have it analyzed by cyber threat experts at DC3. By year 9 of the expanded program, it is estimated DC3 will receive 40,000 responses per year, based on the estimate that each participating company elects to submit 5 informational reports (8,000 participants × 5 reports). Each product takes approximately two hours to create and incurs an hourly labor cost of $51.16 per hour. This equals $102.32 (2 hours × 51.16) per response. The labor cost to the government is forecasted to be $4,092,800 annually after 9 years of growth. In addition to processing cyber threat information, the DoD incurs operational and maintenance costs for the system receiving and storing cyber threat information. This system costs the DoD $5,100,000 annually to maintain (covered under information collection 0704–0489).

Benefits

This program benefits the Department by increasing awareness and improving assessments of cyber incidents that may affect mission critical capabilities and services. It continues to be an important element of the Department's comprehensive effort to defend DoD information, protect U.S. national interests against cyber-attacks, and support military operations and contingency plans worldwide. Once a defense contractor joins the program, they are encouraged to share information, including cyber threat indicators, that they believe may be of value in alerting the Government and others, as appropriate, of adversary activity to enable the development of mitigation strategies and proactively counter threat actor activity. DC3 develops written products that include analysis of the threat, mitigations, and indicators of adversary activity. Even cyber incidents that are not compromises of covered defense information may be of interest to DoD for situational awareness purposes. This information is disseminated as anonymized threat products that are shared with authorized DoD personnel, other Federal agencies, and company-designated POCs participating in the DIB CS Program. With the revisions to the eligibility criteria, the Department will be able to reduce the impact of cyber threat activity on DIB networks and information systems and, in turn, preserve its technological advantage and protect DoD information and warfighting capabilities. The mitigation of the cyber threat targeting defense contractors reinforces the nation's national security and economic vitality.

For DIB participants, this program provides valuable cyber threat information they cannot obtain from anywhere else and technical assistance through analyst-to-analyst exchanges, mitigation and remediation strategies, and cybersecurity best practices in a collaborative environment. The shared unclassified and classified cyber threat information is used to bolster a company's cybersecurity posture and mitigate the growing cyber threat. The program's tailored support for small, mid-size, and large companies with varying cybersecurity maturity levels is an asset for participants. The program remains a key element of DoD's cybersecurity efforts by providing services to help protect DIB CS Program participants and the sensitive DoD information they handle.

Alternatives

Alternative #1

Maintain status quo with the ongoing voluntary cybersecurity program for cleared defense contractors.

Reason for Not Selecting Alternative #1

This option is not selected as it does not allow DoD to increase bilateral information sharing to bolster DIB cybersecurity and safeguard DoD information transiting on DIB networks. In addition, the population of defense contractors with mandatory reporting requirements would continue to exceed those eligible to participate in the DIB CS Program. Companies that submit mandatory reports but are not eligible for the DIB CS Program would continue to be excluded from receiving cyber threat information and technical assistance.

Alternative #2

DoD posts generic cyber threat information and cybersecurity best practices on a publicly accessible website without directly engaging participating companies.

Reason for Not Selecting Alternative #2

This alternative was not selected as companies already have access to open-source cyber threat information and best practices from multiple sources in the public sector. This alternative does not afford access by defense contractors to government-furnished cyber threat information, specifically tailored for the DIB. In addition, this alternative does not enable defense contractor interaction with DC3.

Alternative #3

Revise eligibility requirements to permit all defense contractors who own or operate a covered contractor information system (approximately 80,000 defense contractors) to participate in the DIB CS Program. Using the 10% estimation used for past program participation, the program is forecasted to grow to approximately 8,000 defense contractors.

Reason for Selecting Alternative #3

The revised eligibility criteria allow DoD to perform outreach to a broader DIB community. Being able to share pertinent cyber threat information with the DIB will increase both the DoD and defense contractors' knowledge of the cyber threat landscape. Giving DoD the ability to have greater visibility over issues affecting unclassified networks will allow DoD to share pertinent alerts and threat information with a larger number of DIB organizations. DoD believes that revising the eligibility criteria to apply to contractors that own or operate covered contractor information systems is an important step in managing DoD's operational risk because it will allow additional companies to begin receiving cyber

[13] This is based upon the 2022 General Schedule (GS) pay scale for a GS–9 Step 5 and is adjusted upward by 100% to adjust for overhead and benefits.

threat information to inform and harden their cybersecurity posture. DIB organizations that do not meet the current eligibility requirements to be in a DoD-sponsored cyber threat information sharing program have expressed interest in this change as noted previously by the growing percentage of ineligible applicants.

Regulatory Compliance Analysis

A. Executive Order 12866, ''Regulatory Planning and Review'' and Executive Order 13563, ''Improving Regulation and Regulatory Review''

Executive Order 12866 direct agencies to assess all costs, benefits, and available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health, safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This proposed rule has been designated ''significant,'' under Executive Order 12866.

B. Congressional Review Act (5 U.S.C. 801 et seq.)

Pursuant to the Congressional Review Act, this proposed rule has not been designated a major rule, as defined by 5 U.S.C. 804(2). This proposed rule will not have an economic effect above the $100 million threshold defined in 5 U.S.C. 804(2) or spur a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or have significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets.

C. Public Law 96–354, ''Regulatory Flexibility Act'' (5 U.S.C. 601)

The Office of the DoD Chief Information Officer certifies that this proposed rule is not subject to the Regulatory Flexibility Act (5 U.S.C. 601) because it would not, if promulgated, have a significant economic impact on a substantial number of small entities. This proposed rule will have a significant positive impact on small entities that will become eligible to participate in and receive benefits through the DIB CS Program. For DIB participants, this program provides cyber threat information and technical assistance through analyst-to-analyst exchanges, mitigation and remediation strategies, and cybersecurity best practices in a collaborative environment. The shared threat information is used to bolster a company's cybersecurity posture and mitigate the growing cyber threat. The program's tailored support for small, mid-size, and large companies with varying cybersecurity maturity levels is an asset for participants.

Participation in the DIB CS Program is voluntary. Program application and participation costs are described in the cost analysis section of this proposed rule. These costs are voluntarily incurred and associated with the labor and resource costs to complete the required program paperwork, including execution of the Framework Agreement, to submit information to the Government, and to receive information from the Government. The costs associated with applying to the DIB CS Program are associated exclusively with labor costs and estimated to be $18.15 per company. None of the program's offering come at an additional fee to DIB participants and additional costs related to participation are estimated based on the time investment (labor hours) required to obtain the benefits as described in the cost analysis of this preamble. Therefore, the Regulatory Flexibility Act, as amended, does not require us to prepare a regulatory flexibility analysis.

D. Sec. 202, Public Law 104–4, ''Unfunded Mandates Reform Act''

Section 202 of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1532) requires agencies to assess anticipated costs and benefits before issuing any rule whose mandates require spending in any one year of $100 million in 1995 dollars, updated annually for inflation. When the Federal Government passes legislation requiring a State, local, or tribal government to perform certain actions or offer certain programs but does not include any funds for the actions or programs in the law, an unfunded mandate results. This proposed rule will not mandate any requirements for State, local, or tribal governments, and will not mandate private sector incurred costs above the $100 million threshold defined in 2 U.S.C. 1532.

E. Public Law 96–511, ''Paperwork Reduction Act'' (44 U.S.C. Chapter 35)

This proposed rule contains the following information collection requirements under the Paperwork Reduction Act (PRA) of 1995.

- 0704–0489, ''DoD's Defense Industrial Base (DIB) Cybersecurity (CS) Activities Cyber Incident Reporting,''
- 0704–0490, ''DoD's Defense Industrial Base (DIB) Cybersecurity (CS) Points of Contact (POC) Information.''

With the revisions in eligibility criteria, DoD expects the burden associated with both collections to increase as additional defense contractors join the DIB CS Program and additional cyber threat information is reported. DOD is requesting comments on both collections as part of this proposed rule. Additional information regarding these collections of information—including all background materials—can be found at *https://www.reginfo.gov/public/do/PRAMain* by using the search function to enter either the title of the collection or the Office of Management and Budget (OMB) Control Number.

Comments are invited on: (a) whether the proposed collections of information are necessary for the proper performance of the functions of DoD, including whether the information will have practical utility; (b) the accuracy of the estimate of the burden for both information collections; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden on respondents, including the use of automated collection techniques or other forms of information technology. Specific information on both collections is below.

DoD's Defense Industrial Base (DIB) Cybersecurity (CS) Activities Cyber Incident Reporting—OMB Control Number 0704–0489

Title: DoD's Defense Industrial Base (DIB) Cybersecurity (CS) Activities Cyber Incident Reporting.

Type of Request: Revision.

Number of Participants: Number of DoD contractors eligible to participate in the voluntary program is 80,000. DoD estimates that approximately 1% of the newly eligible population will elect to join the program each year with program growth plateauing at approximately 10% of the population by Year 9. Based on this estimate, after the first three years of the program expansion, 2,400 defense contractors will join the existing 980 participating companies resulting in 3,380 defense contractors submitting voluntary cyber threat information reports.

Projected Responses per Participant: Five reports per participant.

Annual Total Responses: 16,900.

Average Burden per Response: Two hours.

Annual Total Burden Hours: 33,800 hours for all voluntary submissions.

Needs and Uses: DoD designated DC3 as the single focal point for receiving all cyber incident reporting affecting the unclassified networks of DoD contractors from industry and other government agencies. DoD collects cyber incident and threat reports using the Defense Industrial Base Network (DIBNet) portal (*https://dibnet.dod.mil*). Cyber threat reports are analyzed by experts at DC3 and they, in turn, develop written products that include analysis of the threat, mitigations, and indicators of adversary activity. These anonymized products are shared with authorized DoD personnel, authorized personnel from other Federal agencies, and authorized POCs from the DIB CS Program.

Affected Public: Business or other for-profit and not-for-profit institutions.

Frequency: On occasion.

Respondent's Obligation: Voluntary.

DoD's Defense Industrial Base (DIB) Cybersecurity (CS) Points of Contact (POC) Information—OMB Control Number 0704–0490

Title: DoD's Defense Industrial Base (DIB) Cybersecurity (CS) Activities Points of Contact (POC) Information.

Type of Request: Revision.

Number of Participants: DoD contractors impacted is 80,000. DoD estimates that approximately 1% of the newly eligible population (800 defense contractors) will elect to join the program each year with program growth plateauing at approximately 10% of the population by Year 9. Each year, approximately 10% of participating companies will report changes to company contacts. If 10% of the pre-existing companies (2,580 in year 2) submit updates to the POC information and 800 new companies join, by year 3 this would result in 1,058 annual updates.

Projected Responses per Participant: Initial collection is one per company with updates on a case-by-case basis.

Annual Total Responses: 1,058.

Average Burden per Response: 20 minutes.

Annual Total Burden Hours: 353 hours for all participants.

Needs and Uses: Defense contractors complete a program application and sign the DIB CS Program Framework to initiate participation. The Government will collect business POC information from all DIB CS Program participants on a one-time basis, with updates as necessary, to facilitate communications and the sharing of share unclassified and classified cyber threat information.

Affected Public: Business or other for-profit and not-for-profit institutions.

Frequency: On occasion.

Respondent's Obligation: Voluntary.

F. Executive Order 13132, ''Federalism''

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has federalism implications. This proposed rule will not have a substantial effect on State and local governments.

G. Executive Order 13175, ''Consultation and Coordination With Indian Tribal Governments''

Executive Order 13175 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct compliance costs on one or more Indian tribes, preempts tribal law, or effects the distribution of power and responsibilities between the Federal Government and Indian tribes. This proposed rule will not have a substantial effect on Indian tribal governments.

List of Subjects in 32 CFR Part 236

Government contracts, Security measures.

Accordingly, DoD proposes to amend 32 CFR part 236 as follows:

PART 236—DEPARTMENT OF DEFENSE (DoD) DEFENSE INDUSTRIAL BASE (DIB) CYBERSECURITY (CS) ACTIVITIES

■ 1. The authority citation for 32 CFR part 236 continues to read as follows:

Authority: 10 U.S.C. 391, 393, and 2224; 44 U.S.C. 3506 and 3544; 50 U.S.C. 3330.

■ 2. Revise the heading of 32 CFR part 236 to read as set forth above.

§ 236.1 [Amended]

■ 3. Amend § 236.1 by:

■ a. Removing ''eligible DIB participants'' and adding in its place ''eligible DoD contractors''.

■ b. Removing ''DIB CS program'' and adding in its place ''DIB CS Program'' wherever it appears.

■ c. Removing ''DIB CS participants'' and adding in its place ''DIB CS Program participants''.

■ d. Removing ''DIB participants' capabilities'' and adding in its place ''DIB CS Program participants' capabilities''.

§ 236.2 [Amended]

■ 4. Amend § 236.2 by:

■ a. Removing the definition of ''Access to media''.

■ b. In the definition of ''DIB participant'':

■ i. Removing ''DIB participant'' and adding in its place ''DIB CS Program participant''.

■ ii. Removing ''DIB CS program'' and adding in its place ''DIB CS Program''.

■ c. Removing ''DIB CS program'' in the definition of ''Government furnished information (GFI)'' and adding in its place ''DIB CS Program''.

§ 236.3 [Amended]

■ 5. Amend § 236.3 by:

■ a. Removing ''program'' and adding in its place ''Program participants'' in paragraph (b)(1).

■ b. Removing ''DIB CS program'' and adding in its place ''DIB CS Program'' in paragraph (c).

■ 6. Amend § 236.4 by:

■ a. Removing ''*http*'' and adding in its place ''*https*'' in paragraphs (b)(2), (c), and (d).

■ b. Removing ''*http://iase.disa.mil/pki/eca/Pages/index.aspx*'' and adding in its place ''*https://public.cyber.mil/eca/*'' in paragraph (e).

■ c. Revising paragraph (f).

■ d. Adding a comma after ''as appropriate'' in the first sentence in paragraph (g).

■ e. Removing ''paragraph (e)'' and adding in its place ''paragraph (i)'' in paragraph (k).

■ f. In paragraph (m)(4):

■ i. Removing ''DIB contractors'' and adding in its place ''defense contractors''.

■ ii. Removing ''DIB CS program'' and adding in its place ''DIB CS Program''.

■ g. Revising paragraph (p).

The revisions read as follows:

§ 236.4 Mandatory cyber incident reporting procedures.

* * * * *

(f) *Third-party service provider support.* If the contractor utilizes a third-party service provider (SP) for information system security services, the contractor may authorize the SP to report cyber incidents on behalf of the contractor.

* * * * *

(p) *Freedom of Information Act (FOIA).* Agency records, which may include qualifying information received from non-Federal entities, are subject to request under the Freedom of Information Act (5 U.S.C. 552). The Government will notify the non-Government source or submitter (*e.g.,* contractor or DIB CS Program participant) of the information in

accordance with the procedures in 32 CFR 286.10.

* * * * *

■ 7. Amend § 236.5 by:
■ a. Revising section heading and paragraph (a).
■ b. In paragraph (b):
■ i. Removing ''DIB CS program'' and adding in its place ''DIB CS Program''.
■ ii. Removing ''DIB participant'' and adding in its place ''DIB CS Program participant''.
■ c. In paragraph (c):
■ i. Removing ''DIB participant'' and adding in its place ''DIB CS Program participant''.
■ ii. Removing ''individual DIB participants'' and adding in its place ''individual DIB CS Program participants.''
■ d. In paragraph (d):
■ i. Removing ''DoD's DIB CS Program Office'' and adding in its place ''DoD's DIB CS Program Management Office''.
■ ii. Removing ''DoD DIB'' and adding in its place ''DoD–DIB''.
■ iii. Removing ''DIB CS program'' and adding in its place ''DIB CS Program''.
■ e. Removing ''DIB participants'' and adding in its place ''DIB CS Program participants'' in paragraph (e).
■ f. Redesignating paragraphs (f) through (n) as paragraphs (g) through (o).
■ g. Adding new paragraph (f).
■ h. In newly redesignated paragraph (g):
■ i. Removing the heading.
■ ii. Removing ''DIB participants'' and adding in its place ''DIB CS Program participants''.
■ i. Revising newly redesignated paragraphs (h) and (i).
■ j. Removing ''DIB participants'' and adding in its place ''DIB CS Program participants'' in newly redesignated paragraph (j) introductory text.
■ k. In newly redesignated paragraph (k):
■ i. Removing ''DIB participants'' and adding in its place ''DIB CS Program participants''.
■ ii. Removing ''DIB participant'' and adding in its place ''DIB CS Program participant''.
■ l. Removing ''DIB participants'' and adding in its place ''DIB CS Program participants'' in newly redesignated paragraph (l).
■ m. Removing ''DIB participants'' and adding in its place ''DIB CS Program participants'' in newly redesignated paragraph (m).
■ n. In newly redesignated paragraph (n):
■ i. Removing ''DIB participant'' and adding in its place ''DIB CS Program participant'' wherever it appears.
■ ii. Removing ''DIB participant's FA'' and adding in its place ''DIB CS Program participant's FA''.
■ o. In newly redesignated paragraph (o):
■ i. Removing ''DIB participant'' and adding in its place ''DIB CS Program participant'' wherever it appears.
■ ii. Removing ''paragraph (m) of this section'' and adding in its place ''paragraph (n) of this section.''

The revisions and addition read as follows:

§ 236.5 DoD's DIB CS Program.

(a) All defense contractors that meet the requirements set forth in § 236.7 are eligible to join the DIB CS Program as a DIB CS Program participant. Defense contractors meeting the additional eligibility requirements in § 236.7 can elect to access and receive classified information electronically.

* * * * *

(f) As participants of the DIB CS Program, defense contractors are encouraged to share cyber threat indicators and information that they believe are valuable in alerting the Government and other DIB CS Program participants to better counter threat actor activity. Cyber activity that is not covered under § 236.4 may be of interest to DIB CS Program participants and DoD.

* * * * *

(h) Prior to receiving GFI, each DIB CS Program participant shall provide the requisite points of contact information, to include U.S. citizenship and security clearance information, as applicable, for the designated personnel within their company in order to facilitate the DoD–DIB interaction in the DIB CS Program. The Government will confirm the accuracy of the information provided as a condition of that point of contact being authorized to act on behalf of the DIB CS Program participant for this program.

(i) GFI will be issued via both unclassified and classified means. DIB CS Program participants handling and safeguarding of classified information shall be in compliance with 32 CFR part 117. The Government shall specify transmission and distribution procedures for all GFI, and shall inform DIB CS Program participants of any revisions to previously specified transmission or procedures.

* * * * *

§ 236.6 [Amended]

■ 8. Amend § 236.6 by:
■ a. Removing ''program'' and adding in its place ''Program'' in the section heading.
■ b. In paragraph (a):
■ i. Removing ''DIB CS program'' and adding in its place ''DIB CS Program'' wherever it appears.
■ ii. Removing ''DIB participants'' and adding in its place ''DIB CS Program participants''.
■ c. In paragraph (b):
■ i. Removing ''DIB CS participants'' and adding in its place ''DIB CS Program participants''.
■ ii. Removing ''*http://www.dhs.gov/enhanced-cybersecurity-services*'' and adding in its place ''*https://www.cisa.gov/enhanced-cybersecurity-services-ecs*''.
■ d. In paragraph (c):
■ i. Removing ''DIB CS program'' and adding in its place ''DIB CS Program''.
■ ii. Removing ''obligate the DIB participant'' and adding in its place ''obligate the DIB CS Program participant''.
■ iii. Removing ''taken by the DIB participant'' and adding in its place ''taken by the DIB CS Program participant''.
■ iv. Removing ''taken on the DIB participant's'' and adding in its place ''taken on the DIB CS Program participant's''.
■ e. In paragraph (d):
■ i. Removing ''DIB participant's participation'' and adding in its place ''DIB CS Program participant's participation''.
■ ii. Removing ''DIB CS program'' and adding in its place ''DIB CS Program''.
■ iii. Removing ''approval of the DIB participant'' and adding in its place ''approval of the DIB CS Program participant''.
■ f. In paragraph (e):
■ i. Removing ''DIB participant'' and adding in its place ''DIB CS Program participant'' wherever it appears.
■ ii. Removing ''DIB CS program'' and adding in its place ''DIB CS Program''.
■ g. Adding ''change of status as a defense contractor,'' after ''Upon termination of the FA,'' in paragraph (f).
■ h. In paragraph (g):
■ i. Removing ''DIB participants' rights'' and adding in its place ''DIB CS Program participants' rights''.
■ ii. Removing ''DIB CS program'' and adding in its place ''DIB CS Program''.
■ iii. Removing ''the requirement for DIB participants'' and adding in its place ''the requirement for DIB CS Program participants''.
■ 9. Revise § 236.7 to read as follows:

§ 236.7 DoD's DIB CS Program requirements.

(a) To participate in the DIB CS Program, a contractor must own or operate a covered contractor information system and shall execute

the standardized FA with the Government (available during the application process), which implements the requirements set forth in §§ 236.5 and 236.6 and this section.

(b) In order for DIB CS Program participants to receive classified cyber threat information electronically, the company must be a cleared defense contractor and must:

(1) Have an existing active facility clearance level (FCL) to at least the Secret level in accordance with 32 CFR part 117;

(2) Have or acquire a Communication Security (COMSEC) account in accordance with 32 CFR part 117, which provides procedures and requirements for COMSEC activities;

(3) Have or acquire approved safeguarding for at least Secret information, and continue to qualify under 32 CFR part 117 for retention of its FCL and approved safeguarding; and

(4) Obtain access to DoD's secure voice and data transmission systems supporting the voluntary DIB CS Program.

Dated: April 25, 2023.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2023–09021 Filed 5–2–23; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 147

[Docket Number USCG–2023–0277]

RIN 1625–AA00

Safety Zone; Vineyard Wind 1 Wind Farm Project Area, Outer Continental Shelf, Lease OCS–A 0501, Offshore Massachusetts, Atlantic Ocean

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard is proposing to establish 63 temporary 500-meter safety zones around the construction of 62 wind turbine generators (WTGs) and one electrical service platform (ESP) located in the Vineyard Wind 1 Wind Farm (VW1WF) project area within federal waters on the Outer Continental Shelf (OCS), specifically in the northern portion of Bureau of Ocean Energy Management (BOEM) Renewable Energy Lease Area OCS–A 0501, approximately 12 nautical miles (NM) offshore of Martha's Vineyard, Massachusetts and 12 NM offshore Nantucket, Massachusetts. This action is necessary to provide for the safety of life, property, and the environment during the planned construction of each facility's monopile type foundation and subsequent installation of the WTGs turbines and ESP platform from June 15, 2023, to May 31, 2024. When enforced, only attending vessels and those vessels specifically authorized by the First Coast Guard District Commander, or a designated representative, are permitted to enter or remain in the temporary safety zones. We invite your comments on this proposed rulemaking.

DATES: Comments and related material must be received by the Coast Guard on or before June 2, 2023.

ADDRESSES: You may submit comments identified by docket number USCG–2023–0277 using the Federal Decision-Making Portal at *https://www.regulations.gov.* See the ''Public Participation and Request for Comments'' portion of the **SUPPLEMENTARY INFORMATION** section for further instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: If you have questions about this proposed rulemaking, call or email Mr. Craig Lapiejko, Waterways Management, at Coast Guard First District, telephone 617–603–8592, email *craig.d.lapiejko@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

BOEM Bureau of Ocean Energy Management
CFR Code of Federal Regulations
DD Degrees Decimal
DHS Department of Homeland Security
FR Federal Register
NPRM Notice of Proposed Rulemaking
OCS Outer Continental Shelf
OSS Offshore Substation
NAD 83 North American Datum of 1983
NM Nautical Mile
§ Section
U.S.C. United States Code
WTG Wind Turbine Generator
VW1WF Vineyard Wind 1 Wind Farm

II. Background, Purpose, and Legal Basis

On March 15, 2023, Vineyard Wind, LLC, an offshore wind farm developer, notified the Coast Guard that they plan to begin construction of facilities in the VW1WF project area within federal waters on the OCS, specifically in the northern portion of BOEM Renewable Energy Lease Area OCS–A 0501, approximately 12 NM offshore Martha's Vineyard, Massachusetts and 12 NM offshore Nantucket, Massachusetts in June 2023.

The extremely complex offshore construction of these OCS facilities presents many unusually hazardous conditions including hydraulic pile driving hammer operations, heavy lift operations, overhead cutting operations, potential falling debris, increased vessel traffic, and stationary barges in close proximity to the facilities and each other.

Based on these circumstances, the First Coast Guard District Commander has determined that establishment of 63 temporary safety zones through rulemaking is warranted to ensure the safety of life, property, and the environment within a 500-meter radius of each of the 63 facilities during their construction.

The Coast Guard is proposing this rule under the authorities provided in 14 U.S.C. 544, 43 U.S.C. 1333, and Department of Homeland Security (DHS) Delegation No. 00170.1, Revision No. 01.3. As an implementing regulation of this authority, 33 CFR part 147 permits the establishment of safety zones for non-mineral energy resource permanent or temporary structures located on the OCS for the purpose of protecting life and property on the facilities, appurtenances and attending vessels, and on the adjacent waters within the safety zone (see 33 CFR 147.10). Accordingly, a safety zone established under 33 CFR part 147 may also include provisions to restrict, prevent, or control certain activities, including access by vessels or persons to maintain safety of life, property, and the environment. If, as we anticipate, we issue a temporary final rule and make it effective less than 30 days after publication in the **Federal Register**, we will explain in that publication, as required by 5 U.S.C. (d)(3), our good cause for doing so.

III. Discussion of Proposed Rule

The District Commander is proposing to establish 63 temporary 500-meter safety zones around the construction of 62 WTGs and one ESP on the OCS from June 15, 2023, through 11:59 p.m. on May 31, 2024.

The construction of these facilities is expected to take place in mixed phases alternating between the installation of several monopile type foundations followed by the installation of the upper structures then repeating this process throughout the project area until all 63 facilities have been completed. The 63 temporary safety zones would be enforced individually as construction progresses from one structure location to the next throughout the entire process for a period lasting approximately 48 hours. The Coast Guard would make

notice of each enforcement period via the Local Notice to Mariners and issue a Broadcast Notice to Mariners via marine channel 16 (VHF–FM) as soon as practicable in response to an emergency or hazardous condition. The Coast Guard is publishing this rulemaking to be effective, and enforceable, through May 31, 2024, to encompass any construction delays due to weather or other unforeseen circumstances. If the project is completed before May 31, 2024, enforcement of the safety zones would be suspended, and notice given via Local Notice to Mariners.

Additional information about the construction process of the VW1WF can be found at *https://www.boem.gov/vineyard-wind.*

The 63 temporary 500-meter safety zones around the construction of 62 WTGs and one ESP are in the VW1WF project area, specifically in the northern portion of BOEM Renewable Energy Lease Area OCS–A 0501, approximately 12 NM offshore of Martha's Vineyard, Massachusetts and 12 NM offshore Nantucket, Massachusetts, within federal waters on the OCS.

The positions of each individual safety zone proposed by this rulemaking will be referred to using a unique alpha-numeric naming convention outlined in the ''Rhode Island and Massachusetts Structure Labeling Plot (West).'' [1]

Aligning with authorities under 33 CFR 147.15, the proposed safety zones would include the area within 500-meters of the center point of the positions provided in the following table expressed in Decimal Degrees (DD) based on North American Datum 1983 (NAD 83).

Name	Facility type	Latitude	Longitude
AL38	WTG	41.1370161	−70.4638911
AM37	ESP	41.1200616	−70.4851682
AM38	WTG	41.1203387	−70.4635204
AM39	WTG	41.1206168	−70.4414663
AN36	WTG	41.1030927	−70.5072461
AN37	WTG	41.1033791	−70.4851982
AN38	WTG	41.1036612	−70.4631500
AN39	WTG	41.1039392	−70.4411014
AP35	WTG	41.0861251	−70.5289069
AP36	WTG	41.0864155	−70.5068649
AP37	WTG	41.0867017	−70.4848226
AP38	WTG	41.0869837	−70.4627799
AP39	WTG	41.0872615	−70.4407369
AP40	WTG	41.0875351	−70.4186937
AP41	WTG	41.0878044	−70.3966501
AQ34	WTG	41.0691535	−70.5505566
AQ35	WTG	41.0694480	−70.5285205
AQ36	WTG	41.0697382	−70.5064840
AQ37	WTG	41.0700243	−70.4844472
AQ38	WTG	41.0703061	−70.4624101
AQ39	WTG	41.0705837	−70.4403727
AQ40	WTG	41.0708571	−70.4183350
AQ41	WTG	41.0711263	−70.3962970
AQ42	WTG	41.0713913	−70.3742587
AR33	WTG	41.0521781	−70.5721951
AR34	WTG	41.0524766	−70.5501649
AR35	WTG	41.0527709	−70.5281343
AR36	WTG	41.0530609	−70.5061034
AR37	WTG	41.0533468	−70.4840722
AR38	WTG	41.0536285	−70.4620407
AR39	WTG	41.0539059	−70.4400088
AR40	WTG	41.0541792	−70.4179767
AR41	WTG	41.0544482	−70.3959442
AR42	WTG	41.0547130	−70.3739115
AS32	WTG	41.0351987	−70.5938225
AS33	WTG	41.0355012	−70.5717982
AS34	WTG	41.0357995	−70.5497735
AS35	WTG	41.0360937	−70.5277485
AS36	WTG	41.0363836	−70.5057231
AS37	WTG	41.0366693	−70.4836975
AS38	WTG	41.0369508	−70.4616715
AS39	WTG	41.0372281	−70.4396452
AS40	WTG	41.0375012	−70.4176186
AS41	WTG	41.0377701	−70.3955918
AS42	WTG	41.0380347	−70.3735646
AT33	WTG	41.0188243	−70.5714016
AT34	WTG	41.0191225	−70.5493824
AT35	WTG	41.0194164	−70.5273630
AT36	WTG	41.0197062	−70.5053432
AT37	WTG	41.0199917	−70.4833231
AT38	WTG	41.0202731	−70.4613027
AT39	WTG	41.0205502	−70.4392819
AT40	WTG	41.0208231	−70.4172609

[1] The Rhode Island and Massachusetts Structure Labeling Plot (West) is an attachment to the Conditions of Construction and Operations Plan Approval Lease Number OCS–A 0517 (*boem.gov*) and can be found at *https://www.boem.gov/sites/default/files/documents/renewable-energy/state-activities/SFWF-COP-Terms-and-Conditions.pdf.*

Name	Facility type	Latitude	Longitude
AT41	WTG	41.0210918	−70.3952396
AU36	WTG	41.0030287	−70.5049636
AU37	WTG	41.0033141	−70.4829490
AU38	WTG	41.0035953	−70.4609341
AU39	WTG	41.0038722	−70.4389190
AU40	WTG	41.0041450	−70.4169035
AV37	WTG	40.9866364	−70.4825752
AV38	WTG	40.9869174	−70.4605659
AV39	WTG	40.9871942	−70.4385563
AW38	WTG	40.9702395	−70.4601980

The positions of the 63 proposed safety zones are shown on the following chartlets. For scaling purposes, there is approximately one NM spacing between each position.

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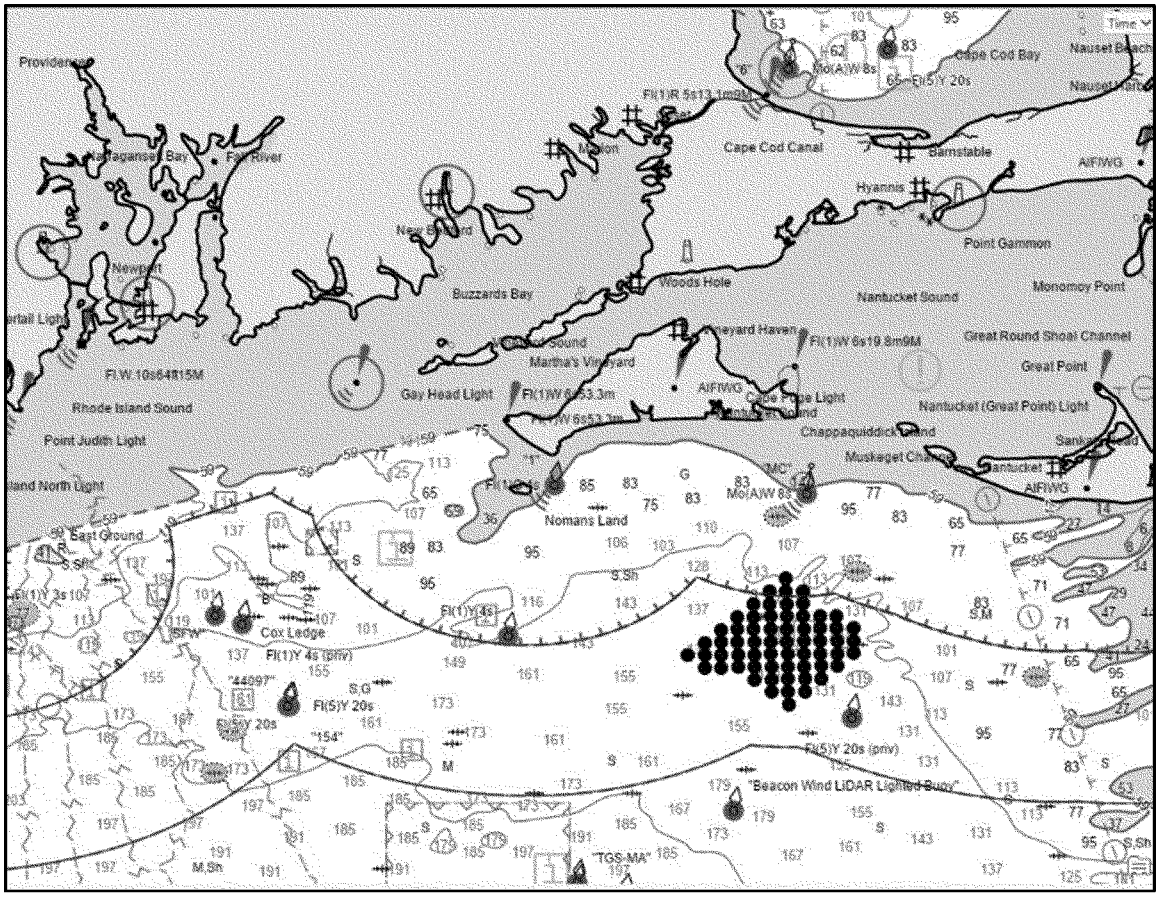
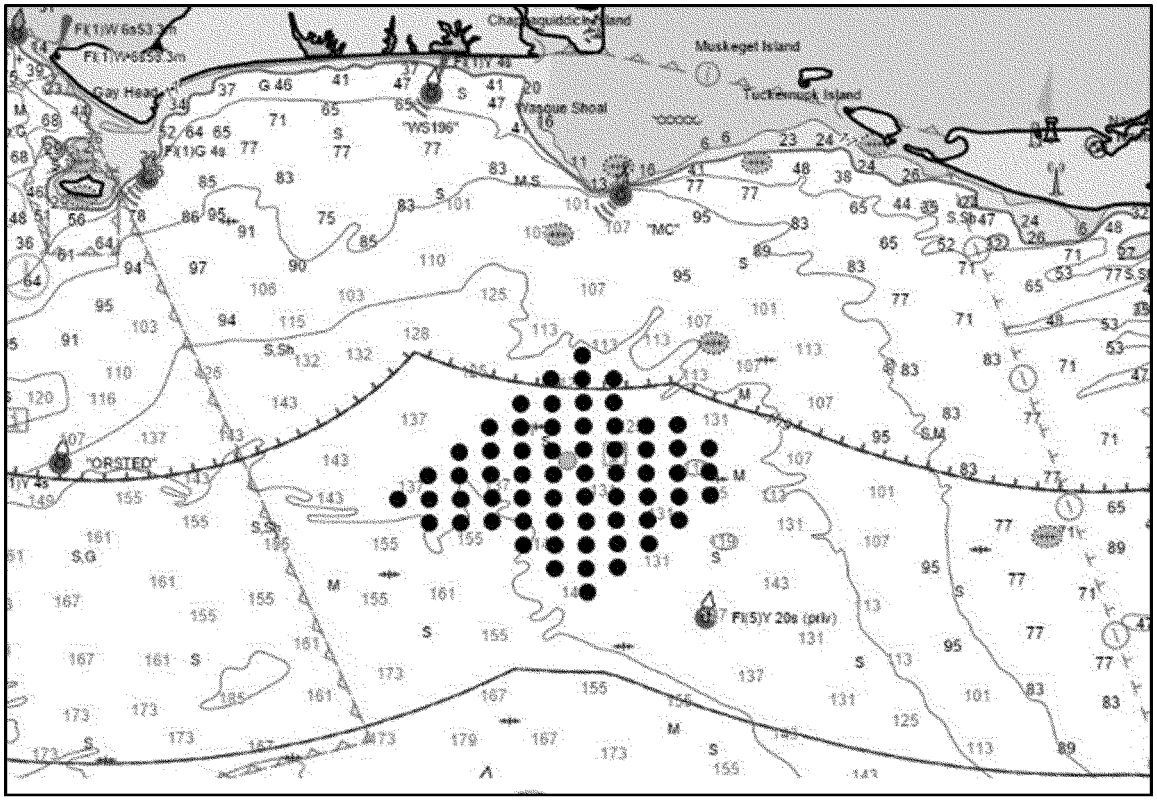
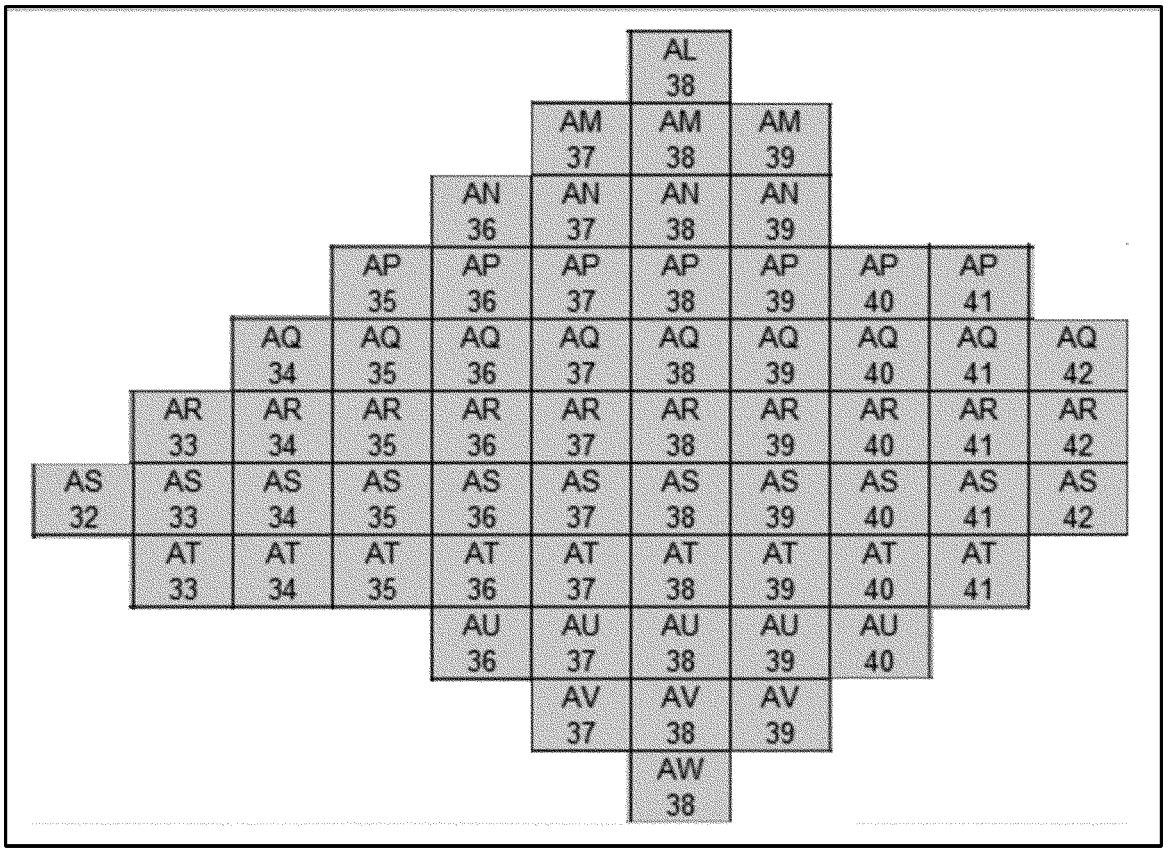


(Small scale chartlet showing the positions of the proposed safety zones.)



(Large scale chartlet showing the positions of the proposed safety zones.)



(Chartlet showing turbine positions using unique alpha-numeric naming convention.)

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Navigation in the vicinity of the proposed safety zones consists of large commercial shipping vessels, fishing vessels, cruise ships, tugs with tows, and recreational vessels.

When enforced, no unauthorized vessel or person would be permitted to enter the safety zone without obtaining permission from the First Coast Guard District Commander or a designated representative. Requests for entry into the safety zone would be considered and reviewed on a case-by-case basis. Persons or vessels seeking to enter the safety zone must request authorization from the First Coast Guard District Commander or designated representative via VHF–FM channel 16 or by phone at 617–603–1560 (First Coast Guard District Command Center). If permission is granted, all persons and vessels shall comply with the instructions of the First Coast Guard District Commander or designated representative.

The proposed regulatory text appears at the end of this document.

IV. Regulatory Analyses

We developed this proposed rule after considering numerous statutes and Executive Orders related to rulemaking. A summary of our analyses based on these statutes and Executive Orders follows.

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. This NPRM has not been designated a ''significant regulatory action,'' under Executive Order 12866. Accordingly, the NPRM has not been reviewed by the Office of Management and Budget (OMB).

Aligning with 33 CFR 147.15, the safety zones established would extend to a maximum distance of 500-meters around the OCS facility measured from its center point. Vessel traffic would be able to safely transit around the proposed safety zones, which would impact a small, designated area in the Atlantic Ocean, without significant impediment to their voyage. This safety zone would provide for the safety of life, property, and the environment during the construction of each structure, in accordance with Coast Guard maritime safety missions.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard certifies under 5 U.S.C. 605(b) that this proposed rule would not have a significant economic impact on a substantial number of small entities.

This rule may affect owners or operators of vessels intending to transit or anchor in the VW1WF, some of which might be small entities. However, these safety zones would not have a significant economic impact on a substantial number of these entities because they are temporarily enforced, allow for deviation requests, and do not impact vessel transit significantly. Regarding the enforcement period, although these safety zones would be in effect from June 15, 2023, through May 31, 2024, vessels would only be prohibited from the regulated zone during periods of actual construction activity in correspondence to the period of enforcement. We expect the enforcement period at each location to last approximately 48 hours as construction progresses from one structure location to the next throughout the mixed phases. Additionally, vessel traffic could pass safely around each safety zone using an alternate route. Use of an alternate route likely will cause minimal delay for the vessel in reaching their destination depending on other traffic in the area and vessel speed. Vessels would also be able to request deviation from this rule to transit through a safety zone. Such requests would be considered on a case by-case basis and may be authorized by the First Coast Guard District Commander or a designated representative. For these reasons, the Coast Guard expects any impact of this rulemaking establishing a temporary safety zone around these OCS facilities to be minimal and have no significant economic impact on small entities.

If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this proposed rule would have a significant economic impact on it, please submit a comment (see **ADDRESSES**) explaining why you think it qualifies and how and to what degree this rule would economically affect it.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this proposed rule. If the proposed rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section. The Coast Guard will not retaliate against small entities that question or complain about this proposed rule or any policy or action of the Coast Guard.

C. Collection of Information

This proposed rule would not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

D. Federalism and Indian Tribal Governments

A rule has implications for federalism under Executive Order 13132 (Federalism), if it has a substantial direct effect on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this proposed rule under that Order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

Also, this proposed rule does not have tribal implications under Executive Order 13175 (Consultation and Coordination with Indian Tribal Governments) because it would not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. If you believe this proposed rule has implications for federalism or Indian tribes, please call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 (adjusted for inflation) or more in any one year. Though this proposed rule would not result in such an expenditure, we do discuss the potential effects of this proposed rule elsewhere in this preamble.

F. Environment

We have analyzed this proposed rule under Department of Homeland Security Directive 023–01, Rev. 1, associated implementing instructions, and Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have made a preliminary determination that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This proposed rule involves the establishment of a safety zone around an OCS facility to protect life, property, and the marine environment. Normally such actions are categorically excluded from further review under paragraph L60 of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1. A preliminary Record of Environmental Consideration supporting this determination is available in the docket. For instructions on locating the docket, see the **ADDRESSES** section of this preamble. We seek any comments or information that may lead to the discovery of a significant environmental impact from this proposed rule.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places, or vessels.

V. Public Participation and Request for Comments

We view public participation as essential to effective rulemaking and will consider all comments and material received during the comment period. Your comment can help shape the outcome of this rulemaking. If you submit a comment, please include the docket number for this rulemaking, indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation.

Submitting comments. We encourage you to submit comments through the Federal Decision-Making Portal at *https://www.regulations.gov.* To do so, go to *https://www.regulations.gov,* type USCG–2023–0277 in the search box and click ''Search.'' Next, look for this document in the Search Results column, and click on it. Then click on the Comment option. If you cannot submit your material by using *https://www.regulations.gov,* call or email the person in the **FOR FURTHER INFORMATION CONTACT** section of this proposed rule for alternate instructions.

Viewing material in docket. To view documents mentioned in this proposed rule as being available in the docket, find the docket as described in the previous paragraph, and then select ''Supporting & Related Material'' in the Document Type column. Public comments will also be placed in our online docket and can be viewed by following instructions on the *https://www.regulations.gov* Frequently Asked Questions web page. We review all comments received, but we will only post comments that address the topic of the proposed rule. We may choose not to post off-topic, inappropriate, or duplicate comments that we receive.

Personal information. We accept anonymous comments. Comments we post to *https://www.regulations.gov* will include any personal information you have provided. For more about privacy and submissions to the docket in response to this document, see DHS's eRulemaking System of Records notice (85 FR 14226, March 11, 2020).

List of Subjects in 33 CFR Part 147

Continental shelf, Marine safety, Navigation (waters).

For the reasons discussed in the preamble, the Coast Guard is proposing to amend 33 CFR part 147 as follows:

PART 147—SAFETY ZONES

■ 1. The authority citation for part 147 continues to read as follows:

Authority: 14 U.S.C. 544; 43 U.S.C. 1333; 33 CFR 1.05–1; Department of Homeland Security Delegation No. 00170.1, Revision No. 01.3.

■ 2. Add § 147.T01–0277 to read as follows:

§ 147.T01–0277 Safety Zones; Vineyard Wind 1 Wind Farm Project Area, Outer Continental Shelf, Lease OCS–A 0501, Offshore Massachusetts, Atlantic Ocean.

(a) *Description.* The area within 500-meters of the center point of the positions provided in the table 1 is a safety zone:

TABLE 1 TO PARAGRAPH (a)

Name	Facility type	Latitude	Longitude
AL38	WTG	41.1370161	−70.4638911
AM37	ESP	41.1200616	−70.4851682
AM38	WTG	41.1203387	−70.4635204
AM39	WTG	41.1206168	−70.4414663
AN36	WTG	41.1030927	−70.5072461
AN37	WTG	41.1033791	−70.4851982
AN38	WTG	41.1036612	−70.4631500
AN39	WTG	41.1039392	−70.4411014
AP35	WTG	41.0861251	−70.5289069
AP36	WTG	41.0864155	−70.5068649
AP37	WTG	41.0867017	−70.4848226
AP38	WTG	41.0869837	−70.4627799
AP39	WTG	41.0872615	−70.4407369
AP40	WTG	41.0875351	−70.4186937
AP41	WTG	41.0878044	−70.3966501
AQ34	WTG	41.0691535	−70.5505566
AQ35	WTG	41.0694480	−70.5285205
AQ36	WTG	41.0697382	−70.5064840
AQ37	WTG	41.0700243	−70.4844472
AQ38	WTG	41.0703061	−70.4624101
AQ39	WTG	41.0705837	−70.4403727
AQ40	WTG	41.0708571	−70.4183350
AQ41	WTG	41.0711263	−70.3962970
AQ42	WTG	41.0713913	−70.3742587

TABLE 1 TO PARAGRAPH (a)—Continued

Name	Facility type	Latitude	Longitude
AR33	WTG	41.0521781	−70.5721951
AR34	WTG	41.0524766	−70.5501649
AR35	WTG	41.0527709	−70.5281343
AR36	WTG	41.0530609	−70.5061034
AR37	WTG	41.0533468	−70.4840722
AR38	WTG	41.0536285	−70.4620407
AR39	WTG	41.0539059	−70.4400088
AR40	WTG	41.0541792	−70.4179767
AR41	WTG	41.0544482	−70.3959442
AR42	WTG	41.0547130	−70.3739115
AS32	WTG	41.0351987	−70.5938225
AS33	WTG	41.0355012	−70.5717982
AS34	WTG	41.0357995	−70.5497735
AS35	WTG	41.0360937	−70.5277485
AS36	WTG	41.0363836	−70.5057231
AS37	WTG	41.0366693	−70.4836975
AS38	WTG	41.0369508	−70.4616715
AS39	WTG	41.0372281	−70.4396452
AS40	WTG	41.0375012	−70.4176186
AS41	WTG	41.0377701	−70.3955918
AS42	WTG	41.0380347	−70.3735646
AT33	WTG	41.0188243	−70.5714016
AT34	WTG	41.0191225	−70.5493824
AT35	WTG	41.0194164	−70.5273630
AT36	WTG	41.0197062	−70.5053432
AT37	WTG	41.0199917	−70.4833231
AT38	WTG	41.0202731	−70.4613027
AT39	WTG	41.0205502	−70.4392819
AT40	WTG	41.0208231	−70.4172609
AT41	WTG	41.0210918	−70.3952396
AU36	WTG	41.0030287	−70.5049636
AU37	WTG	41.0033141	−70.4829490
AU38	WTG	41.0035953	−70.4609341
AU39	WTG	41.0038722	−70.4389190
AU40	WTG	41.0041450	−70.4169035
AV37	WTG	40.9866364	−70.4825752
AV38	WTG	40.9869174	−70.4605659
AV39	WTG	40.9871942	−70.4385563
AW38	WTG	40.9702395	−70.4601980

(b) *Definitions.* As used in this section, *designated representative* means a Coast Guard Patrol Commander, including a Coast Guard coxswain, petty officer, or other officer operating a Coast Guard vessel and a Federal, State, and local officer designated by or assisting the First Coast Guard District Commander in the enforcement of the safety zones.

(c) *Regulations.* No vessel may enter or remain in the safety zones described in paragraph (a) of this section except for the following:

(1) An attending vessel as defined in 33 CFR 147.20;

(2) A vessel authorized by the First Coast Guard District Commander or a designated representative.

(d) *Request for Permission.* Persons or vessels seeking to enter the safety zone must request authorization from the First Coast Guard District Commander or a designated representative. If permission is granted, all persons and vessels must comply with lawful instructions of the First Coast Guard District Commander or designated representative via VHF–FM channel 16 or by phone at 617–223–1560 (First Coast Guard District Command Center).

(e) *Effective and enforcement periods.* This section will be effective from June 15, 2023, through 11:59 p.m. on May 31, 2024. It will only be enforced during active construction or other instances which may cause a hazard to navigation deemed necessary by the First Coast Guard District Commander. The First Coast Guard District Commander will make notification of the exact dates and times in advance of each enforcement period for the locations above in paragraph (a) of this section to the local maritime community through the Local Notice to Mariners and will issue a Broadcast Notice to Mariners via marine channel 16 (VHF–FM) as soon as practicable in response to an emergency. If the project is completed before May 31, 2024, enforcement of the safety zones will be suspended, and notice given via Local Notice to Mariners. The First Coast Guard District Local Notice to Mariners can be found at: *http://www.navcen.uscg.gov.*

Dated: April 27, 2023.

J.W. Mauger,

Rear Admiral, U.S. Coast Guard, Commander, First Coast Guard District.

[FR Doc. 2023–09415 Filed 5–2–23; 8:45 am]

BILLING CODE 9110–04–P

LIBRARY OF CONGRESS

U.S. Copyright Office

37 CFR Parts 222 and 235

[Docket No. 2023–4]

Copyright Claims Board: Agreement-Based Counterclaims

AGENCY: U.S. Copyright Office, Library of Congress.

ACTION: Notice of proposed rulemaking; request for comments.

SUMMARY: The U.S. Copyright Office is amending its regulations governing

Copyright Claims Board proceedings to address the filing of agreement-based counterclaims and related discovery requirements.

DATES: Written comments must be received no later than 11:59 p.m. Eastern Time on June 20, 2023.

ADDRESSES: For reasons of Government efficiency, the Copyright Office is using the *regulations.gov* system for the submission and posting of public comments in this proceeding. All comments are therefore to be submitted electronically through *regulations.gov.* Specific instructions for submitting comments are available on the Copyright Office's website at *https://www.copyright.gov/rulemaking/agreement-based-counterclaims/.* If electronic submission of comments is not feasible due to lack of access to a computer or the internet, please contact the Copyright Office using the contact information below for special instructions.

FOR FURTHER INFORMATION CONTACT: Rhea Efthimiadis, Assistant to the General Counsel, by email at *meft@copyright.gov* or telephone at 202–707–8350.

SUPPLEMENTARY INFORMATION:

I. Background

The Copyright Alternative in Small-Claims Enforcement (''CASE'') Act of 2020 [1] directed the Copyright Office to establish the Copyright Claims Board (''CCB''), a voluntary forum for parties seeking resolution of certain copyright disputes that have a total monetary value of $30,000 or less. As an alternative forum to Federal district court, the CCB is designed to be accessible to *pro se* individuals and individuals without much knowledge of copyright law.[2] In early 2021, the Office published a notification of inquiry (''NOI'') asking for public comments on the CCB's operations and procedures.[3]

Following the NOI, the Office published multiple notices of proposed rulemaking governing the conduct of proceedings before the CCB, including filing claims and counterclaims, responses to claims and counterclaims, and discovery.[4] After receiving and considering comments submitted by the public, the Office published corresponding final rules.[5] On June 16, 2022, the CCB began receiving claims through its website *dockets.ccb.gov.*

After reviewing its regulations, the Office is proposing to add rules specifically governing agreement-based counterclaims.

II. Proposed Rule and Request for Comments

The CASE Act provides that the CCB may hear only certain types of counterclaims: those that arise ''under section 106 or section 512(f) and out of the same transaction or occurrence that is the subject of a claim of infringement[,] . . . a claim of noninfringement[,] . . . or a claim of misrepresentation'' and those that ''arise[ ] under an agreement pertaining to the same transaction or occurrence that is the subject of a claim of infringement . . . if the agreement could affect the relief awarded to the claimant.'' [6] This last category of counterclaims are referred to here as ''agreement-based counterclaims.''

Asserting and Responding to Agreement-Based Counterclaims

In an earlier rulemaking, ''the Office propose[d] that the information required to assert a counterclaim should closely mirror the information required to assert a claim'' for counterclaims that arise under section 106 or section 512(f).[7] After reviewing the public comments, the Office promulgated final rules requiring that a counterclaim arising under section 106 or section 512(f) include a description of ''[t]he facts leading the counterclaimant to believe the work has been infringed.'' [8] At that time, the Office did not propose separate rules to address agreement-based counterclaims.

After reviewing its regulations, the Office has concluded that such counterclaims should have their own content requirements. Specifically, the Office proposes that agreement-based counterclaims should include the identification of the agreement that the agreement-based counterclaim is based upon, a brief statement describing how the agreement pertains to the same transaction or occurrence that is the subject of the infringement claim against the counterclaimant, and a brief statement describing how the agreement could affect the relief awarded to the claimant.

The Office also believes that regulations are necessary to specify the required contents of a counterclaim respondent's [9] response to an agreement-based counterclaim. A counterclaim respondent should describe in detail its disagreement with the facts in the counterclaim, including any description of defenses to the counterclaim, and an explanation of why the counterclaim respondent believes the counterclaimant's position regarding the agreement lacks merit.

Standard Interrogatories for Agreement-Based Counterclaims

The proposed rule also addresses standard interrogatories for agreement-based counterclaims that supplement the standard interrogatories common to all claim types. The additional standard interrogatories will include: identification and a description of the specific terms or provisions of the agreement, written or oral, that the counterclaimant alleges have been violated; the basis for the counterclaimant's belief that the agreement was both valid and violated; the reasons why the counterclaimant believes the agreement could affect the relief that might be awarded; a description of the counterclaimant's performance under the agreement, as relevant to the counterclaim; and identification of any alleged failure in the counterclaim respondent's performance under the agreement.

In turn, the additional standard interrogatories that an agreement-based counterclaim respondent must answer will address the following: all applicable defenses to the counterclaim and the facts supporting those defenses; any other reasons the counterclaim respondent believes that it did not violate the agreement or that the agreement was not valid; the basis for any belief by the counterclaim respondent that the agreement does not affect the relief that might be awarded; a description of the counterclaim respondent's performance under the agreement, as relevant to the counterclaim; and any inadequacies in performance under the agreement by the counterclaimant.

Standard Requests for the Production of Documents for Agreement-Based Counterclaims

In addition to the standard document requests that all parties must satisfy, the Office proposes that both agreement-

[1] Public Law 116–260, sec. 212, 134 Stat. 1182, 2176 (2020).

[2] *See, e.g.,* H.R. Rep. No. 116–252, at 18–20 (2019); S. Rep. No. 116–105, at 7–8 (2019).

[3] 86 FR 16156 (Mar. 26, 2021).

[4] 86 FR 69890 (Dec. 8, 2021); 86 FR 53897 (Sept. 29, 2021).

[5] 87 FR 12861 (Mar. 8, 2022) (initial proceedings partial final rule); 87 FR 16989 (Mar. 25, 2022) (initial proceedings final rule); 87 FR 24056 (Apr. 22, 2022) (initial proceedings correction); 87 FR 30060 (May 17, 2022) (active proceedings final rule); 87 FR 36060 (June 15, 2022) (active proceedings correction).

[6] 17 U.S.C. 1504(c)(4)(B)(i)–(ii).

[7] 86 FR 53897, 53903.

[8] 87 FR 16989, 16999–17000, 17005; *see also* 37 CFR 222.9(c)(3)(iii)(D).

[9] The term ''counterclaim respondent'' refers to a claimant that has received a counterclaim.

based counterclaimants and counterclaim respondents should be subject to several additional requests. These standard document requests for agreement-based counterclaims should include: the agreement at issue and documents related to that agreement, including any amendments or revisions; documents related to the validity of the agreement; and documents related to the parties' performance under the agreement. In addition, with regard to a counterclaimant's damages claim, the Office proposes slightly different document requests for a counterclaimant and a counterclaim respondent. Agreement-based counterclaimants must produce documents relevant to damages arising out of the counterclaim, including documents sufficient to show the damages suffered due to the violation of the agreement in question. In turn, counterclaim respondents must produce documents relevant to damages, including any documents sufficient to show the lack of damages suffered by the counterclaimant from the alleged violation of the agreement.

The Office remains committed to ensuring that ''the discovery regulations strike the right balance between allowing necessary access to information and being too burdensome.'' [10] It previously adjusted the language for infringement-related standard discovery requests after hearing from the public that the initially proposed language may have been unnecessarily burdensome.[11] With respect to the proposed rules for document requests for parties to agreement-based counterclaims, the Office is interested in hearing whether the proposed ''relevant to'' language for damages document requests strikes the right balance. The Office notes that the ''relevant to'' language is not included in damages-related document requests for infringement, declaration of noninfringement, or misrepresentation claims or counterclaims, which are all limited to documents ''sufficient to show'' damages.[12]

List of Subjects in 37 CFR Parts 222 and 225

Claims, Copyright.

Proposed Regulations

For the reasons stated in the preamble, the U.S. Copyright Office amends 37 CFR parts 222 and 225 as follows:

[10] 87 FR 30060, 30060.

[11] *See id.* at 30070–71.

[12] 37 CFR 225.3(b)(6), (c)(4), (d)(4).

PART 222—PROCEEDINGS

■ 1. The authority citation for part 222 continues to read as follows:

Authority: 17 U.S.C. 702, 1510.

■ 2. Amend § 222.9 by redesignating paragraphs (c)(6) through (c)(8) as paragraphs (c)(7) through (c)(9) and adding paragraph (c)(6) to read as follows.

§ 222.9 Counterclaim.

* * * * *

(c) * * *

(6) For a counterclaim arising under an agreement asserted under paragraph (c)(2)(iv) of this section—

(i) A description of the agreement that the counterclaim is based upon;

(ii) A brief statement describing how the agreement pertains to the same transaction or occurrence that is the subject of the infringement claim against the counterclaimant; and

(iii) A brief statement describing how the agreement could affect the relief awarded to the claimant;

* * * * *

■ 3. Amend § 222.10 by redesignating paragraph (b)(6) as paragraph (b)(7) and adding paragraph (b)(6) to read as follows:

§ 222.10 Response to counterclaim.

* * * * *

(b) * * *

(6) For counterclaims arising under an agreement, as set forth in 37 CFR 222.9(c)(2)(iv), a statement describing in detail the dispute regarding the contractual counterclaim, including any defenses as well as an explanation of why the counterclaim respondent believes the counterclaimant's position regarding the agreement lacks merit; and

* * * * *

PART 225—DISCOVERY

■ 4. The authority citation for part 225 continues to read as follows:

Authority: 17 U.S.C. 702, 1510.

■ 5. Amend § 225.2 by redesignating paragraph (f) as paragraph (h) and adding paragraphs (f) and (g) to read as follows:

§ 225.2 Standard interrogatories.

* * * * *

(f) *For a counterclaimant asserting a counterclaim arising under an agreement.* In addition to the information in paragraph (a) of this section, the *standard interrogatories* for a counterclaimant asserting a counterclaim arising under an agreement shall consist of information pertaining to:

(1) Identification and a description of the specific terms or provisions of the agreement the counterclaim respondent is alleged to have violated;

(2) The basis for the counterclaimant's belief that the agreement was valid;

(3) The basis for the counterclaimant's belief that the agreement was violated;

(4) The basis for the counterclaimant's belief that the agreement could affect the relief that might be awarded to the claimant;

(5) A description of the counterclaimant's performance under the agreement, as relevant to the counterclaim;

(6) Identification and a description of any inadequacies in performance under the agreement by the counterclaim respondent; and

(7) If the agreement at issue in the counterclaim is oral, a description of the terms and provisions of the agreement.

(g) *For a counterclaim respondent responding to a counterclaim arising under an agreement.* In addition to the information in paragraph (a) of this section, the *standard interrogatories* for a counterclaim respondent responding to a counterclaim arising under an agreement shall consist of information pertaining to:

(1) All defenses asserted to the counterclaim arising under an agreement and the basis for those assertions. Defenses listed in timely answers and timely updated answers to the *standard interrogatories* shall be considered by the Board and will not require an amendment of the counterclaim response;

(2) The basis for any other reasons the counterclaim respondent believes that it did not violate the agreement or that the agreement was not valid;

(3) The basis for any belief by the counterclaim respondent that the agreement does not affect the relief that might be awarded to the claimant;

(4) A description of the counterclaim respondent's performance under the agreement, as relevant to the counterclaim; and

(5) Identification and a description of any inadequacies in performance under the agreement by the counterclaimant.

* * * * *

■ 6. Amend § 225.3 by redesignating paragraphs (f) and (g) as paragraphs (h) and (i) and adding paragraphs (f) and (g) to read as follows:

§ 225.3 Standard requests for the production of documents.

* * * * *

(f) *For a counterclaimant asserting a counterclaim arising under an agreement.* In addition to the information in paragraph (a) of this

section, the *standard requests for the production of documents* for a party asserting a counterclaim arising under an agreement shall include copies of:

(1) The agreement at issue in the counterclaim arising under an agreement, including any amendments or revisions;

(2) Documents related to the agreement at issue, including any amendments or revisions and documents related to the validity of and the parties' performance under the agreement; and

(3) Documents relevant to damages arising out of the counterclaim, including documents sufficient to show the damages suffered by the counterclaimant related to violation of the agreement in question.

(g) *For a counterclaim respondent responding to a counterclaim arising under an agreement.* In addition to the information in paragraph (a) of this section, the *standard requests for the production of documents* for a counterclaim respondent responding to a counterclaim arising under an agreement shall include copies of:

(1) The agreement at issue in the counterclaim arising under an agreement, including any amendments or revisions;

(2) Documents related to the agreement at issue, including any amendments or revisions and documents related to the validity of and the parties' performance under the agreement; and

(3) Documents relevant to damages, including documents sufficient to show the lack of damages suffered by the counterclaimant related to the counterclaim respondent's alleged violation of the agreement in question.

* * * * *

Dated: April 25, 2023.

Suzanne V. Wilson,

General Counsel and Associate Register of Copyrights.

[FR Doc. 2023–09055 Filed 5–2–23; 8:45 am]

BILLING CODE 1410–30–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

41 CFR Parts 51–2, 51–3, and 51–5

RIN 3037–AA14

Supporting Competition in the AbilityOne Program; Extension of Comment Period

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Proposed rule; extension of comment period.

SUMMARY: On March 13, 2023, the Committee for Purchase from People Who Are Blind or Severely Disabled (Committee), operating as the U.S. AbilityOne Commission (Commission), published a proposed rule, Supporting Competition in the AbilityOne Program, with a 60-day comment period ending on May 11, 2023. The Commission has determined that a 30-day extension of the comment period, until June 12, 2023, is appropriate. The Commission is taking this action in response to requests for an extension to allow interested persons additional time to submit comments.

DATES: The comment period for the proposed rule, Supporting Competition in the AbilityOne Program, published March 13, 2023, at 88 FR 15360, is extended. Electronic comments should be received no later than 11:59 p.m. Eastern Time on June 12, 2023.

ADDRESSES: Interested persons may submit comments by using the following method: internet—Federal eRulemaking Portal. Electronic comments may be submitted through *https://www.regulations.gov.* To locate the proposed rule, use RIN 3037–AA14. Follow the instructions for submitting comments. Please be advised that comments received will be posted without change to *https://www.regulations.gov,* including any personal information provided.

Accessible Format: On request to the program contact person listed under **FOR FURTHER INFORMATION CONTACT**, individuals with disabilities can obtain this document in an alternative accessible format.

FOR FURTHER INFORMATION CONTACT: Cassandra Assefa, Regulation and Policy Counsel, by telephone at 202–430–9886 or by email at *cassefa@abilityone.gov.*

SUPPLEMENTARY INFORMATION: On March 13, 2023, the Commission published a proposed rule, Supporting Competition in the AbilityOne Program. The proposed rule would clarify the Commission's authority to consider different pricing methodologies in establishing the Fair Market Price (FMP) for Procurement List (PL) additions and changes to the FMP; better define the parameters for conducting fair and equitable competitive allocations amongst multiple qualified Nonprofit Agencies (NPAs); and clarify the responsibilities and procedures associated with authorizing and deauthorizing NPA.

The Commission has received requests for an extension of the 60-day comment period. The Commission has considered the requests and is extending the comment period for the proposed rule until June 12, 2023. The Commission believes that this extension allows adequate time for interested persons to submit comments.

Michael R. Jurkowski,

Acting Director, Business Operations.

[FR Doc. 2023–09236 Filed 5–2–23; 8:45 am]

BILLING CODE 6350–01–P

NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

45 CFR Part 1110

Removal of Freedom of Information Act Regulation Issued by National Foundation on the Arts and the Humanities

AGENCY: National Endowment for the Arts, National Endowment for the Humanities, Institute of Museum and Library Services, National Foundation on the Arts and the Humanities.

ACTION: Notice of proposed rulemaking.

SUMMARY: This rulemaking rescinds the National Foundation on the Arts and the Humanities' (the ''Foundation'') regulations implementing the Freedom of Information Act (''FOIA''). These regulations are obsolete because each of the Foundation's constituent agencies—the National Endowment for the Arts (''NEA''), the National Endowment for the Humanities (''NEH''), the Institute of Museum and Library Services (''IMLS''), and the Federal Council on the Arts and the Humanities (''FCAH'')—either have adopted their own, agency-specific regulations, or are not required to implement Freedom of Information Act regulations.

DATES: The public comment period for the proposed rule opens on May 3, 2023. Written comments must be received on or before June 2, 2023.

ADDRESSES: You may submit comments, identified by RIN 3135–AA26, by any of the following methods:

(a) *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments.

(b) *Email: generalcounsel@arts.gov.* Include RIN 3135–AA26 in the subject line of the message.

(c) *Mail:* National Endowment for the Arts, Office of General Counsel, 400 7th Street SW, Second Floor, Washington, DC 20506.

(d) *Hand Delivery/Courier:* National Endowment for the Arts, Office of the General Counsel, 400 7th Street SW, Second Floor, Washington, DC 20506.

Instructions: All submissions received must include the agency name and docket number or Regulatory Information Number (3135–AA26) for this rulemaking.

Docket: For access to the docket to read background documents or comments received, go to 400 7th Street SW, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Daniel Fishman, Assistant General Counsel, National Endowment for the Arts, 400 7th St. SW, Washington, DC 20506, Telephone: 202–682–5418.

SUPPLEMENTARY INFORMATION:

1. Background

The Foundation operates under the National Foundation on the Arts and the Humanities Act of 1965, as amended (20 U.S.C. 951 *et seq.*), and consists of the NEA, NEH, IMLS, and FCAH (collectively, the ''Foundation's constituent agencies'').

The Foundation's FOIA regulations located at 45 CFR 1100 are now obsolete. The NEA, NEH, and IMLS have each adopted their own, agency-specific regulations. On February 27, 2019, the NEA promulgated FOIA regulations to 45 CFR Chapter XI, Subchapter B (45 CFR part 1148), which only apply to the NEA, effectively superseding the Foundation's FOIA regulations and rendering them duplicative. NEH and IMLS had previously added NEH- and IMLS-specific FOIA regulations to 45 CFR, Subchapters D and E (45 CFR parts 1171 & 1184), respectively, which replaced the Foundation's FOIA regulations with respect to NEH and IMLS. FCAH relies upon the NEA and NEH for its administration and does not maintain any systems of records of its own; thus, any requests for information or documents would be better directed to the other two constituent agencies of the Foundation to obtain the same information.

Accordingly, the Foundation's constituent agencies propose rescinding the Foundation's regulations located at 45 CFR 1100.

2. Compliance

Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

Executive Order 12866 (E.O. 12866) established a process for review of rules by the Office of Information and Regulatory Affairs, which is within the Office of Management and Budget (OMB). Only ''significant'' proposed and final rules are subject to review under this Executive Order. ''Significant,'' as used in E.O. 12866, means ''economically significant.'' It refers to rules (1) with an impact on the economy of $100 million or more or that adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public safety or health, or State, local or tribal Governments or communities; or that (2) were inconsistent or interfered with an action taken or planned by another agency; (3) materially altered the budgetary impact of entitlements, grants, user fees, or loan programs or the rights or obligations of their recipients; or (4) raised novel legal or policy issues.

This proposed rule would not be a significant policy change, and OMB has not reviewed this proposed rule under E.O. 12866. We have made the assessments required by E.O. 12866 and determined that this proposed rulemaking: (1) will not have an effect of $100 million or more on the economy and will not adversely affect in a material way the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or Tribal governments or communities; (2) will not create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) does not alter the budgetary effects of entitlements, grants, user fees, or loan programs or the rights or obligations of their recipients; and (4) does not raise novel legal or policy issues.

Executive Order 12988: Civil Justice Reform

This proposed rule meets the applicable standards set forth in sections 3(a) and 3(b)(2) of E.O. 12988. Specifically, this proposed rule is written in clear language designed to help reduce litigation.

Paperwork Reduction Act of 1995 (''PRA'')

This proposed rule does not impose an information collection burden under the PRA. This proposed rule contains no provisions constituting a collection of information under the PRA.

Regulatory Flexibility Act of 1980 (''RFA'')

This proposed rule will not have a significant adverse impact on a substantial number of small entities, including small businesses, small governmental jurisdictions, or certain small not-for-profit organizations.

Unfunded Mandates Reform Act of 1995 (''UMRA'')

This proposed rule does not contain a Federal mandate that will result in the expenditure by State, local, and tribal Governments, in the aggregate, or by the private sector of $100 million or more in any one year.

Executive Order 13132 (Federalism)

This proposed rulemaking does not have federalism implications, as set forth in E.O. 13132. As used in this order, federalism implications mean ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' The NEA has determined that this proposed rulemaking will not have federalism implications within the meaning of E.O. 13132.

Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

Under the criteria in E.O. 13175, we have evaluated this proposed rule and determined that it would have no potential effects on Federally recognized Indian Tribes.

Executive Order 12630: Takings

Under the criteria in E.O. 12630, this proposed rule does not have significant takings implications. Therefore, a takings implication assessment is not required.

List of Subjects in 45 CFR Part 1110

Administrative practice and procedure, Archives and records, Freedom of information.

For the reasons stated in the preamble, and under the authority of 5 U.S.C. 552, the NEA, NEH (for itself and on behalf of FCAH, for which NEH provides legal counsel), and IMLS propose to amend 45 CFR Chapter XI Subchapter A as follows:

PART 1100—[Removed]

■ 1. Remove Part 1100.

Valencia Rainey,

Acting General Counsel, National Endowment for the Arts.

Michael P. McDonald,

General Counsel, National Endowment for the Humanities.

Nancy E. Weiss,

General Counsel, Institute of Museum and Library Services.

[FR Doc. 2023–09054 Filed 5–2–23; 8:45 am]

BILLING CODE 7537–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 64

[WC Docket Nos. 12–375, 23–62; DA 23–355; FR ID [139745]]

Incarcerated People's Communications Services; Implementation of the Martha Wright-Reed Act; Rates for Interstate Inmate Calling Services

AGENCY: Federal Communications Commission.

ACTION: Proposed rule; solicitation of comments.

SUMMARY: The Federal Communications Commission (Commission) seeks comment on the contours and specific requirements of the proposed 2023 Mandatory Data Collection for incarcerated people's communications services. The Commission has drafted proposed instructions, templates, and a certification form for the proposed 2023 Mandatory Data Collection. The Commission seeks comment on all aspects of these documents.

DATES: Comments are due June 2, 2023. Reply comments are due June 20, 2023.

ADDRESSES: You may submit comments, identified by WC Docket Nos. 12–375 and 23–62, by either of the following methods:

- *Electronic Filers:* Comments may be filed electronically using the internet by accessing the Electronic Comment Filing System (ECFS): *https://www.fcc.gov/ecfs/.*
- *Paper Filers:* Parties who choose to file by paper must file an original and one copy of each filing. Filings can be sent by commercial overnight courier, or by first-class or overnight U.S. Postal Service mail. Currently, the Commission does not accept any hand or messenger delivered filings as a temporary measure taken to help protect the health and safety of individuals, and to mitigate the transmission of COVID–19. All filings must be addressed to the Commission's Secretary, Office of the Secretary, Federal Communications Commission.

The Commission adopted a new Protective Order in this proceeding which incorporates all materials previously designated by the parties as confidential. Filings that contain confidential information should be appropriately redacted and filed pursuant to the procedure described in that Order.

People with Disabilities: The Commission asks that requests for accommodations be made as soon as possible in order to allow the agency to satisfy such requests whenever possible. Send an email to *fcc504@fcc.gov* or call the Consumer and Governmental Affairs Bureau at (202) 418–0530.

FOR FURTHER INFORMATION CONTACT: Ahuva Battams, Pricing Policy Division of the Wireline Competition Bureau, at (202) 418–1565 or via email at *ahuva.battams@fcc.gov.* Please copy *mandatorydatacollection@fcc.gov* on any email correspondence.

SUPPLEMENTARY INFORMATION: This is a summary of a document that the Federal Communications Commission's Wireline Competition Bureau released on April 28, 2023. A full-text version of the document is available at the following internet address: *https://www.fcc.gov/document/proposed-2023-ipcs-mandatory-data-collection-public-notice.*

Synopsis

Introduction and Background

1. By this document, the Wireline Competition Bureau (WCB) and Office of Economics and Analytics (OEA) (collectively, WCB/OEA) seek comment on the contours and specific requirements of the proposed 2023 Mandatory Data Collection for incarcerated people's communications services (IPCS). In issuing this document, they act pursuant to the Federal Communications Commission's (Commission) directive so that it is able to implement the Martha Wright-Reed Just and Reasonable Communications Act of 2022 (Martha Wright-Reed Act or Act). *Incarcerated People's Communications Services; Implementation of the Martha Wright-Reed Act; Rates for Interstate Inmate Calling Services,* Order, 88 FR 19001, March 30, 2023 (*2023 IPCS Order*), and Notice of Proposed Rulemaking, 88 FR 20804, April 7, 2023 (*2023 IPCS Notice*); Martha Wright-Reed Act, Public Law 117–338, 136 Stat. 6156.

2. The Martha Wright-Reed Act directs the Commission to ''promulgate any regulations necessary to implement'' the Act, including its mandate that the Commission establish a ''compensation plan'' ensuring that all rates and charges for IPCS ''are just and reasonable,'' not earlier than 18 months and not later than 24 months after the Act's January 5, 2023 enactment. The Act requires the Commission to consider, as part of its implementation, the costs of ''necessary'' safety and security measures, as well as ''differences in costs'' based on facility size, or ''other characteristics.'' It also allows the Commission to ''use industry-wide average costs of telephone service and advanced communications services and the average costs of service of a communications service provider'' in determining just and reasonable rates.

3. In recent years, the Commission has collected data from providers of calling services for incarcerated people as part of its ongoing efforts to establish just and reasonable rates for those services that reduce the financial burdens imposed on incarcerated people and their loved ones, while ensuring that providers are fairly compensated for their services. In requiring or allowing the Commission to consider certain types of costs, the new Act contemplates that the Commission would undertake an additional data collection. To ensure that it has the data it needs to meet its substantive and procedural responsibilities under the Act, in the *2023 IPCS Order* the Commission delegated authority to WCB/OEA to ''update and restructure'' the Commission's most recent data collection (the Third Mandatory Data Collection) ''as appropriate in light of the requirements of the new statute.'' This delegation requires that WCB/OEA collect ''data on all incarcerated people's communications services from all providers of those services now subject to'' the Commission's ratemaking authority, including, but not limited to, requesting ''more recent data for additional years not covered by the [Third Mandatory Data Collection].'' The Commission directed WCB/OEA to modify the template and instructions of the most recent data collection to the extent appropriate to timely collect such information to cover the additional services and providers now subject to the Commission's authority.

4. In seeking comment on their proposals for the proposed 2023 Mandatory Data Collection, WCB/OEA do not seek additional comment on the questions and other issues previously raised in other relevant Commission notices. Such comment is more appropriately submitted during the comment period specifically established for those notices. Thus, comments in response to this document need not include advocacy regarding issues raised in those notices, including how the Commission should interpret the language of the Martha Wright-Reed Act to ensure that it implements the statute in a manner that fulfills Congress's intent, the extent to which particular types of safety and security measures are necessary to provide IPCS, or the appropriate treatment of site commissions.

Overall Approach

5. Pursuant to their delegated authority, WCB/OEA propose updated

instructions, a template, and a certification form for the proposed 2023 Mandatory Data Collection, as posted on the Commission's website. The template consists of a Word document (Word template) and Excel spreadsheets (Excel template). WCB/OEA seek comment on all aspects of these proposed documents. Do the proposed documents seek all the information the Commission will need to establish a compensation plan ensuring that IPCS rates and charges are just and reasonable and that IPCS providers are fairly compensated, consistent with the Martha Wright-Reed Act? If not, what steps should WCB/OEA take to improve the proposed documents? The Commission's prior data collections have demonstrated that detailed and specific instructions and templates are essential to ensure that providers use comparable procedures to determine and report their costs, revenues, demand units, and other data. WCB/OEA invite comment on whether the proposed instructions and template are sufficiently detailed to accomplish this objective. If not, what additional instructions, inquiries, or fields should be added? Conversely, are there any instructions, inquiries, or fields that could be removed because they are unnecessary?

6. WCB/OEA propose to retain the overall structure of the Third Mandatory Data Collection, while revising and supplementing the definitions, instructions, and template to accommodate the Commission's expanded authority. To a large extent, the specific information they propose to collect, and the related instructions (including those relating to cost allocation), parallel the information collected by, and the instructions for, the Third Mandatory Data Collection. WCB/OEA invite comment on this approach. They ask that any commenter supporting an alternative approach, either with regard to the data collection as a whole or a particular aspect, explain in detail how that alternative approach would enable the Commission to discharge its responsibilities under the Martha Wright-Reed Act and the Communications Act of 1934, as amended (the Communications Act).

7. *Reporting Period.* In the Third Mandatory Data Collection, WCB/OEA required providers to submit data and other information for calendar years 2019, 2020, and 2021. WCB/OEA propose to generally limit the forthcoming data collection to calendar year 2022 data. They invite comment on this proposal. Does it properly balance the need for information, including cost data, on the video and intrastate services that were not previously subject to the Commission's ratemaking authority against the additional burdens providers would encounter in developing that information for years prior to 2022? Should WCB/OEA instead require providers to incorporate information on their video and intrastate IPCS operations into their data collection responses for 2020 and 2021, and to report that information in addition to information for 2022?

8. *Cost Categories.* The Martha Wright-Reed Act expands the Commission's authority under section 276(b)(1)(A) of the Communications Act to include ''advanced communications services,'' as defined in section 3(1)(A), (B), (D), and new (E) of the Communications Act. Those provisions of section 3(1), in turn, define ''advanced communications services'' as including (1) ''interconnected VoIP [Voice over internet Protocol] service,'' (2) ''non-interconnected VoIP service,'' (3) ''interoperable video conferencing service,'' and (4) ''any audio or video communications service used by inmates for the purpose of communicating with individuals outside the correctional institution where the inmate is held, regardless of technology used.'' The Act also extends the Commission's ratemaking authority to intrastate as well as interstate and international IPCS.

9. WCB/OEA propose to require providers to allocate their investments and expenses among audio IPCS, video IPCS, safety and security measures, various types of ancillary services, and other services and products, on both a company-wide and a facility-specific basis for 2022 (the types of ancillary services are automated payment services, live agent service, paper bill/statement service, single-call and related services, third-party financial transaction services, and other ancillary services). WCB/OEA invite comment on this proposal. Should any additional categories be specified for providers to use? Alternatively, would a more limited group of cost categories still allow the Commission to discharge its ratemaking responsibilities?

10. Are separate cost data for audio IPCS and video IPCS services necessary, or sufficient, for the Commission to ensure just and reasonable rates for those services? If not, what alternative approach should be used? What are the challenges of allocating IPCS costs between audio and video services? Do IPCS providers maintain sufficient records to directly assign or directly attribute significant percentages of their costs to audio IPCS and video IPCS? If not, how should providers allocate their IPCS costs between these two categories of services?

11. The proposed instructions and template would not require providers to subdivide their audio IPCS costs or their video IPCS costs into more discrete categories. WCB/OEA seek comment on this approach. What different types of audio and video services do IPCS providers offer to incarcerated people? Do the costs of providing audio IPCS vary depending on whether it is a traditional voice service, an interconnected VoIP service, a non-interconnected VoIP service, or another type of audio service used by incarcerated people to communicate with the non-incarcerated? For example, do providers pay intercarrier compensation charges for some types of IPCS but not for others? Do non-interconnected voice services have their own unique costs? Are the net cost differences among types of video IPCS sufficiently significant and measurable in a meaningful way to justify the additional burden of separate reporting? If separate reporting is justified, how should the proposed instructions and template be revised to capture those cost differences? Similarly, do the costs of providing video IPCS vary depending on the nature of the video service? To the extent there are such variations, how should WCB/OEA revise the instructions and templates to capture them?

12. *Intrastate and International IPCS.* In the Third Mandatory Data Collection, WCB/OEA required providers to report the costs of providing inmate calling services on a total company basis, without separating them into interstate/international and intrastate components. Although companies had the option to allocate their total company costs between interstate/international and intrastate inmate calling services, no provider exercised this option. Accordingly, WCB/OEA propose to follow their previous approach and require companies to report costs for IPCS without separation between these jurisdictions and provide an option for separate reporting for companies that elect to do so. WCB/OEA seek comment on this proposal. Do the costs of either audio IPCS or video IPCS vary significantly depending on whether they are interstate, intrastate, or international? If so, how should WCB/OEA revise the proposed instructions and templates to capture those differences? In the Third Mandatory Data Collection, WCB/OEA required inmate calling services providers to report their payments to carriers for terminating international communications as an operating

expense without jurisdictional separation on both a total-company and a facility-by-facility basis. The proposed instructions and Excel template would continue this approach.

13. The proposed instructions also require providers to separately report expenses related to routing and completing communications to international destinations as operating expenses. Will the proposed instructions yield accurate and usable data sufficient for the Commission to evaluate these expenses? Why or why not? Are there changes WCB/OEA should consider to the proposed instructions in this regard? If so, what are they?

14. *Costs of Providers' Safety and Security Measures.* The Martha Wright-Reed Act specifies that the Commission ''shall consider,'' as part of its ratemaking, ''costs associated with any safety and security measures necessary to provide'' telephone service and advanced communications services in correctional institutions. To facilitate the Commission's consideration of such costs, WCB/OEA propose to require providers to report the costs they incurred to provide safety and security measures during 2022, both in the aggregate and in specific categories. Determining those costs would involve several steps.

15. First, the proposed instructions would require providers to allocate a portion of their total-company investments and expenses to a company-wide ''safety and security measures'' category and to exclude those investments and expenses from all other cost categories. This allocation would be done in accordance with the detailed cost allocation hierarchy set forth in the instructions. The ''safety and security measures'' category thus would encompass all safety and security services and products that the companies provide, regardless of whether they are provided in connection with audio, video, or nonregulated services, or in connection with traditional telephone or advanced communications services. Do commenters agree with this approach? Instead, should providers be required to report their costs of safety and security measures separately for different categories of services? Why or why not? If safety and security costs are not treated as a separate service or as multiple separate services, then how should the Commission organize the data collection to be able to consider the costs of necessary safety and security measures?

16. Second, the proposed instructions would require each provider to allocate their annual total expenses incurred in providing safety and security measures among seven company-level categories using the provider's best estimate of the percentage of those expenses attributable to each category. As set out in the proposed instructions, annual total expenses are the sum of annual operating expenses and annual capital expenses. The seven company-level categories are: (1) expenses related to Communications Assistance for Law Enforcement Act, (2) law enforcement support services, (3) communication security services, (4) communication recording services, (5) communication monitoring services, (6) voice biometrics services, and (7) other safety and security measures. WCB/OEA seek comment on the benefits and burdens of this approach. They invite comment on the categories of safety and security measures in the proposed instructions. How, if at all, should these categories be changed? Are there other examples of specific safety and security measures that should be included in the illustrative lists included in each of the categories? If so, what are these measures and how should they be categorized? Are there other categories of safety and security measures that should be included? If so, which ones? Alternatively, are there categories that should be removed? If so, which ones should be removed and why? Do commenters agree with the proposed approach of requiring providers to allocate annual total expenses on an estimated percentage basis or should WCB/OEA instead require providers to perform a detailed allocation of actual investments and expenses among the seven categories? To the extent commenters argue that a more detailed cost allocation would be more appropriate, commenters should explain and justify in detail the cost allocation method they propose and the benefits and burdens of their approach.

17. Third, after reporting the best estimate of the percentage of the company's annual total expenses of providing safety and security measures for each category, the proposed instructions would direct providers to report for each of those same categories the company's best estimate of the percentage of safety and security expenses attributable to audio IPCS, video IPCS, ancillary services, and other services and products. Would this approach provide reasonably accurate data on the portions of each category of providers' safety and security costs that are attributable to audio IPCS, video IPCS, ancillary services, and other services and products? Why or why not? If not, is there another allocation method WCB/OEA should consider? If so, what do commenters propose and why would it be preferable to the allocation set forth in the proposed instructions?

18. Providers would also report facility-level safety and security costs for each facility. The proposed instructions would require providers to first identify whether they provide safety and security measures at each facility they serve. Providers would do so by indicating ''Yes'' or ''No'' in the appropriate cell on the Excel template for each of the seven identified categories of safety and security measures at each facility. Wherever providers offer a given safety and security measure, the proposed instructions would then require the provider to allocate its company-wide safety and security annual total expenses for that category among the individual facilities at which that service is offered. Providers would then further allocate those amounts at each facility between audio IPCS, video IPCS, ancillary services, and other services and products. WCB/OEA seek comment on this approach. Would it accurately capture the costs of providing the seven identified categories of safety and security measures at each facility? Why or why not? If not, how could the facility-level reporting be changed to identify the safety and security measures providers offer at the facilities they serve and the cost of providing those measures? Will the subsequent allocation between audio IPCS, video IPCS, ancillary services, and other services and products be sufficiently accurate to capture the costs of providing those safety and security measures in connection with these other services? Why or why not? Are there other methods WCB/OEA should consider that would allow the Commission to evaluate the costs of safety and security measures offered in connection with audio IPCS, video IPCS, ancillary services and other services and products, to the extent cost differences exist? If so, what do commenters propose and why?

19. *Costs of Facilities' Safety and Security Measures.* In the *2023 IPCS Notice,* the Commission sought comment on how it could determine the costs associated with necessary safety and security measures ''to the extent resources of the facilities are used to provide these measures.'' Consistent with that request, WCB/OEA propose to require providers to report any verifiable, reliable, and accurate information in their possession about the costs the facilities they serve incur

to provide safety and security measures in connection with the provision of IPCS. To the extent providers have such information for any specific facility, the instructions would direct providers to report the annual total expenses facilities incur using the same seven categories proposed in connection with reporting provider-incurred safety and security costs. WCB/OEA seek comment on the benefits and burdens of this approach. Is there a better approach the Commission could use to obtain the costs facilities incur in providing safety and security measures? The proposed instructions require providers to be able to reproduce, on request, documentation sufficient to explain and justify the accuracy and reliability of any data they report regarding the expenses incurred by facilities for safety and security measures. Do commenters agree with this approach? Will it enable the Commission to evaluate the reliability and accuracy of any data receives? If not, how should providers be required to demonstrate the accuracy and reliability of the data they provide regarding the costs facilities incur to provide safety and security measures? To the extent providers are not able to establish the accuracy and reliability of the data they rely on, how should the Commission accurately account for these expenses?

20. To assist the Commission in obtaining the broadest possible view of the costs that facilities incur, the proposed instructions also ask providers to indicate whether they have any verifiable, reliable, and accurate information on other facility-incurred costs that are not safety and security costs. To the extent providers have such information, the proposed instructions require that providers be able to reproduce, on request, documentation sufficient to fully explain and justify the accuracy and reliability of any data they report regarding the expenses incurred by facilities that are not safety and security costs.

Specific Instructions

21. WCB/OEA seek comment on the proposed instructions and whether they provide sufficient guidance to ensure that providers use uniform methodologies and report the required information in a consistent manner. Are there any changes that would clarify the proposed instructions or increase uniformity across providers' responses, particularly regarding how to report and allocate their costs? If so, what specific changes should be made? Is there alternative or additional language that would minimize ambiguity in any instruction? Commenters should explain the potential benefits and burdens of alternative or additional language they propose.

22. The proposed instructions also address many data requests that are not specifically described below. WCB/OEA seek comment on all aspects of the proposed instructions, including on requests that they do not specifically seek comment on in this document.

23. *Definitions.* The proposed instructions contain new and revised definitions reflecting the Commission's expanded authority over IPCS. WCB/OEA seek comment on these definitions. Are they sufficiently clear? If not, how should they be modified? Are there any undefined terms that should be defined? Are there any terms that should be added to the proposed instructions that would assist filers in furnishing the Commission with the relevant data? If so, what are they and how should they be defined? Should any proposed definitions be removed?

24. *Required Information.* The proposed instructions would provide guidance for the collection of a variety of data on audio IPCS, video IPCS, safety and security measures, various types of ancillary services, and other services and products. WCB/OEA seek detailed comment on whether additional data should be collected or, conversely, whether the data providers are required to submit be reduced. Commenters urging that WCB/OEA should request different data should explain how their proposals would affect the Commission's ability to meet its responsibilities under the Martha Wright-Reed Act and the Communications Act. Would the benefits of requesting different data justify the costs? Why or why not?

25. *Response Granularity.* WCB/OEA propose that all providers submit data both at the company-wide level and for each correctional facility in which the provider offered IPCS during 2022. They seek comment on this approach. WCB/OEA propose this method to fully account in a coherent way for the shared costs providers incur as some of the assets or labor they use to provide IPCS are also used to provide other services, and are used to provide IPCS to multiple facilities. If parties believe that a different level of granularity is appropriate, please explain. Assuming WCB/OEA should require providers to report data on a facility-level basis, how should providers that do not track costs on a facility level be required to respond? Are the cost allocation procedures set forth in the proposed instructions sufficient to enable these providers to allocate costs down to the facility and, if not, what additional procedures should be required? Are there any additional data WCB/OEA should seek that would help ensure that providers allocate costs to facilities in a manner that more accurately reflects how such costs are incurred?

26. *Cost Allocation.* WCB/OEA propose several steps for providers to follow in allocating their costs among various services, as set forth in the proposed instructions. What refinements, if any, should be made to the proposed cost allocation methodology? Is there an alternative methodology that would better ensure that providers allocate their costs in a manner consistent with how they are incurred? If so, what is that methodology and why would it produce more accurate results than the proposed method? Would the benefits of an alternative methodology justify the costs?

27. *Financial Information.* The proposed instructions retain the requirements that providers report financial data in accordance with generally accepted accounting principles (GAAP) and asset values that reflect the results of recent impairment testing. Under GAAP, an asset or asset group is impaired when its carrying amount, that is, the value reflected on the balance sheet, net of depreciation or amortization, exceeds its fair market value. In that case, the value of the impaired asset or asset group is written down and the reduced value is reflected on the balance sheet and a loss is recorded on the income statement. Is this the correct approach? If not, why not? Are other or additional instructions needed to ensure that the carrying value of any provider's assets is not misstated? If so, what other instructions should be adopted?

28. *Site Commissions.* The proposed instructions retain in large part the questions concerning company-wide and facility-level site commission data from the Third Mandatory Data Collection. Are there specific changes WCB/OEA should consider, either to the overall structure or level of disaggregation for site commission data? If so, what changes do commenters suggest and why? As explained in the proposed instructions, WCB/OEA propose new narrative questions in a separate Word template designed to obtain information about interstate, intrastate, and international site commissions, including whether and how the formulas providers use to calculate monetary site commissions differ among interstate, intrastate, and international communications. WCB/OEA also propose a new Word template question seeking information about

whether providers pay site commissions separately on audio and video services and how those site commissions are calculated. WCB/OEA invite comment on these proposed questions and ask commenters to suggest alternative questions that would help the Commission obtain reliable and accurate data and information on site commission payments for interstate, intrastate, and international, as well as for audio and video, communications.

29. *Ancillary Services.* While the proposed instructions retain essentially the same company-wide and facility-level questions about ancillary services that were asked as part of the Third Mandatory Data Collection, WCB/OEA invite comment on potential changes that they should consider. Do commenters suggest that WCB/OEA add or remove questions in these sections? If so, what should be added or removed? Is there a better structure or approach that would yield more accurate, reliable, or useful data? If so, what do commenters propose? Given the Commission's expanded authority under the Martha Wright-Reed Act, WCB/OEA propose new Word template questions that would seek information on how providers assess ancillary service charges on interstate, intrastate, and international communications, in light of the Commission's previous conclusion that ''ancillary service charges generally cannot be practically segregated between the interstate and intrastate jurisdiction.'' WCB/OEA also propose to add Word template questions regarding the ancillary service charges or other charges assessed in connection with video services and whether there are any differences between the types of ancillary service charges assessed in connection with video and audio IPCS. WCB/OEA invite comment on these questions. Are there other questions they should ask that would assist the Commission in evaluating any differences based on either the jurisdiction of the communications service or whether the charges are being assessed in connection with an audio or video service? Are providers currently assessing any other charges in connection with video communications that fall outside of the five ancillary service charges permitted under the Commission's rules? If so, what are they and how should they be addressed in the data collection? Are there particular questions WCB/OEA should ask to help the Commission understand how providers assess ancillary service charges in circumstances where service offerings might be mixed between audio and video services?

Reporting Template

30. WCB/OEA propose to require providers to submit the requisite data using a reporting template, to be filed through the Commission's Electronic Comment Filing System (ECFS). The proposed template consists of a Word document (Appendix A to the instructions) for responses requiring narrative information and Excel spreadsheets (Appendix B to the instructions) for responses that require numeric or other information. WCB/OEA seek comment on proposed modifications in the template seeking data relevant to the Commission's expanded jurisdiction, including modifications to collect data on video IPCS and safety and security measures. WCB/OEA also seek suggestions for improvements they can make to the template. Is there an alternative organization that would reduce any perceived burdens, without compromising the reliability and accuracy of the data WCB/OEA are able to collect? Are there other organizational or substantive improvements they can make to the reporting template? Do any questions require clarification?

Timeframe for Provider Responses to the Data Collection

31. WCB/OEA invite comment on the timeframe for provider responses to the data collection. In the *2023 IPCS Order,* the Commission explained that ''[a]ny new or modified requirements that require approval from the Office of Management and Budget (OMB) under the Paperwork Reduction Act shall be effective on the date specified in a notice published in the **Federal Register** announcing OMB's approval.'' Importantly, the Martha Wright-Reed Act imposes a statutory requirement that the Commission ''promulgate any regulations necessary to implement'' the Act, not earlier than 18 months and not later than 24 months after the Act's January 5, 2023 enactment. As the Commission explained in *the 2023 IPCS Order,* ''[a]ny unnecessary delay in our efforts to collect appropriate information would be inconsistent with, and undermine the Commission's ability to meet the deadlines contained in, the Act.'' Given these constraints, WCB/OEA propose to require providers to file their responses to the data collection within 90 days of the release of the order approving the data collection. Do commenters agree with this timeframe? Would it afford providers sufficient time to prepare and submit their responses while also allowing the Commission to act expeditiously to implement the Martha Wright-Reed Act within the statutory timeframe? Why or why not? Should WCB/OEA instead consider a shorter, or longer, timeframe for providers to respond to the data collection? If so, what timeframe do commenters propose and why?

Digital Equity and Inclusion

32. As part of the Commission's continuing effort to advance communications equity for all, including people of color and others who have been historically underserved, marginalized, and adversely affected by persistent poverty and inequality, WCB/OEA invite comment on any equity-related considerations and benefits that may be associated with the upcoming data collection. Specifically, WCB/OEA seek comment on how their proposals for that collection may promote or inhibit advances in diversity, equity, inclusion, and accessibility. WCB/OEA define the term ''equity'' consistent with Executive Order 13985 as the consistent and systematic fair, just, and impartial treatment of all individuals, including individuals who belong to underserved communities that have been denied such treatment, such as Black, Latino, and Indigenous and Native American persons, Asian Americans and Pacific Islanders and other persons of color; members of religious minorities; lesbian, gay, bisexual, transgender, and queer (LGBTQ+) persons; persons with disabilities; persons who live in rural areas; and persons otherwise adversely affected by persistent poverty or inequality. Exec. Order No. 13985, 86 FR 7009, Executive Order on Advancing Racial Equity and Support for Underserved Communities Through the Federal Government (Jan. 20, 2021).

Procedural Matters

33. *Ex Parte Presentations.* This proceeding shall be treated as a ''permit-but-disclose'' proceeding in accordance with the Commission's ex parte rules. Persons making *ex parte* presentations must file a copy of any written presentation or a memorandum summarizing any oral presentation within two business days after the presentation (unless a different deadline applicable to the Sunshine period applies). Persons making oral *ex parte* presentations are reminded that memoranda summarizing the presentation must (1) list all persons attending or otherwise participating in the meeting at which the *ex parte* presentation was made, and (2) summarize all data presented and arguments made during the presentation. If the presentation

consisted in whole or in part of the presentation of data or arguments already reflected in the presenter's written comments, memoranda, or other filings in the proceeding, the presenter may provide citations to such data or arguments in the prior comments, memoranda, or other filings (specifying the relevant page and/or paragraph numbers where such data or arguments can be found) in lieu of summarizing them in the memorandum. Documents shown or given to Commission staff during *ex parte* meetings are deemed to be written *ex parte* presentations and must be filed consistent with § 1.1206(b) of the Commission's rules. Participants in this proceeding should familiarize themselves with the Commission's *ex parte* rules.

34. *Supplemental Initial Regulatory Flexibility Act Analysis.* As required by the Regulatory Flexibility Act, the Commission has prepared a Supplemental Initial Regulatory Flexibility Analysis (Supplemental IRFA) of the possible significant economic impact on small entities by the policies and rules proposed in this document. The Commission requests written public comments on the Supplemental IRFA. Comments must be identified as responses to the Supplemental IRFA and must be filed by the deadlines for comments provided in this document. The Commission will send a copy of this document, including this Supplemental IRFA, to the Chief Counsel for Advocacy of the Small Business Administration (SBA). In addition, summaries of this document and the Supplemental IRFA will be published in the **Federal Register**.

35. *Initial Paperwork Reduction Act Analysis.* This document, and the instructions and templates, contain new or modified information collection requirements subject to the Paperwork Reduction Act of 1995 (PRA), Public Law 104–13. It will be submitted to OMB for review under section 3507(d) of the PRA. OMB, the general public, and other Federal agencies are invited to comment on the new or modified information collection requirements contained in this proceeding. Contemporaneously with the publication of this Notice in the **Federal Register**, WCB/OEA will publish a notice in the **Federal Register** seeking comment pursuant to the PRA on the information collection requirements for the proposed 2023 Mandatory Data Collection in the *2023 IPCS Notice* and this document. WCB/OEA will consider comments submitted in response to both **Federal Register** notices in finalizing this information collection for submission to OMB. In addition, WCB/OGC note that pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198; *see* 44 U.S.C. 3506(4), they seek comment on how the Commission may further reduce the information collection burden for small business concerns with fewer than 25 employees.

Supplemental Initial Regulatory Flexibility Analysis

36. As required by the Regulatory Flexibility Act of 1980, as amended (RFA), WCB/OEA have prepared this Supplemental IRFA of the possible significant economic impact on small entities by the policies and rules proposed in this document to supplement the Commission's Regulatory Flexibility Analyses completed in the *2023 IPCS Notice* and *2023 IPCS Order.* WCB/OEA request written public comment on this Supplemental IRFA. Comments must be identified as responses to the Supplemental IRFA and must be filed by the deadlines for comments provided in this document. The Commission will send a copy of this document, including this Supplemental IRFA, to the Chief Counsel for Advocacy of the SBA. This present Supplemental IRFA conforms to the RFA.

Need for, and Objectives of, the Proposed Rules

37. In this document, WCB/OEA seek comment on the contours and specific requirements of the proposed 2023 Mandatory Data Collection for IPCS. In issuing this document, WCB/OEA act pursuant to the Commission's directive so that it will be able to implement the Martha Wright-Reed Act. The Commission determined that this data collection would enable it to ''meet both [its] procedural obligations (to consider certain types of data) and [its] substantive responsibilities (to set just and reasonable rates and charges)'' under the Martha Wright-Reed Act and the Communications Act. Likewise, it directed WCB/OEA ''to update and restructure the most recent data collection as appropriate to implement the Martha Wright-Reed Act.''

38. Pursuant to their delegated authority, WCB/OEA have drafted instructions, a template, and a certification form for the proposed 2023 Mandatory Data Collection and are issuing this document to seek comment on all aspects of these proposed documents.

Legal Basis

39. The proposed action is pursuant sections 1, 2, 4(i)–(j), 5(c), 201(b), 218, 220, 225, 255, 276, 403 and 716 of the Communications Act of 1934, as amended, 47 U.S.C. 151, 152, 154(i)–(j), 155(c), 201(b), 218, 220, 225, 255, 276, 403, and 617, and the Martha Wright-Reed Act, Public Law 117–338, 136 Stat. 6156 (2022).

Description and Estimate of the Number of Small Entities to Which the Proposed 2023 Rules Would Apply

40. The RFA directs agencies to provide a description of, and where feasible, an estimate of the number of small entities that may be affected by the proposed 2023 Mandatory Data Collection. The RFA generally defines the term ''small entity'' as having the same meaning as the terms ''small business,'' ''small organization,'' and ''small governmental jurisdiction.'' In addition, the term ''small business'' has the same meaning as the term ''small-business concern'' under the Small Business Act. A ''small-business concern'' is one which: (1) is independently owned and operated; (2) is not dominant in its field of operation; and (3) satisfies any additional criteria established by the SBA.

41. As noted above, an IRFA was incorporated in the *2023 IPCS Notice.* In that analysis, the Commission described in detail the small entities that might be affected. Accordingly, in this document, for the Supplemental IRFA, WCB/OEA hereby incorporate by reference the descriptions and estimates of the number of small entities from the *2023 IPCS Notice's* IRFA.

Description of Project Reporting, Recordkeeping, and Other Compliance Requirements for Small Entities

42. This document seeks comment on the specifics of the proposed 2023 Mandatory Data Collection to ensure that the Commission receives the data it needs to meet its substantive and procedural responsibilities under the Act. The proposed 2023 Mandatory Data Collection would require IPCS providers to submit, among other things, data and other information on calls, demand, operations, company and contract information, information about facilities served, revenues, site commission payments, the costs of safety and security measures, video IPCS, and ancillary fees. The proposed 2023 Mandatory Data Collection may require entities, including small entities and IPCS providers of all sizes, currently subject to the Commission's inmate calling services rules to be subject to modified or new reporting or other compliance obligations. This may also be the case for providers newly subject to the Commission's expanded regulatory authority, such as providers

offering only intrastate or certain advanced communications. In addition, WCB/OEA recognize that their actions in this proceeding may affect the reporting, recordkeeping, and other compliance requirements for several groups of small entities. In assessing the cost of compliance for small entities and for providers of incarcerated people's communications services of all sizes, at this time WCB/OEA are not in a position to determine whether the proposed 2023 Mandatory Data Collection will impose any significant costs for compliance in general. WCB/OEA anticipate the information they receive in comments, including any cost and benefit analyses, will help the Commission identify and evaluate relevant compliance matters for small entities, including compliance costs and other burdens that may result from the proposals and inquiries they make in this document.

Steps Taken To Minimize the Significant Economic Impact on Small Entities and Significant Alternatives Considered

43. The RFA requires an agency to describe any significant alternatives that it has considered in reaching its proposed approach, which may include the following four alternatives (among others): ''(1) the establishment of differing compliance or reporting requirements or timetables that take into account the resources available to small entities; (2) the clarification, consolidation, or simplification of compliance and reporting requirements under the rules for such small entities; (3) the use of performance rather than design standards; and (4) an exemption from coverage of the rule, or any part thereof, for such small entities.'' WCB/OEA will consider all of these factors when they receive substantive comment from the public and potentially affected entities.

44. The proposed 2023 Mandatory Data Collection is a one-time request and does not impose a recurring obligation on providers. Because the Commission's *2023 IPCS Order* requires all IPCS providers to comply with the proposed 2023 Mandatory Data Collection, the collection will affect smaller as well as larger IPCS providers. WCB/OEA have taken steps to ensure that the data collection template is competitively neutral and not unduly burdensome for any set of providers. For example, this document proposes to collect data for a single calendar year instead of three calendar years, as in the previous data collection. Additionally, this document asks whether there are ways of minimizing the burden of the data collection on providers while still ensuring that the Commission collects all the data needed to meet its goals.

45. WCB/OEA will consider the economic impact on small entities, as identified in comments filed in response to this document and this Supplemental IRFA, in reaching their final conclusions and finalizing the instructions, the template, and certification form for the proposed 2023 Mandatory Data Collection.

Federal Rules That May Duplicate, Overlap, or Conflict With the Proposed Rules

46. None.

(Authority: 47 U.S.C. 151–63)

Federal Communications Commission.

Lynne Engledow,

Deputy Chief, Pricing Policy Division, Wireline Competition Bureau.

[FR Doc. 2023–09502 Filed 5–2–23; 8:45 am]

BILLING CODE 6712–01–P

Notices

Federal Register
Vol. 88, No. 85
Wednesday, May 3, 2023

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Submission for OMB Review; Comment Request

The Department of Agriculture has submitted the following information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Comments are requested regarding: whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; ways to enhance the quality, utility and clarity of the information to be collected; and ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Comments regarding this information collection received by June 2, 2023 will be considered. Written comments and recommendations for the proposed information collection should be submitted within 30 days of the publication of this notice on the following website *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

An agency may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

National Institute of Food and Agriculture

Title: Small Business Innovation Research (SBIR) Program.

OMB Control Number: 0524–0049.

Summary of Collection: The Small Business Innovation Research (SBIR) program at the U.S. Department of Agriculture (USDA) makes competitively awarded grants to qualified small businesses to support high quality, advanced concepts research related to important scientific problems and opportunities in agriculture that could lead to significant public benefit if successful. The objectives of the SBIR Program are to: stimulate technological innovation in the private sector; strengthen the role of small businesses in meeting Federal research and development needs; increase private sector commercialization of innovations derived from USDA-supported research and development efforts; and foster and encourage participation by women-owned and socially and economically disadvantaged small business firms in technological innovation. The USDA SBIR Program is administered by the National Institute of Food and Agriculture (NIFA) of the USDA.

Need and Use of the Information: The USDA SBIR Program Office proposes to contact Phase II awardees to determine their success in achieving commercial application of a market ready technology that was funded under the USDA SBIR Program. The survey would collect information from Phase II companies that received funding during the years of 2016 to 2019. Data from the survey will be used to provide information that currently does not exist. The data will be used internally by the USDA SBIR Office to identify past and current activities of Phase II grantees in the areas of technology development, commercialization success, product development or services, and factors that may have prevented the technology from entering into the marketplace.

Description of Respondents: Business or other for-profit.

Number of Respondents: 121.

Frequency of Responses: Reporting: On occasion.

Total Burden Hours: 61.

Ruth Brown,

Departmental Information Collection Clearance Officer.

[FR Doc. 2023–09324 Filed 5–2–23; 8:45 am]

BILLING CODE 3410–09–P

DEPARTMENT OF AGRICULTURE

Food and Nutrition Service

Agency Information Collection Activities: Proposed Collection; Comment Request—The Special Supplemental Nutrition Program for Women, Infants and Children (WIC) Breastfeeding Award of Excellence

AGENCY: Food and Nutrition Service (FNS), USDA.

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice invites the general public and other public agencies to comment on this proposed information collection. This collection is a revision of a currently approved collection for awarding local agencies for excellence in WIC breastfeeding services and support.

DATES: Written comments must be received on or before July 3, 2023.

ADDRESSES: The Food and Nutrition Service, USDA, invites interested persons to submit written comment.

- *Preferred Method:* Federal eRulemaking Portal. Go to *http://www.regulations.gov* and follow the online instructions for submitting comments electronically.
- *Mail:* Send comments to: Kristin Garcia, Director, Food Safety and Nutrition Division, Food and Nutrition Service, U.S. Department of Agriculture, 1320 Braddock Pl., Alexandria, VA 22314.

All responses to this notice will be summarized and included in the request for Office of Management and Budget approval. All comments will be a matter of public record.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of this information collection should be directed to Valery Soto, Chief, Nutrition Services and Promotion Branch, Food Safety and Nutrition Division, FNS, USDA, 1320 Braddock

Pl., Alexandria, VA 22314. Telephone: (703) 305–2742.

SUPPLEMENTARY INFORMATION: Section 231 of the Healthy, Hunger-Free Kids Act of 2010, Public Law 111–296, requires that the Department of Agriculture (USDA) establish a program to recognize WIC local agencies and clinics that demonstrate exemplary breastfeeding promotion and support activities.

Comments are invited on: (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions that were used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on those who are to respond, including use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Title: Special Supplemental Nutrition Program for Women, Infants and Children (WIC) Breastfeeding Award of Excellence.

Form Number: Not applicable.

OMB Number: 0584–0591.

Expiration Date: 11/30/2023.

Type of Request: Revision of a currently approved collection.

Abstract: This information collection is mandated by section 231 of the Healthy, Hunger-Free Kids Act of 2010 (HHFKA) (Pub. L. 111–296). Section 231 of the HHFKA, which requires USDA to implement a program to recognize exemplary breastfeeding support practices at WIC local agencies and clinics. The WIC Program provides breastfeeding promotion and support for pregnant and postpartum mothers as a part of its mission to improve the health of the approximately 6 million Americans it serves each month. Breastfeeding is a priority in WIC and WIC mothers are strongly encouraged to breastfeed their infants unless medically contraindicated.

In recognizing exemplary local agencies and clinics, the HHFKA requires the Secretary to consider the following criteria: (1) performance measurements of breastfeeding; (2) the effectiveness of a peer counselor program; (3) the extent to which the agency or clinic has partnered with other entities to build a supportive breastfeeding environment for women participating in WIC; and (4) other criteria the Secretary considers appropriate after consultation with State and local program agencies. The information will be submitted voluntarily by WIC local agencies who will be applying for an award. FNS will use the information collected to evaluate the components of existing breastfeeding programs and support in WIC local agencies and make decisions about awards. This program is expected to provide models and motivate local agencies and clinics to strengthen their breastfeeding promotion and support activities.

A notable improvement from past collection requests is that FNS hosts the application process for local agencies fully online. The State agencies continue to conduct their evaluation on PartnerWeb. FNS plans to explore ways to streamline the evaluation for State agencies to improve their user experience. The total estimated time to complete the application is not expected to change.

Affected Public: State, local and Tribal government: Respondent groups identified include local and State WIC agencies.

Estimated Number of Respondents: The total estimated number of participants is 239: 150 local WIC agencies, 89 State WIC agencies.

WIC Peer Counseling is an FNS initiative that equips WIC programs with an implementation and management model—the ''WIC Breastfeeding Model for Peer Counseling''—to serve as a framework for designing, building, and sustaining peer counseling programs, a requirement for award eligibility. Since the inception of the program in 2015, a total of 728 awards have been given. In fiscal year (FY) 2020, 138 eligible local agencies applied for an award; in FY 2021, 130 eligible local agencies applied for an award; in FY 2022, 127 eligible local agencies applied for an award; and in FY 2023, 143 eligible local agencies applied for awards. FNS estimates the annual submitted applications will range from 130–150 applications submitted annually. For small entities WIC estimates that 7–8% (11 applications) of local agency applications do not come from health departments. The estimated number of respondents for the State agency application verification is derived from the total number of State WIC agencies.

Estimated Number of Responses per Respondent: The estimated number of responses per respondent for the WIC local agency is one, as each eligible WIC local agency can submit one application. The estimated number of responses per respondent for the WIC State agency is 2.0, as each WIC State agency will evaluate approximately 2.0 applications annually. These estimates were derived by dividing the total number of responses for the WIC Local Agency Application or the State Agency Evaluation by the respective number of respondents. Overall, the estimated number of responses per respondent across the entire collection is 1.4, which is derived by dividing the total number of responses (328) by the total estimated number of respondents (239).

Estimated Total Annual Responses: 328.

Estimated Time per Response: FNS estimates the WIC local agency application response is 2.5 hours, and the WIC State agency response is 1.5 hours. Overall, the average estimated time for all of the award participants is 2 hours. The estimated average number of hours per response was derived by dividing the number of estimated total hours (642), by the number of total annual responses by all respondents (328). The time for the WIC local agency is an estimated time for the agency to voluntarily review the instructions, fill out the ''WIC Breastfeeding Award of Excellence'' application, and attach supportive documentation. The time for the State WIC agency is an estimated time for the agency to review the instructions, evaluate the components of the local WIC agencies applications, and make a recommendation for an award.

Estimated Total Annual Burden on Respondents: 642.0 hours.

See the Burden table below for estimated total annual burden for each type of respondent.

Respondent	Estimated number of respondent	Responses annually per respondent	Total annual responses	Estimated avg. number of hours per response *	Estimated total hours
Reporting Burden					
Small Entity Application	11.0	1.0	11.0	2.5	27.5
WIC Local Agency Application	139.0	1.0	139.0	2.5	347.5
WIC State Agency Evaluation	89.0	2.0	178.0	1.5	267.0
Total Reporting Burden	239.0	1.4	328.0	2.0	642.0

* Estimated average # of hours per response includes .5 hours for reviewing instructions.

Tameka Owens,

Assistant Administrator, Food and Nutrition Service.

[FR Doc. 2023–09359 Filed 5–2–23; 8:45 am]

BILLING CODE 3410–30–P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meeting of the Arizona Advisory Committee

AGENCY: U.S. Commission on Civil Rights.

ACTION: Announcement of virtual briefing.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission) and the Federal Advisory Committee Act (FACA) that a briefing of the Arizona Advisory Committee (Committee) to the Commission will convene via *ZoomGov* on Tuesday, May 23, 2023, from 12:00 p.m.–3:00 p.m. Arizona Time. The purpose of the briefing is to collect testimony from invited panelists regarding racial and/or ethnic disparities in pediatric healthcare in Arizona.

DATES: The briefing will take place on:

- Friday, May 23, 2023, from 12:00 p.m.–3:00 p.m. Arizona Time

ADDRESSES:

Access Information:

Link to Join (Audio/Visual):

https://www.zoomgov.com/j/1612316896?pwd=bkNaOHZIdzhxZDhXSDJNSk5VZEJtdz09.

Telephone (Audio Only) Dial: 1–833–435–1820 (US Toll-free); Meeting ID: 161 231 6896#.

FOR FURTHER INFORMATION CONTACT: Kayla Fajota, DFO, at *kfajota@usccr.gov* or (434) 515–2395.

SUPPLEMENTARY INFORMATION: Committee meetings are available to the public through the videoconference link above. Any interested member of the public may listen to the meeting. An open comment period will be provided to allow members of the public to make a statement as time allows. Per the Federal Advisory Committee Act, public minutes of the meeting will include a list of persons who are present at the meeting. If joining via phone, callers can expect to incur regular charges for calls they initiate over wireless lines, according to their wireless plan. The Commission will not refund any incurred charges. Closed captioning will be available for individuals who are deaf, hard of hearing, or who have certain cognitive or learning impairments. To request additional accommodations, please email *kfajota@usccr.gov* at least 10 business days prior to the meeting.

Members of the public are entitled to make comments during the open period at the end of the meeting. Members of the public may also submit written comments; the comments must be received in the Regional Programs Unit within 30 days following the meeting. Written comments may be mailed to the Western Regional Office, U.S. Commission on Civil Rights, 300 North Los Angeles Street, Suite 2010, Los Angeles, CA 90012 or email Kayla Fajota (DFO) at *kfajota@usccr.gov.*

Records and documents discussed during the meeting will be available for public viewing prior to and after the meetings at *https://www.facadatabase.gov/FACA/FACAPublicViewCommitteeDetails?id=a10t0000001gzl2AAA.*

Please click on the ''Committee Meetings'' tab. Records generated from these meetings may also be inspected and reproduced at the Regional Programs Unit, as they become available, both before and after the meetings. Persons interested in the work of this Committee are directed to the Commission's website, *https://www.usccr.gov,* or may contact the Regional Programs Unit at the above email or street address.

Agenda

I. Welcome, Roll Call, and Opening Remarks
II. Panelist Presentations
III. Committee Q & A
IV. Public Comment
V. Adjournment

Dated: April 27, 2023.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2023–09310 Filed 5–2–23; 8:45 am]

BILLING CODE P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meeting of the Minnesota Advisory Committee to the U.S. Commission on Civil Rights

AGENCY: Commission on Civil Rights.

ACTION: Notice of public meeting.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission) and the Federal Advisory Committee Act, that the Minnesota Advisory Committee (Committee) to the U.S. Commission on Civil Rights will hold a public meeting via Zoom at 12:30 p.m. CT on Thursday, May 25, 2023, to discuss the Committee's draft project proposal on housing affordability in the state.

DATES: Thursday, May 25, 2023, from 12:30 p.m.–1:30 p.m. Central Time.

ADDRESSES: The meeting will be held via Zoom.

Registration Link (Audio/Visual): https://www.zoomgov.com/j/1612943387.

Join by Phone (Audio Only): (833) 435–1820 USA Toll-Free; Meeting ID: 161 294 3387.

FOR FURTHER INFORMATION CONTACT: David Barreras, Designated Federal Officer, at *dbarreras@usccr.gov* or (202) 656–8937.

SUPPLEMENTARY INFORMATION: This committee meeting is available to the public through the registration link above. Any interested member of the public may listen to the meeting. An open comment period will be provided to allow members of the public to make a statement as time allows. Per the Federal Advisory Committee Act, public minutes of the meeting will include a list of persons who are present at the

meeting. If joining via phone, callers can expect to incur regular charges for calls they initiate over wireless lines, according to their wireless plan. The Commission will not refund any incurred charges. Callers will incur no charge for calls they initiate over land-line connections to the toll-free telephone number. Closed captioning will be available for individuals who are deaf, hard of hearing, or who have certain cognitive or learning impairments. To request additional accommodations, please email Liliana Schiller, Support Services Specialist, at *lschiller@usccr.gov* at least 10 business days prior to the meeting.

Members of the public are entitled to submit written comments; the comments must be received in the regional office within 30 days following the meeting. Written comments may be emailed to David Barreras at *dbarreras@usccr.gov.* Persons who desire additional information may contact the Regional Programs Coordination Unit at (312) 353–8311.

Records generated from this meeting may be inspected and reproduced at the Regional Programs Coordination Unit Office, as they become available, both before and after the meeting. Records of the meetings will be available via *www.facadatabase.gov* under the Commission on Civil Rights, Minnesota Advisory Committee link. Persons interested in the work of this Committee are directed to the Commission's website, *http://www.usccr.gov,* or may contact the Regional Programs Coordination Unit at *lschiller@usccr.gov.*

Agenda

I. Welcome & Roll Call
II. Discussion: Housing Affordability in Minnesota
III. Public Comment
IV. Next Steps
V. Adjournment

Dated: April 27, 2023.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2023–09325 Filed 5–2–23; 8:45 am]

BILLING CODE P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meeting of the Minnesota Advisory Committee to the U.S. Commission on Civil Rights

AGENCY: Commission on Civil Rights.

ACTION: Notice of public meeting.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission) and the Federal Advisory Committee Act, that the Minnesota Advisory Committee (Committee) to the U.S. Commission on Civil Rights will hold a public meeting via Zoom at 12:30 p.m. CT on Thursday, June 8, 2023, to discuss the Committee's project on housing affordability in the state.

DATES: Thursday, June 8, 2023, from 12:30 p.m.–1:30 p.m. Central Time.

ADDRESSES: The meeting will be held via Zoom.

Registration Link (Audio/Visual): https://www.zoomgov.com/j/1617325509.

Join by Phone (Audio Only): (833) 435–1820 USA Toll-Free; Meeting ID: 161 732 5509.

FOR FURTHER INFORMATION CONTACT: David Barreras, Designated Federal Officer, at *dbarreras@usccr.gov* or (202) 656–8937.

SUPPLEMENTARY INFORMATION: This committee meeting is available to the public through the registration link above. Any interested member of the public may listen to the meeting. An open comment period will be provided to allow members of the public to make a statement as time allows. Per the Federal Advisory Committee Act, public minutes of the meeting will include a list of persons who are present at the meeting. If joining via phone, callers can expect to incur regular charges for calls they initiate over wireless lines, according to their wireless plan. The Commission will not refund any incurred charges. Callers will incur no charge for calls they initiate over land-line connections to the toll-free telephone number. Closed captioning will be available for individuals who are deaf, hard of hearing, or who have certain cognitive or learning impairments. To request additional accommodations, please email Liliana Schiller, Support Services Specialist, at *lschiller@usccr.gov* at least 10 business days prior to the meeting.

Members of the public are entitled to submit written comments; the comments must be received in the regional office within 30 days following the meeting. Written comments may be emailed to David Barreras at *dbarreras@usccr.gov.* Persons who desire additional information may contact the Regional Programs Coordination Unit at (312) 353–8311.

Records generated from this meeting may be inspected and reproduced at the Regional Programs Coordination Unit Office, as they become available, both before and after the meeting. Records of the meetings will be available via *www.facadatabase.gov* under the Commission on Civil Rights, Minnesota Advisory Committee link. Persons interested in the work of this Committee are directed to the Commission's website, *http://www.usccr.gov,* or may contact the Regional Programs Coordination Unit at *lschiller@usccr.gov.*

Agenda

I. Welcome & Roll Call
II. Discussion: Housing Affordability in Minnesota
III. Public Comment
IV. Next Steps
V. Adjournment

Dated: April 27, 2023.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2023–09326 Filed 5–2–23; 8:45 am]

BILLING CODE P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B–30–2023]

Foreign-Trade Zone (FTZ) 7, Notification of Proposed Production Activity; AbbVie Ltd.; (Pharmaceutical Products); Barceloneta, Puerto Rico

AbbVie Ltd., submitted a notification of proposed production activity to the FTZ Board (the Board) for its facility in Barceloneta, Puerto Rico within Subzone 7I. The notification conforming to the requirements of the Board's regulations (15 CFR 400.22) was received on April 25, 2023.

Pursuant to 15 CFR 400.14(b), FTZ production activity would be limited to the specific foreign-status material(s)/component(s) and specific finished product(s) described in the submitted notification (summarized below) and subsequently authorized by the Board. The benefits that may stem from conducting production activity under FTZ procedures are explained in the background section of the Board's website—accessible via *www.trade.gov/ftz.* The proposed finished product(s) and material(s)/component(s) would be added to the production authority that the Board previously approved for the operation, as reflected on the Board's website.

The proposed finished product is vraylar (cariprazine) capsules (duty-free).

The proposed foreign-status material is cariprazine hydrochloride active pharmaceutical ingredient (duty rate 6.5%).

Public comment is invited from interested parties. Submissions shall be

addressed to the Board's Executive Secretary and sent to: *ftz@trade.gov.* The closing period for their receipt is June 12, 2023.

A copy of the notification will be available for public inspection in the ''Online FTZ Information System'' section of the Board's website.

For further information, contact Christopher Wedderburn at *Chris.Wedderburn@trade.gov.*

Dated: April 27, 2023.

Elizabeth Whiteman,

Acting Executive Secretary.

[FR Doc. 2023–09351 Filed 5–2–23; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[C–834–811]

Silicon Metal From Kazakhstan: Rescission of Countervailing Duty Administrative Review; 2020–2021

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) is rescinding the administrative review of the countervailing duty (CVD) order on silicon metal from the Republic of Kazakhstan (Kazakhstan) for the period of review (POR) December 3, 2020, through December 31, 2021.

DATES: Applicable May 3, 2023.

FOR FURTHER INFORMATION CONTACT: Genevieve Coen, AD/CVD Operations, Office V, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–3251.

SUPPLEMENTARY INFORMATION:

Background

On April 1, 2022, Commerce published in the **Federal Register** a notice of opportunity to request an administrative review of the CVD order on silicon metal from Kazakhstan.[1] On June 9, 2022, pursuant to a request from interested parties, Commerce initiated an administrative review with respect to JSC NMC Tau-Ken Samruk and Tau-Ken Temir LLP (collectively, TKT),[2] in accordance with section 751(a) of the Tariff Act of 1930, as amended (the Act), and 19 CFR 351.213(b).[3] On June 22, 2022, we placed on the record U.S. Customs and Border Protection (CBP) data for entries of silicon metal from Kazakhstan during the POR, showing no reviewable POR entries.[4] We sought comments regarding the data and indicated our intent to rescind this review.[5] TKT, the Government of Kazakhstan (GOK), and the petitioners [6] filed comments and rebuttal comments.[7] No parties argued that there are any reviewable POR entries of subject merchandise. For a full discussion of the comments raised by interested parties and our analysis, *see* the Rescission Memorandum.[8]

Rescission of Review

It is Commerce's practice to rescind an administrative review of a CVD order, pursuant to 19 CFR 351.213(d)(3), when there are no reviewable entries of subject merchandise during the POR for which liquidation is suspended.[9] Normally, upon completion of an administrative review, the suspended entries are liquidated at the CVD assessment rate calculated for the review period.[10] Therefore, for an administrative review to be conducted, there must be a reviewable, suspended entry that Commerce can instruct CBP to liquidate at the CVD assessment rate calculated for the review period.[11] Accordingly, in the absence of suspended entries of subject merchandise during the POR for TKT, we are hereby rescinding this administrative review in accordance with 19 CFR 351.213(d)(3).

Notification Regarding Administrative Protective Order

This notice serves as the only reminder to parties subject to administrative protective order (APO) of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of the return or destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a sanctionable violation.

Notification to Interested Parties

This notice is issued and published in accordance with sections 751(a)(1) and 777(i)(1) of the Act, and 19 CFR 351.213(d)(4).

Dated: April 27, 2023.

James Maeder,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2023–09395 Filed 5–2–23; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–044]

1,1,1,2-Tetrafluoroethane (R–134a) From the People's Republic of China: Preliminary Results of Antidumping Duty Administrative Review, Partial Rescission, and Preliminary Determination of No Shipments; 2021–2022

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) preliminarily determines that the sole mandatory respondent under review sold subject merchandise at less than normal value (NV) during the period of review (POR) April 1, 2021, through March 31, 2022. Additionally, Commerce preliminarily finds that one company had no shipments of subject merchandise during the POR and that it is appropriate to rescind this review with

[1] *See Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity to Request Administrative Review,* 87 FR 35165 (April 1, 2022).

[2] *See Silicon Metal from the Republic of Kazakhstan: Preliminary Affirmative Countervailing Duty Determination and Alignment of Final Determination with Final Antidumping Duty Determination,* 85 FR 78122 (December 3, 2020), and accompanying Preliminary Decision Memorandum at 6, unchanged in *Silicon Metal from the Republic of Kazakhstan: Final Affirmative Countervailing Duty Determination,* 86 FR 11725 (February 26, 2021).

[3] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 87 FR 35165 (June 9, 2022).

[4] *See* Memorandum, ''CBP Data Release and Intent to Rescind,'' dated June 22, 2022.

[5] *Id.*

[6] The petitioners in this proceeding are Globe Specialty Metals, Inc. and Mississippi Silicon LLC.

[7] *See* TKT's Letters, ''Tau-Ken Temir LLP (TKT) Comments on Intent to Rescind,'' dated July 13, 2022; ''Silicon Metal from Kazakhstan,'' and ''Tau-Ken Temir LLP (TKT) Comments on Intent to Rescind,'' dated July 18, 2022; and ''Silicon Metal from Kazakhstan—This CVD Administrative Review Should Continue,'' dated August 1, 2022; *see also* the GOK's Letter, ''Rebuttal Comments,'' dated July 20, 2022; and Petitioners' Letters, ''Petitioners' Rebuttal Comments Supporting Commerce's Intent to Rescind the Administrative Review,'' dated July 20, 2022; and ''Petitioners' Request to Reject TKT's August 1 Submission,'' dated August 3, 2022.

[8] *See* Memorandum, ''First Administrative Review of the Countervailing Duty Order on Silicon Metal from the Republic of Kazakhstan: Rescission of the Review,'' dated concurrently with this notice (Rescission Memorandum).

[9] *See Lightweight Thermal Paper from the People's Republic of China: Notice of Rescission of Countervailing Duty Administrative Review; 2015,* 82 FR 14349 (March 20, 2017); *see also Aluminum Wire and Cable from the People's Republic of China: Rescission of Countervailing Duty Administrative Review; 2019,* 86 FR 36522 (July 12, 2021).

[10] *See* 19 CFR 351.212(b)(2).

[11] *See* 19 CFR 351.213(d)(3).

respect to 22 companies because all requests for review of these companies were withdrawn. Interested parties are invited to comment on these preliminary results.

DATES: Applicable May 3, 2023.

FOR FURTHER INFORMATION CONTACT: Patrick Barton, AD/CVD Operations, Office III, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–0012.

SUPPLEMENTARY INFORMATION:

Background

On April 19, 2017, Commerce published in the **Federal Register** the antidumping duty (AD) order on 1,1,1,2-Tetrafluoroethane (R–134a) from the People's Republic of China (China).[1] On June 9, 2022, pursuant to section 751(a)(1) of the Tariff Act of 1930, as amended (the Act), Commerce initiated an administrative review of *Order*.[2] The review covers 25 companies, including mandatory respondent Zhejiang Sanmei Chemical Ind. Co., Ltd. (Zhejiang Sanmei).[3]

For events that occurred since the *Initiation Notice* and the analysis behind the preliminary results herein, *see* the Preliminary Decision Memorandum.[4] The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov.* In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly at *https://access.trade.gov/public/FRNoticesListLayout.aspx.* A list of topics discussed in the Preliminary Decision Memorandum is included as Appendix I to this notice.

Scope of the Order[5]

The product covered by the *Order* is R–134a from China. For a complete description of the scope of the *Order, see* the Preliminary Decision Memorandum.

Partial Rescission of Review

Pursuant to 19 CFR 351.213(d)(1), Commerce will rescind an administrative review, in whole or in part, if a party who requested the review withdraws the request within 90 days of the date of publication of the notice of initiation of the requested review. On September 7, 2022, the American HFC Coalition (the petitioner) timely withdrew its review request for 22 companies listed in the *Initiation Notice.* No other parties requested a review of these companies. Accordingly, pursuant to 19 CFR 351.213(d)(1), Commerce is rescinding the administrative review with respect to the companies listed in Appendix II. Zhejiang Sanmei, T.T. International Co., Ltd. (TTI), and Zhejiang Quhua Fluor-Chemistry Co., Ltd. (Zhejiang Quhua) remain under review.[6]

Preliminary Determination of No Shipments

We preliminarily determine that TTI had no shipments of subject merchandise during the POR. Consistent with our practice in non-market economy (NME) cases, Commerce is not rescinding this review with respect to TTI but, rather, we intend to complete the review and issue appropriate instructions to U.S. Customs and Border Protection (CBP) based on the final results of the review.[7] For further discussion, *see* the Preliminary Decision Memorandum.

Separate Rates

We preliminarily determine that the Zhejiang Sanmei single entity is entitled to separate rate status. Moreover, because Zhejiang Quhua did not submit a separate rate application or certification, we preliminarily find that the company has not established its eligibility for a separate rate.

The China-Wide Entity

Commerce's policy regarding conditional review of the China-wide entity applies to this administrative review.[8] Under this policy, the China-wide entity will not be under review unless a party specifically requests, or Commerce self-initiates, a review of the entity. Because no party requested a review of the China-wide entity, the entity is not under review, and the entity's rate, *i.e.,* 167.02 percent, is not subject to change.[9] Because Zhejiang Quhua did not establish its eligibility for a separate rate in this administrative review, we preliminarily consider Zhejiang Quhua to be part of the China-wide entity.

Methodology

We are conducting this administrative review in accordance with section 751(a)(1)(B) of the Act and 19 CFR 351.213. We calculated export prices for Zhejiang Sanmei in accordance with section 772(a) of the Act. Because China is an NME within the meaning of section 771(18) of the Act, we calculated NV in accordance with section 773(c) of the Act. For a full description of the methodology underlying the preliminary results of this review, *see* the Preliminary Decision Memorandum.

Preliminary Results of Review

We preliminarily determine that the following weighted-average dumping margin exists for the period April 1, 2021, through March 31, 2022:

Exporter	Weighted-average dumping margin (percent)
Zhejiang Sanmei Chemical Ind. Co., Ltd./Jiangsu Sanmei Chemical Ind. Co., Ltd./Fujian Qingliu Dongying Chemical Ind. Co. Ltd	147.08

[1] *See 1,1,1,2-Tetrafluoroethane (R–134a) from the People's Republic of China: Antidumping Duty Order,* 82 FR 18422 (April 19, 2017) (*Order*).

[2] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 87 FR 35165 (June 9, 2022) (*Initiation Notice*).

[3] We have preliminarily determined to treat Zhejiang Sanmei, Jiangsu Sanmei Chemical Ind. Co., Ltd. (Jiangsu Sanmei), and Fujian Qingliu Dongying Chemical Ind. Co., Ltd. (Fujian Qingliu) as a single entity for purposes of this administrative review. For further discussion, *see* Memorandum, ''Decision Memorandum for the Preliminary Results of Antidumping Duty Administrative Review: 1,1,1,2-Tetrafluoroethane (R–134a) from the People's Republic of China; 2021–2022,'' dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

[4] *See* Preliminary Decision Memorandum.

[5] *See Order.*

[6] *See* Preliminary Decision Memorandum; *see also* Petitioner's Letter, ''Partial Withdrawal of Request for Administrative Review of Antidumping Duty Order,'' dated September 7, 2022.

[7] *See Non-Market Economy Antidumping Proceedings: Assessment of Antidumping Duties,* 76 FR 65694, 65694–95 (October 24, 2011) (*NME AD Assessment*).

[8] *See Antidumping Proceedings: Announcement of Change in Department Practice for Respondent Selection in Antidumping Duty Proceedings and Conditional Review of the Nonmarket Economy Entity in NME Antidumping Duty Proceedings,* 78 FR 65963 (November 4, 2013).

[9] *See Order,* 82 FR at 18423.

Disclosure and Public Comment

We intend to disclose to interested parties the calculations performed for these preliminary results in accordance with 19 CFR 351.224(b). Interested parties may submit case briefs no later than 30 days after the date of publication of these preliminary results of review.[10] Rebuttal briefs, limited to issues raised in case briefs, may be submitted no later than seven days after the deadline date for case briefs.[11] Pursuant to 19 CFR 351.309(c)(2) and (d)(2), parties who submit case briefs or rebuttal briefs in this review are encouraged to submit with each argument: (1) a statement of the issue; (2) a brief summary of the argument; and (3) a table of authorities. Executive summaries should be limited to five pages total, including footnotes. Case and rebuttal briefs should be filed using ACCESS[12] and must be served on interested parties.[13] Note that Commerce has temporarily modified certain of its requirements for serving documents containing business proprietary information, until further notice.[14]

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing, limited to issues raised in the case and rebuttal briefs, must submit a written request to the Assistant Secretary for Enforcement and Compliance, U.S. Department of Commerce, filed electronically via Commerce's electric records system, ACCESS. An electronically-filed request must be received successfully in its entirety by 5:00 p.m. Eastern Time within 30 days after the date of publication of this notice.[15] Requests should contain the party's name, address, and telephone number, the number of participants, whether any participant is a foreign national, and a list of the issues to be discussed. If a request for a hearing is made, Commerce intends to hold the hearing at a time and date to be determined.[16] Parties should confirm by telephone the date and time of the hearing two days before the scheduled date.

Unless otherwise extended, we intend to issue the final results of this administrative review, which will include the results of our analysis of the issues raised in the case and rebuttal briefs, within 120 days of publication of these preliminary results in the **Federal Register**, pursuant to section 751(a)(3)(A) of the Act and 19 CFR 351.213(h).

Assessment Rates

Upon issuance of the final results, Commerce will determine, and CBP shall assess, antidumping duties on all appropriate entries covered by this review, in accordance with 19 CFR 351.212(b)(1). Commerce intends to issue assessment instructions to CBP 35 days after the publication of the final results of this review. If a timely summons is filed at the U.S. Court of International Trade, the assessment instructions will direct CBP not to liquidate relevant entries until the time for parties to file a request for a statutory injunction has expired (*i.e.,* within 90 days of publication).

If the *ad valorem* weighted-average dumping margin for the Zhejiang Sanmei, Jiangsu Sanmei, and Fujian Qingliu single entity is not zero or *de minimis* (*i.e.,* less than 0.50 percent) in the final results of this review, Commerce will calculate importer-specific assessment rates on the basis of the ratio of the total amount of dumping calculated for the importer's examined sales and the total quantity of those sales, in accordance with 19 CFR 351.212(b)(1).[17] We will instruct CBP to assess antidumping duties on all appropriate entries covered by this review when the importer-specific *ad valorem* assessment rate calculated in the final results of this review is not zero or *de minimis.*

In addition, if in the final results we continue to find no shipments of subject merchandise for TTI, any suspended entries of subject merchandise associated with TTI will be liquidated at the China-wide rate.[18]

For the companies for which the administrative review is rescinded, antidumping duties shall be assessed at a rate equal to the cash deposit of estimated antidumping duties required at the time of entry, or withdrawal from warehouse, for consumption, in accordance with 19 CFR 351.212(c)(1)(i). We intend to issue appropriate assessment instructions to CBP with respect to the companies for which this administrative review is rescinded 35 days after the publication of this notice in the **Federal Register**.

Cash Deposit Requirements

The following cash deposit requirements will be effective upon publication of the final results of this review for all shipments of the subject merchandise from China entered, or withdrawn from warehouse, for consumption on or after the publication date, as provided for by section 751(a)(2)(C) of the Act: (1) the cash deposit rate for the Zhejiang Sanmei, Jiangsu Sanmei, and Fujian Qingliu single entity will be that rate established in the final results of this review (except, if the rate is *de minimis,* then a cash deposit rate of zero will be required); (2) for a previously investigated or reviewed exporter of subject merchandise not listed in the final results of review that has a separate rate, the cash deposit rate will continue to be the exporter's existing cash deposit rate; (3) for all Chinese exporters of subject merchandise that have not been found to be entitled to a separate rate, the cash deposit rate will be the rate for the China-wide entity (*i.e.,* 167.02 percent); and (4) for all exporters of subject merchandise that are not located in China and are not eligible for a separate rate, the cash deposit rate will be the rate applicable to the Chinese exporter(s) that supplied that non-Chinese exporter. These cash deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice also serves as a preliminary reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in Commerce's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

Notification to Interested Parties

We are issuing and publishing the preliminary results of this review in accordance with sections 751(a)(l) and 777(i)(l) of the Act, and 19 CFR 351.213(d)(4), 19 CFR 351.213(h)(1), and 19 CFR 351.221(b)(4).

[10] *See* 19 CFR 351.309(c).

[11] *See* 19 CFR 351.309(d); *see also Temporary Rule Modifying AD/CVD Service Requirements Due to COVID–19,* 85 FR 17006, 17007 (March 26, 2020) (''To provide adequate time for release of case briefs via ACCESS, E&C intends to schedule the due date for all rebuttal briefs to be 7 days after case briefs are filed (while these modifications remain in effect).'').

[12] *See generally* 19 CFR 351.303.

[13] *See* 19 CFR 351.303(f).

[14] *See Temporary Rule Modifying AD/CVD Service Requirements Due to COVID–19; Extension of Effective Period,* 85 FR 41363 (July 10, 2020).

[15] *See* 19 CFR 351.310(c).

[16] *See* 19 CFR 351.310(d).

[17] In these preliminary results, Commerce applied the assessment rate calculation method adopted in *Antidumping Proceedings: Calculation of the Weighted-Average Dumping Margin and Assessment Rate in Certain Antidumping Proceedings: Final Modification,* 77 FR 8101 (February 14, 2012).

[18] *See NME AD Assessment.*

Dated: April 26, 2023.

Lisa W. Wang,

Assistant Secretary for Enforcement and Compliance.

Appendix I

List of Topics Discussed in the Preliminary Decision Memorandum

I. Summary
II. Background
III. Period of Review
IV. Scope of the *Order*
V. Respondent Selection
VI. Partial Rescission of Administrative Review
VII. Preliminary Determination of No Shipments
VIII. Single Entity Treatment
IX. Discussion of the Methodology
X. Recommendation

Appendix II

Companies for Which the Administrative Review Is Being Rescinded

1. Electrochemical Factory of Zhejiang Juhua Co., Ltd.
2. Fujian Qingliu Dongying Chemical Ind. Co., Ltd.
3. Hongkong Richmax Ltd.
4. Huantai Dongyue International Trade Co. Ltd.
5. Jiangsu Bluestar Green Technology Co., Ltd.
6. Jiangsu Sanmei Chemicals Co., Ltd.
7. Jinhua Binglong Chemical Technology Co., Ltd.
8. Jinhua Yonghe Fluorochemical Co., Ltd.
9. Puremann, Inc.
10. Shandong Dongyue Chemical Co., Ltd.
11. Shandong Huaan New Material Co., Ltd.
12. Sinochem Environmental Protection Chemicals (Taicang) Co., Ltd.
13. Weitron International Refrigeration Equipment (Kunshan) Co., Ltd. (aka Weichang Refrigeration Equipment (Kunshan) Co., Ltd.)
14. Zhejiang Juhua Co., Ltd.
15. Zhejiang Morita New Materials Co., Ltd.
16. Zhejiang Organic Fluor-Chemistry Plant, Zhejiang Juhua Co., Ltd.
17. Zhejiang Quhua Juxin Fluorochemical Industry Co., Ltd.
18. Zhejiang Quzhou Juxin Fluorine Chemical Co., Ltd.
19. Zhejiang Quzhou Lianzhou Refrigerants Co., Ltd.
20. Zhejiang Yonghe Refrigerant Co., Ltd.
21. Zhejiang Zhonglan Refrigeration Technology Co., Ltd.
22. Zibo Feiyuan Chemical Co., Ltd.

[FR Doc. 2023–09349 Filed 5–2–23; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–201–857]

Certain Freight Rail Couplers and Parts Thereof From Mexico: Preliminary Affirmative Determination of Sales at Less Than Fair Value Preliminary Negative Determination of Critical Circumstances, Postponement of Final Determination, and Extension of Provisional Measures

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) preliminarily determines that certain freight rail couplers and parts thereof (freight rail couplers) from Mexico are being, or are likely to be, sold in the United States at less than fair value (LTFV). The period of investigation (POI) is July 1, 2021, through June 30, 2022. Interested parties are invited to comment on this preliminary determination.

DATES: Applicable May 3, 2023.

FOR FURTHER INFORMATION CONTACT: Jonathan Hall-Eastman, AD/CVD Operations, Office III, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–1468.

SUPPLEMENTARY INFORMATION:

Background

This preliminary determination is made in accordance with section 733(b) of the Tariff Act of 1930, as amended (the Act). Commerce published the notice of initiation of this investigation on October 25, 2022.[1] On February 10, 2023, Commerce postponed the preliminary determination of this investigation until April 26, 2023.[2]

For a complete description of the events that followed the initiation of this investigation, *see* the Preliminary Decision Memorandum.[3] A list of topics included in the Preliminary Decision Memorandum is included as Appendix II to this notice. The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov.* In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly at *https://access.trade.gov/public/FRNoticesListLayout.aspx.*

Scope of the Investigation

The products covered by this investigation are freight rail couplers from Mexico. For a complete description of the scope of this investigation, *see* Appendix I.

Scope Comments

In accordance with the preamble to Commerce's regulations,[4] the *Initiation Notice* set aside a period of time for parties to raise issues regarding product coverage (*i.e.,* scope).[5] Certain interested parties commented on the scope of the investigation as it appeared in the *Initiation Notice.* For a summary of the product coverage comments and rebuttal responses submitted to the record for this preliminary determination, and accompanying discussion and analysis of all comments timely received, *see* the Preliminary Scope Decision Memorandum.[6] Commerce preliminarily modified the scope language as it appeared in the *Initiation Notice. See* the revised scope in Appendix I to this notice. Commerce established a separate briefing schedule for interested parties to address the preliminary scope determination.[7]

Methodology

Commerce is conducting this investigation in accordance with section 731 of the Act. Constructed export prices have been calculated in accordance with section 772(b) of the Act. Normal value is calculated in accordance with section 773 of the Act. For a full description of the methodology underlying the preliminary determination, *see* the Preliminary Decision Memorandum.

[1] *See Certain Freight Rail Couplers and Parts Thereof from the People's Republic of China and Mexico: Initiation of Less-Than-Fair-Value Investigations,* 87 FR 64444 (October 25, 2022) (*Initiation Notice*).

[2] *See Certain Freight Rail Couplers and Parts Thereof From Mexico: Postponement of Preliminary Determination in the Less-Than-Fair-Value Investigation,* 88 FR 10092 (February 16, 2023).

[3] *See* Memorandum, ''Decision Memorandum for the Preliminary Determination in the Less-Than-Fair-Value Investigation of Certain Freight Rail Couplers and Parts Thereof from Mexico'' dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

[4] *See Antidumping Duties; Countervailing Duties,* 62 FR 27296, 27323 (May 19, 1997).

[5] *See Initiation Notice.*

[6] *See* Memorandum, ''Freight Rail Couplers from Mexico and the People's Republic of China: Preliminary Scope Decision Memorandum,'' dated March 28, 2023 (Preliminary Scope Decision Memorandum).

[7] *Id.* at 3.

Preliminary Negative Determination of Critical Circumstances

In accordance with section 733(e) of the Act and 19 CFR 351.206, Commerce preliminarily finds that critical circumstances do not exist for ASF–K de Mexico S. de R.L. de C.V. (ASF–K). For a full description of the methodology and results of Commerce's critical circumstances analysis, *see* the Preliminary Decision Memorandum.

All-Others Rate

Sections 733(d)(1)(ii) and 735(c)(5)(A) of the Act provide that in the preliminary determination Commerce shall determine an estimated all-others rate for all exporters and producers not individually examined. This rate shall be an amount equal to the weighted average of the estimated weighted-average dumping margins established for exporters and producers individually investigated, excluding any zero and *de minimis* margins, and any margins determined entirely under section 776 of the Act.

Commerce calculated an individual estimated weighted-average dumping margin for ASF–K, the only individually examined exporter/producer in this investigation. Because the only individually calculated dumping margin is not zero, *de minimis,* or based entirely on facts otherwise available, the estimated weighted-average dumping margin calculated for ASF–K is the margin assigned to all other producers and exporters, pursuant to section 735(c)(5)(A) of the Act.

Preliminary Determination

Commerce preliminarily determines that the following estimated weighted-average dumping margins exist:

Exporter/producer	Estimated weighted-average dumping margin (percent)
ASF–K de Mexico S. de R.L. de C.V	47.82
All Others	47.82

Suspension of Liquidation

In accordance with section 733(d)(2) of the Act, Commerce will direct U.S. Customs and Border Protection (CBP) to suspend liquidation of entries of subject merchandise, as described in Appendix I, entered, or withdrawn from warehouse, for consumption on or after the date of publication of this notice in the **Federal Register**. Further, pursuant to section 733(d)(1)(B) of the Act and 19 CFR 351.205(d), Commerce will instruct CBP to require a cash deposit equal to the estimated weighted-average dumping margin or the estimated all-others rate, as follows: (1) the cash deposit rate for the respondents listed above will be equal to the company-specific estimated weighted-average dumping margins determined in this preliminary determination; (2) if the exporter is not a respondent identified above, but the producer is, then the cash deposit rate will be equal to the company-specific estimated weighted-average dumping margin established for that producer of the subject merchandise; and (3) the cash deposit rate for all other producers and exporters will be equal to the all-others estimated weighted-average dumping margin. These suspension of liquidation instructions will remain in effect until further notice.

Disclosure

Commerce intends to disclose its calculations and analysis performed to interested parties in this preliminary determination within five days of any public announcement or, if there is no public announcement, within five days of the date of publication of this notice in accordance with 19 CFR 351.224(b).

Verification

As provided in section 782(i)(1) of the Act, Commerce intends to verify the information relied upon in making its final determination.

Public Comment

Case briefs or other written comments may be submitted to the Assistant Secretary for Enforcement and Compliance no later than seven days after the date on which the last verification report is issued in this investigation. Note that Commerce has temporarily modified certain of its requirements for serving documents containing business proprietary information, until further notice.[8] Pursuant to 19 CFR 351.309(c)(2) and (d)(2), parties who submit case briefs or rebuttal briefs in this investigation are encouraged to submit with each argument: (1) a statement of the issue; (2) a brief summary of the argument; and (3) a table of authorities.

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing, limited to issues raised in the case and rebuttal briefs, must submit a written request to the Assistant Secretary for Enforcement and Compliance, U.S. Department of Commerce, within 30 days after the date of publication of this notice. Requests should contain the party's name, address, and telephone number, the number of participants, whether any participant is a foreign national, and a list of the issues to be discussed. If a request for a hearing is made, Commerce intends to hold the hearing at a time and date to be determined. Parties should confirm by telephone the date, time, and location of the hearing two days before the scheduled date.

Postponement of Final Determination and Extension of Provisional Measures

Section 735(a)(2) of the Act provides that a final determination may be postponed until not later than 135 days after the date of the publication of the preliminary determination if, in the event of an affirmative preliminary determination, a request for such postponement is made by exporters who account for a significant proportion of exports of the subject merchandise, or in the event of a negative preliminary determination, a request for such postponement is made by the petitioner. Section 351.210(e)(2) of Commerce's regulations requires that a request by exporters for postponement of the final determination be accompanied by a request for extension of provisional measures from a four-month period to a period not more than six months in duration.

On April 20, 2023, pursuant to 19 CFR 351.210(e), ASF–K requested that Commerce postpone the final determination and that provisional measures be extended to a period not to exceed six months.[9] In accordance with section 735(a)(2)(A) of the Act and 19 CFR 351.210(b)(2)(ii), because: (1) the preliminary determination is affirmative; (2) the requesting exporters accounts for a significant proportion of exports of the subject merchandise; and (3) no compelling reasons for denial exist, Commerce is postponing the final determination and extending the provisional measures from a four-month period to a period not greater than six months. Accordingly, Commerce will make its final determination no later than 135 days after the date of publication of this preliminary determination.

U.S. International Trade Commission Notification

In accordance with section 733(f) of the Act, Commerce will notify the U.S. International Trade Commission (ITC) of its preliminary determination. If the

[8] *See Temporary Rule Modifying AD/CVD Service Requirements Due to COVID–19; Extension of Effective Period,* 85 FR 41363 (July 10, 2020).

[9] *See* ASF–K and Amsted Rail Company, Inc.'s Letter, ''Amsted Request for Postponement of Final Determination,'' dated April 20, 2023.

final determination is affirmative, the ITC will determine before the later of 120 days after the date of this preliminary determination or 45 days after the final determination whether these imports are materially injuring, or threaten material injury to, the U.S. industry.

Notification to Interested Parties

This determination is issued and published in accordance with sections 733(f) and 777(i)(1) of the Act and 19 CFR 351.205(c).

Dated: April 26, 2023.

Lisa W. Wang,

Assistant Secretary for Enforcement and Compliance.

Appendix I—Scope of the Investigation

The scope of this investigation covers certain freight railcar couplers (also known as ''fits'' or ''assemblies'') and parts thereof. Freight railcar couplers are composed of two main parts, namely knuckles and coupler bodies but may also include other items (*e.g.,* coupler locks, lock lift assemblies, knuckle pins, knuckle throwers, and rotors). The parts of couplers that are covered by the investigation include: (1) E coupler bodies, (2) E/F coupler bodies, (3) F coupler bodies, (4) E knuckles, and (5) F knuckles, as set forth by the Association of American Railroads (AAR). The freight rail coupler parts (*i.e.,* knuckles and coupler bodies) are included within the scope of the investigation when imported separately. Coupler locks, lock lift assemblies, knuckle pins, knuckle throwers, and rotors are covered merchandise when imported in an assembly but are not covered by the scope when imported separately.

Subject freight railcar couplers and parts are included within the scope whether finished or unfinished, whether imported individually or with other subject or nonsubject parts, whether assembled or unassembled, whether mounted or unmounted, or if joined with nonsubject merchandise, such as other nonsubject parts or a completed railcar. Finishing includes, but is not limited to, arc washing, welding, grinding, shot blasting, heat treatment, machining, and assembly of various parts. When a subject coupler or subject parts are mounted on or to other nonsubject merchandise, such as a railcar, only the coupler or subject parts are covered by the scope.

The finished products covered by the scope of this investigation meet or exceed the AAR specifications of M–211, ''Foundry and Product Approval Requirements for the Manufacture of Couplers, Coupler Yokes, Knuckles, Follower Blocks, and Coupler Parts'' and/or AAR M–215 ''Coupling Systems,'' or other equivalent domestic or international standards (including any revisions to the standard(s)).

The country of origin for subject couplers and parts thereof, whether fully assembled, unfinished or finished, or attached to a railcar, is the country where the subject coupler parts were cast or forged. Subject merchandise includes coupler parts as defined above that have been further processed or further assembled, including those coupler parts attached to a railcar in third countries. Further processing includes, but is not limited to, arc washing, welding, grinding, shot blasting, heat treatment, painting, coating, priming, machining, and assembly of various parts. The inclusion, attachment, joining, or assembly of nonsubject parts with subject parts or couplers either in the country of manufacture of the in-scope product or in a third country does not remove the subject parts or couplers from the scope.

The couplers that are the subject of this investigation are currently classifiable in the Harmonized Tariff Schedule of the United States (HTSUS) statistical reporting number 8607.30.1000. Unfinished subject merchandise may also enter under HTSUS statistical reporting number 7326.90.8688. Subject merchandise attached to finished railcars may also enter under HTSUS statistical reporting numbers 8606.10.0000, 8606.30.0000, 8606.91.0000, 8606.92.0000, 8606.99.0130, 8606.99.0160, or under subheading 9803.00.50. Subject merchandise may also be imported under HTSUS statistical reporting number 7325.99.5000. These HTSUS subheadings are provided for convenience and customs purposes only; the written description of the scope of this investigation is dispositive.

Appendix II—List of Topics Discussed in the Preliminary Decision Memorandum

[FR Doc. 2023–09350 Filed 5–2–23; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[A–583–867]

Common Alloy Aluminum Sheet From Taiwan: Rescission of Antidumping Duty Administrative Review; 2020–2022

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) is rescinding the administrative review of the antidumping duty order on common alloy aluminum sheet (CAAS) from Taiwan, covering the period of review (POR) October 15, 2020, through March 31, 2022.

DATES: Applicable May 3, 2023.

FOR FURTHER INFORMATION CONTACT: Mark Hoadley, AD/CVD Operations, Office VII, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–3148.

SUPPLEMENTARY INFORMATION:

Background

On April 1, 2022, Commerce published in the **Federal Register** a notice of opportunity to request an administrative review of the antidumping duty order on CAAS from Taiwan, covering the POR.[1] On May 2, 2022, C.S. Aluminium Corporation (CSAC) timely requested that Commerce conduct an administrative review of CSAC.[2] On May 2, 2022, the petitioners [3] also requested that Commerce conduct an administrative review of CSAC.[4] On July 14, 2022, Commerce published in the **Federal Register** a notice of initiation of an administrative review with respect to CSAC in accordance with section 751(a) of the Tariff Act of 1930, as amended (the Act).[5]

On February 17, 2023, Commerce issued a memorandum stating its intent to rescind the administrative review of the antidumping duty order on CAAS

[1] *See Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity to Request* Administrative Review and Join Annual Inquiry Service List, 87 FR 19075 (April 1, 2022).

[2] *See* CSAC's Letter, ''Request for Administrative Review,'' dated May 2, 2022.

[3] The petitioners are the: Aluminum Association Common Alloy Aluminum Sheet Trade Enforcement Working group and its individual members, Arconic Corporation; Commonwealth Rolled Products Inc.; Constellium Rolled Products Ravenswood, LLC; JW Aluminum Company; Novelis Corporation; and Texarkana Aluminum Inc. (collectively, the petitioners).

[4] *See* Petitioners' Letter, ''Petitioners' Request for Initiation of First Administrative Review,'' dated May 2, 2022.

[5] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 87 FR 42144 (July 14, 2022) (*Initiation Notice*).

from Taiwan.[6] For a history of events that have occurred since the issuance of the Intent to Rescind Review, *see* the Issues and Decision Memorandum.[7]

Scope of the Order

The products covered by the order are CAAS. For a complete description of the scope of the order, *see* the Issues and Decision Memorandum.

Analysis of Comments Received

Commerce addressed the issue raised in the case and rebuttal briefs in the Issues and Decision Memorandum. This issue is identified in the appendix to this notice. The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov.* In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at *https://access.trade.gov/public/FRNoticesListLayout.aspx.*

Rescission of Review

Pursuant to 19 CFR 351.213(d)(3), it is Commerce's practice to rescind an administrative review of an antidumping duty order where it concludes there were no suspended entries of subject merchandise during the POR for an exporter or producer. Normally, upon completion of an administrative review, the suspended entries are liquidated at the antidumping duty assessment rate(s) based on the final results for the review period. Therefore, for an administrative review to be conducted, there must be a suspended entry that Commerce can instruct U.S. Customs and Border Protection to liquidate at the calculated antidumping duty assessment rate for the review period. As explained in detail in the Issues and Decision Memorandum, there were no suspended entries of subject merchandise from CSAC during the POR. Accordingly, in the absence of suspended entries of subject merchandise during the POR, we are rescinding this administrative review in accordance with 19 CFR 351.213(d)(3).

[6] *See* Memorandum, ''Intent to Rescind Review,'' dated February 17, 2023 (Intent to Rescind Review).

[7] *See* Memorandum, ''Issues and Decision Memorandum for the Rescission of the Antidumping Duty Administrative Review: Common Alloy Aluminum Sheet from Taiwan; 2020–2022,'' dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

Cash Deposit Requirements

As Commerce is rescinding this administrative review, cash deposit rates will not change. Accordingly, the current cash deposit requirements shall remain in effect until further notice.

Administrative Protective Order

This notice also serves as a reminder to parties subject to an administrative protective order (APO) of their responsibility concerning the destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of the return or destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and the terms of an APO is a sanctionable violation.

Notification to Interested Parties

This notice is published in accordance with section 751 of the Act and 19 CFR 351.213(d)(4).

Dated: April 26, 2023.

James Maeder,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

Appendix

List of Topics Discussed in the Issues and Decision Memorandum

I. Summary
II. Background
III. Scope of the Order
IV. Discussion of the Issue Comment: Rescission of the Administrative Review
V. Recommendation

[FR Doc. 2023–09392 Filed 5–2–23; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XC981]

Western Pacific Fishery Management Council (Council); Public Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice; public meeting.

SUMMARY: The Western Pacific Stock Assessment Review (WPSAR) Steering Committee will convene a public meeting to discuss and approve the 5-year calendar for stock assessments, and to address any other concerns related to the WPSAR process.

DATES: The Steering Committee will meet from 1 p.m. to 3 p.m. on May 15, 2023.

ADDRESSES: The meetings will be held by web conference. Specific information on joining the meeting, connecting to the web conference and providing oral public comments will be posted on the Council website at *www.wpcouncil.org.* For assistance with the web conference connection, contact the Council office at (808) 522–8220.

FOR FURTHER INFORMATION CONTACT: Kitty Simonds; telephone: (808) 522–8220, or email: *kitty.simonds@noaa.gov.*

SUPPLEMENTARY INFORMATION: The WPSAR Steering Committee consists of the Council's Executive Director, the Acting Science Director of the NMFS Pacific Islands Fisheries Science Center, and the Acting Regional Administrator of the NMFS Pacific Islands Regional Office. You may read more about WPSAR at *https://www.pifsc.noaa.gov/peer_reviews/wpsar/index.php.*

The public will have an opportunity to comment during the meeting. The agenda order may change. The meeting will run as late as necessary to complete scheduled business.

Agenda for the WPSAR Steering Committee

- Introductions
- Stock assessments
- Discuss and update stock assessment review schedule
- Discuss and update review levels for stock assessments
- Discuss and nominate additional science products for review by the Center for Independent Experts, if necessary
- Discuss review and potential updates to the WPSAR policy
- Funding of WPSAR when conducted in the Territories
- Other business
- Public comment

Special Accommodations

The meeting is accessible to people with disabilities. Make direct requests for sign language interpretation or other auxiliary aids to Mark Fitchett, (808) 522–8141, or *mark.d.fitchett@noaa.gov,* at least 5 days prior to the meeting date.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: April 27, 2023.

Rey Israel Marquez,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2023–09305 Filed 5–2–23; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XC975]

Pacific Fishery Management Council; Public Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of public meeting.

SUMMARY: The Pacific Fishery Management Council's (Pacific Council) Ad Hoc Marine Planning Committee (MPC) will hold an online public meeting.

DATES: The online meeting will be held Thursday, May 18, 2023, from 10 a.m. to 4 p.m. Pacific Daylight Time or until business for the day has been completed.

ADDRESSES: This meeting will be held online. Specific meeting information, including a proposed agenda and directions on how to join the meeting and system requirements will be provided in the meeting announcement on the Pacific Council's website (see *www.pcouncil.org*). You may send an email to Mr. Kris Kleinschmidt (*kris.kleinschmidt@noaa.gov*) or contact him at (503) 820–2412 for technical assistance.

Council address: Pacific Fishery Management Council, 7700 NE Ambassador Place, Suite 101, Portland, OR 97220–1384.

FOR FURTHER INFORMATION CONTACT: Kerry Griffin, Staff Officer, Pacific Council; telephone: (503) 820–2409.

SUPPLEMENTARY INFORMATION: The purpose of this online meeting is for the MPC to consider current offshore wind energy issues and to provide information and advice to the Pacific Council for consideration at its June 2023 meeting. Topics may include discussion of pending draft Wind Energy Areas (WEAs) off the Oregon Coast, an update on California offshore wind energy lease sales, and other related topics.

Although non-emergency issues not contained in the meeting agenda may be discussed, those issues may not be the subject of formal action during this meeting. Action will be restricted to those issues specifically listed in this document and any issues arising after publication of this document that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the intent to take final action to address the emergency.

Special Accommodations

Requests for sign language interpretation or other auxiliary aids should be directed to Mr. Kris Kleinschmidt (*kris.kleinschmidt@noaa.gov;* (503) 820–2412) at least 10 days prior to the meeting date.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: April 27, 2023.

Rey Israel Marquez,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2023–09306 Filed 5–2–23; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF DEFENSE

Department of the Air Force

[23–RI–L–02]

Notice of Intent To Grant an Exclusive License With a Joint Ownership Agreement

AGENCY: Department of the Air Force, Department of Defense.

ACTION: Notice of intent.

SUMMARY: Pursuant to the Bayh-Dole Act and implementing regulations, the Department of the Air Force hereby gives notice of its intent to grant an exclusive license with a joint ownership agreement to Tensor Networks, an Inc. duly organized, validly existing, and in good standing in the State of California having a place of business at 1289 Reamwood Ave., Ste. G, Sunnyvale, CA 94089.

DATES: Written objections must be filed no later than fifteen (15) calendar days after the date of publication of this Notice.

ADDRESSES: Submit written objections to Stephen Colenzo, AFRL/RI, 525 Brooks Road, Rome, New York 13441; or email: *stephen.colenzo@us.af.mil.* Include Docket No. 23–RI–L–02 in the subject line of the message.

FOR FURTHER INFORMATION CONTACT: Stephen Colenzo, AFRL/RI, 525 Brooks Road, Rome, New York 13441; (315) 330–7665 or e mail: *stephen.colenzo@us.af.mil.*

Abstract of Patent Application(s)

In accordance with various embodiments of the disclosed subject matter, a method and framework configured for modeling a pattern of life (POL) by processing both categorical data and non-categorical data (*e.g.,* numeric, spatial etc.), conducting pattern of life estimation (POLE), and detecting anomalous data in a multi-dimensional data set in a substantially simultaneous manner by comparing statistical PoL results.

Intellectual Property

—POTTENGER ET AL, U.S. Patent No. 11,308,384, issued on 19 April 2022, and entitled ''*Method and Framework for Pattern of Life Analysis.*''

The Department of the Air Force may grant the prospective license unless a timely objection is received that sufficiently shows the grant of the license would be inconsistent with the Bayh-Dole Act or implementing regulations. A competing application for a patent license agreement, completed in compliance with 37 CFR 404.8 and received by the Air Force within the period for timely objections, will be treated as an objection and may be considered as an alternative to the proposed license.

Authority: 35 U.S.C. 209; 37 CFR 404.

Mia Day,

Acting Air Force Federal Register Liaison Officer.

[FR Doc. 2023–09345 Filed 5–2–23; 8:45 am]

BILLING CODE 5001–10–P

DEPARTMENT OF DEFENSE

Department of the Air Force

[ARX–220921A–PL]

Notice of Intent To Grant a Partially Exclusive Patent License

AGENCY: Department of the Air Force, Department of Defense.

ACTION: Notice of intent.

SUMMARY: Pursuant to the Bayh-Dole Act and implementing regulations, the Department of the Air Force hereby gives notice of its intent to grant a partially exclusive patent license (in the fields of commercial and defense composite manufacturing using structural bonding; load bearing bonding; and electrical bonding) to Unmanned Systems Incorporated—DBA Albers Aerospace, a C Corporation duly organized, validly existing, and in good standing in the State of Nevada, having a place of business at 1476 Industrial Blvd., McKinney TX.

DATES: Written objections must be filed no later than fifteen (15) calendar days after the date of publication of this Notice.

ADDRESSES: Submit written objections to Jeremy Gratsch, AFRL/RXOP, 2977 Hobson Way, Building 653, Wright-Patterson AFB, OH 45433; Phone: 937–255–0017; or Email: *AFRL.RX.T2@us.af.mil.* Include Docket No. ARX–220921A–PL in the subject line of the message.

FOR FURTHER INFORMATION CONTACT: Jeremy Gratsch, AFRL/RXOP, 2977 Hobson Way, Building 653, Wright-Patterson AFB, OH 45433; Phone: 937–255–0017; or Email: *AFRL.RX.T2@us.af.mil.*

Abstract of Patent Application(s)

The present invention discloses cured composites having improved surfaces and processes of making and methods of using same. Such processes use ultra-short pulse lasers, for example, a femto-second laser to ablate material without the detrimental heat affected zones of other laser processes. Such process can not only increases surface roughness and clean contaminates, but can also selectively remove the matrix material and expose the surface fibers of cured composites. The treated cured composites have improved thermal and electrical pathways that can dissipate unwanted heat and electricity when two or more prepregs and/or cured composites are bonded or cured to form a single article.

Intellectual Property

U.S. Application Publication No. 2022/0274369, published on 1 September 2022, and entitled *PREPREGS AND CURED COMPOSITES HAVING IMPROVED SURFACES AND PROCESSES OF MAKING AND METHODS OF USING SAME.*

The Department of the Air Force may grant the prospective license unless a timely objection is received that sufficiently shows the grant of the license would be inconsistent with the Bayh-Dole Act or implementing regulations. A competing application for a patent license agreement, completed in compliance with 37 CFR 404.8 and received by the Air Force within the period for timely objections, will be treated as an objection and may be considered as an alternative to the proposed license.

Authority: 35 U.S.C. 209; 37 CFR 404.

Mia Day,

Acting Air Force Federal Register Liaison Officer.

[FR Doc. 2023–09343 Filed 5–2–23; 8:45 am]

BILLING CODE 5001–10–P

DEPARTMENT OF DEFENSE

Office of the Secretary

Defense Science Board; Notice of Federal Advisory Committee Meeting

AGENCY: Under Secretary of Defense for Research and Engineering, Defense Science Board, Department of Defense (DoD).

ACTION: Notice of Federal advisory committee meeting.

SUMMARY: The DoD is publishing this notice to announce that the following Federal advisory committee meeting of the Defense Science Board (DSB) will take place.

DATES: Closed to the public Wednesday, May 3, 2023 from 8 a.m. to 4 p.m.

ADDRESSES: The address of the closed meeting is conference room 3A912A at the Pentagon, Washington, DC 20301.

FOR FURTHER INFORMATION CONTACT: Mr. Kevin Doxey, Designated Federal Officer (DFO), (703) 571–0081 (Voice), (703) 697–1860 (Facsimile), *kevin.a.doxey.civ@mail.mil* (Email). Mailing address is Defense Science Board, 3140 Defense Pentagon, Room 3B888A, Washington, DC 20301–3140. Website: *http://www.acq.osd.mil/dsb/.* The most up-to-date changes to the meeting agenda can be found on the website.

SUPPLEMENTARY INFORMATION: This meeting is being held under the provisions of chapter 10 of title 5, United States Code (U.S.C.) (commonly known as the ''Federal Advisory Committee Act (FACA)''); 5 U.S.C. 552b(c) (commonly known as the ''Government in the Sunshine Act''); and sections 102–3.140 and 102–3.150 of title 41, Code of Federal Regulations (CFR).

Due to circumstances beyond the control of the Designated Federal Officer, the Defense Science Board was unable to provide public notification required by 41 CFR 102–3.150(a) concerning its May 3, 2023 meeting. Accordingly, the Advisory Committee Management Officer for the Department of Defense, pursuant to 41 CFR 102–3.150(b), waives the 15-calendar day notification requirement.

Purpose of the Meeting: The mission of the DSB is to provide independent advice and recommendations on matters relating to the DoD's scientific and technical enterprise. The objective of the meeting is to obtain, review, and evaluate classified information related to the DSB's mission. DSB membership will meet with DoD Leadership to discuss classified current and future national security challenges and priorities within the DoD.

Agenda: The meeting will begin on May 3, 2023 at 8 a.m. with opening remarks from Mr. Kevin Doxey, the Designated Federal Officer, and Dr. Eric Evans, DSB Chair. The first briefing will be from Brigadier General Jason T. Hinds, Director of Plans, Programs, and Analyses, U.S. Air Forces in Europe-Air Forces Africa, who will provide classified remarks on current events in Europe. Following break, Vice Admiral Jon Hill, Director, Missile Defense Agency (MDA), will provide classified remarks on MDA's priorities. Following break, the Board will deliberate and vote on the DSB Quick Task Force on National Security Innovation Activities' findings and recommendations. Following break, the Honorable Carlos Del Toro, Secretary of the Navy, will provide classified remarks on the Navy's technical challenges and priorities. Next, the Honorable Susanna V. Blume, Director, Cost Assessment and Program Evaluation (CAPE), will provide classified remarks on CAPE's challenges and priorities. Finally, Dr. Kathleen Hicks, accompanied by Dr. Craig Martell, Chief Digital and Artificial Intelligence Officer, and Ms. Heidi Shyu, Under Secretary of Defense for Research and Engineering, will provide classified remarks on the DoD's technical challenges and priorities. The meeting will adjourn at 4 p.m.

Meeting Accessibility: In accordance with 5 U.S.C. 1009(d) and 41 CFR 102–3.155, the DoD has determined that the DSB meeting will be closed to the public. Specifically, the Under Secretary of Defense for Research and Engineering, in consultation with the DoD Office of the General Counsel, has determined in writing that the meeting will be closed to the public because it will consider matters covered by 5 U.S.C. 552b(c)(1). The determination is based on the consideration that it is expected that discussions throughout will involve classified matters of national security concern. Such classified material is so intertwined with the unclassified material that it cannot reasonably be segregated into separate discussions without defeating the effectiveness and meaning of the overall meetings. To permit the meeting to be open to the public would preclude discussion of such matters and would greatly diminish the ultimate utility of the DSB's findings and recommendations to the Secretary of Defense and to the Under Secretary of Defense for Research and Engineering.

Written Statements: In accordance with 5 U.S.C. 1009(a)(3) and 41 CFR 102–3.105(j) and 102–3.140, interested

persons may submit a written statement for consideration by the DSB at any time regarding its mission or in response to the stated agenda of a planned meeting. Individuals submitting a written statement must submit their statement to the DSB DFO at the email address provided in the **FOR FURTHER INFORMATION CONTACT** section at any point; however, if a written statement is not received at least three calendar days prior to the meeting, which is the subject of this notice, then it may not be provided to or considered by the DSB until a later date.

Dated: April 28, 2023.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2023–09417 Filed 5–2–23; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF EDUCATION

Applications for New Awards; Mental Health Personnel Technical Assistance Center

AGENCY: Office of Elementary and Secondary Education, Department of Education.

ACTION: Notice.

SUMMARY: The Department of Education (Department) is issuing a notice inviting applications for fiscal year (FY) 2023 for the Mental Health Personnel Technical Assistance Center (MHP TA Center), Assistance Listing Number 84.184U. This notice relates to the approved information collection under OMB control number 1894–0006.

DATES:

Applications Available: May 3, 2023.

Deadline for Notice of Intent to Apply: June 2, 2023.

Deadline for Transmittal of Applications: July 3, 2023.

Deadline for Intergovernmental Review: August 31, 2023.

Pre-Application Webinar Information: The Department will hold a preapplication presentation via webinar for prospective applicants on May 23, 2023, at 1:30 p.m. Eastern time. To register, please visit the program website at: *https://oese.ed.gov/offices/office-of-formula-grants/safe-supportive-schools/.*

ADDRESSES: For the addresses for obtaining and submitting an application, please refer to our Common Instructions for Applicants to Department of Education Discretionary Grant Programs, published in the **Federal Register** on December 7, 2022 (87 FR 75045), and available at *https://www.federalregister.gov/documents/2022/12/07/2022-26554/common-instructions-for-applicants-to-department-of-education-discretionary-grant-programs.* Please note that these Common Instructions supersede the version published on December 27, 2021.

FOR FURTHER INFORMATION CONTACT: Carlette Kyser Pegram, U.S. Department of Education, 400 Maryland Avenue SW, Room 3E257, Washington, DC 20202. Telephone: 202–453–6732. Email: *OESE.OSSS@ed.gov.*

If you are deaf, hard of hearing, or have a speech disability and wish to access telecommunications relay services, please dial 7–1–1.

SUPPLEMENTARY INFORMATION:

Full Text of Announcement

I. Funding Opportunity Description

Purpose of Program: The purpose of the MHP TA Center is to provide technical assistance to current Department grantees awarded funds under the fiscal years 2022 and 2023 Mental Health Service Professional Demonstration (MHSP) and the School-Based Mental Health Services (SBMH) grant programs and to disseminate resources and information to support State educational agencies (SEAs), local educational agencies (LEAs), institutions of higher education (IHEs), and other stakeholders, more broadly, in the preparation of school-based mental health services providers.

Background: The Department awarded nearly 300 MHSP and SBMH grants with historic funding provided under the Bipartisan Safer Communities Act (BSCA) and the Fiscal Year 2022 Omnibus Appropriations to address the critical need in prekindergarten (PK)–12 schools for school-based mental health services providers, a need exacerbated by the COVID–19 pandemic. Findings from the Department's Institute of Education Sciences April 2022 School Pulse Panel reinforce the challenges schools face in addressing student mental health needs. Specifically, 70 percent of public schools reported that the percentage of students who have sought mental health services increased since the start of the COVID–19 pandemic, and 29 percent of public schools reported that the percentage of staff who have sought mental health services increased since the start of the COVID–19 pandemic (U.S. Department of Education, Institute of Education Sciences, National Center for Education Statistics, School Pulse Panel (April 12–25, 2022)).

To help address the need for additional school-based mental health services providers, the MHSP program provides competitive grants to support and demonstrate innovative partnerships among SEAs, LEAs, and consortia of LEAs and IHEs to train school-based mental health services providers for employment in schools and LEAs, with the goal of increasing the number and diversity of high-quality, trained providers available to address the shortages of school-based mental health services providers in high-need LEAs. The SBMH program provides competitive grants to SEAs, LEAs, and consortia of LEAs to increase the number of credentialed school-based mental health services providers providing mental health services to students in LEAs with demonstrated need. Collectively, both programs aim to significantly increase the ability of schools to address the mental health needs of students and staff and help ensure safer, healthier, more inclusive, and positive school environments.

The MHP TA Center will support MHSP and SBMH grantees in meeting the goals and objectives of their respective grants. The Center will also identify, develop, and disseminate resources to enhance the efforts of IHEs, SEAs, LEAs, and schools to address the social, emotional, and mental health needs of PK–12 students and staff.

Priority: This competition has one absolute priority. We are establishing this priority for the FY 2023 grant competition and any subsequent year in which we make awards from the list of unfunded applications from this competition, in accordance with section 437(d)(1) of the General Education Provisions Act (GEPA), 20 U.S.C. 1232(d)(1).

Absolute Priority: For FY 2023 and any subsequent year in which we make awards from the list of unfunded applications from this competition, this priority is an absolute priority. Under 34 CFR 75.105(c)(3), we consider only applications that meet this priority.

This priority is:

A project to—

(1) Provide technical assistance to fiscal years 2022 and 2023 MHSP and SBMH grantees (grantees) through a tiered approach that includes universal support to all grantees, targeted support on select topics for subsets of grantees, and intensive support for individual grantees, as directed by the Office of Elementary and Secondary Education;

(2) Support high-quality grantee data through—

(a) Developing a system for collecting, reviewing, and analyzing specific performance data (*e.g.,* common annual performance measures across the MHSP and SBMH grant programs);

(b) Assisting MHSP and SBMH grantees in submitting valid and reliable data in the annual and final performance reports; and

(c) Conducting a review and analysis of the annual and final performance reports, aggregating the data, and preparing a report for the Department describing successes, challenges, exemplars, and noteworthy trends; and

(3) Disseminate best practices in credentialing, recruiting, training and developing, and retaining school-based mental health services providers, including best practices on establishing and sustaining partnerships with IHEs to create and provide innovative high-quality training and credentialing options and maintain a robust pipeline of school-based mental health services providers.

Requirements: We are establishing the following program requirements and application requirements for the FY 2023 grant competition and any subsequent year in which we make awards from the list of unfunded applications from this competition, in accordance with GEPA.

Program Requirements: The project must—

(a) Include at least one partnership with a Historically Black College and University (HBCU), Tribal College and University (TCU), or other Minority Serving Institution (MSI) in order to address a key focus of the MHSP and SBMH programs, specifically ensuring a pipeline of school-based mental health services providers from diverse backgrounds or from the communities that they serve;

(b) Develop and maintain a 508-compliant website to assist the MHP TA Center to (1) disseminate best practices in credentialing, recruiting, training and developing, and retaining school-based mental health services providers, including mental health service providers from diverse backgrounds or from the communities that they serve; and (2) disseminate free, online open educational resources (OER) that can be used to (i) meet ongoing training and professional development requirements for school-based mental health services providers and other school staff and (ii) provide training alternatives, such as micro-credentials, professional development certificates, and online courses, for new students pursuing a credential to provide mental health services in schools that States may choose to incorporate as part of their credentialing process, including OERs that address school climate (*e.g.,* ensuring inclusive environments for all students; ensuring school and school-related activities where students are free from bullying and harassment; and promoting strong relationships among students, teachers, families, and schools);

(c) Provide technical assistance (such as webinars or virtual meetings) for preparing, collecting, and submitting valid and reliable data to be included in annual and final performance reports; annually review and analyze annual and final reports; and annually prepare a report for the Department aggregating the data from annual and final performance reports and describing successes, challenges, exemplars, and noteworthy trends;

(d) Disseminate information (*e.g.,* instructional videos, toolkits, and briefs), best practices, and evidence-based practices to a variety of education stakeholders, including IHE and SEA and LEA personnel, via multiple mechanisms such as the MHP TA Center website, social media, and other channels, as appropriate, regarding how these entities can work together to increase the number and diversity of school-based mental health services providers and ensure continuity of mental health services as students progress through PK–12 schooling and postsecondary education;

(e) Annually provide forums (such as communities of practice) for grantees to share resources and experiences related to specific areas of MHSP and SBMH grant implementation. Specific areas should include creating culturally and linguistically inclusive and identity-safe environments for all students and other areas to be identified based on input from grantees, the Department, and other stakeholders, obtained through focus groups, for example; and

(f) Develop, identify, and disseminate information regarding evaluation of the implementation and impact of MHSP and SBMH grants, including providing webinars or other convenings focused specifically on conducting such evaluations and using ongoing data yielded from such evaluations to engage in continuous improvement of grant programs.

Application Requirements: In the application, an applicant must—

(a) Explain how the applicant's program design will create high-quality technical assistance for MHSP and SBMH grantees, including by providing a logic model that articulates a tiered approach to providing support to MHSP and SBMH grantees, a cycle of continuous improvement, and a process for program adjustments based on ongoing and emergent grantee needs;

(b) Demonstrate expert knowledge in credentialing, recruiting, training, developing, and retaining school-based mental health services providers;

(c) Demonstrate expert knowledge in—

(1) The statutory and regulatory requirements related to the MHSP and SBMH grant programs;

(2) Best practices in supporting school-based mental health services providers along the continuum from credentialing to retention in high-need schools; and

(3) Evidence-based approaches to supporting student and staff social, emotional, and mental health and well-being;

(d) Describe their experience in providing training, information, and support to IHEs, SEAs, LEAs, schools, and other organizations on evidence-based strategies to support pre- and in-service training that enhance the skills and knowledge of school-based mental health services providers and contribute to creating and maintaining supportive, positive, identity-safe, and inclusive school climates;

(e) Describe their experience providing training and resources to IHEs, LEAs, schools, and school-based mental health services providers regarding evidence-based practices, to ensure access to services for student groups not limited to but including students with disabilities, students experiencing homelessness, LGBTQ+ students, and English learners; and

(f) Describe their expertise in approaches to supporting valid and reliable data, conducting data quality reviews, collecting and analyzing data, and evaluating the effectiveness of programs intended to support student social, emotional, and mental health and well-being.

Definitions: For FY 2023 and any subsequent year in which we make awards from the list of unfunded applications from this competition, the following definitions apply. The definitions of ''demonstrates a rationale,'' ''evidence-based,'' ''experimental study,'' ''logic model'' ''moderate evidence,'' ''project component,'' ''promising evidence,'' ''quasi-experimental design study,'' ''relevant outcome,'' ''strong evidence,'' and ''What Works Clearinghouse Handbooks'' are from 34 CFR 77.1(c). The definitions of ''local educational agency'' and ''State educational agency'' are from section 8101 of the Elementary and Secondary Education Act of 1965, as amended (ESEA). The definition of ''school-based mental health services provider'' is from section 4102(6) of the ESEA.

Demonstrates a rationale means a key project component included in the

project's logic model is informed by research or evaluation findings that suggest the project component is likely to improve relevant outcomes.

Evidence-based means the proposed project component is supported by one or more of strong evidence, moderate evidence, promising evidence, or evidence that demonstrates a rationale.

Experimental study means a study that is designed to compare outcomes between two groups of individuals (such as students) that are otherwise equivalent except for their assignment to either a treatment group receiving a project component or a control group that does not. Randomized controlled trials, regression discontinuity design studies, and single-case design studies are the specific types of experimental studies that, depending on their design and implementation (*e.g.,* sample attrition in randomized controlled trials and regression discontinuity design studies), can meet What Works Clearinghouse (WWC) standards without reservations as described in the WWC Handbooks:

(i) A randomized controlled trial employs random assignment of, for example, students, teachers, classrooms, or schools to receive the project component being evaluated (the treatment group) or not to receive the project component (the control group).

(ii) A regression discontinuity design study assigns the project component being evaluated using a measured variable (*e.g.,* assigning students reading below a cutoff score to tutoring or developmental education classes) and controls for that variable in the analysis of outcomes.

(iii) A single-case design study uses observations of a single case (*e.g.,* a student eligible for a behavioral intervention) over time in the absence and presence of a controlled treatment manipulation to determine whether the outcome is systematically related to the treatment.

Local educational agency (LEA) means:

(a) In General. A public board of education or other public authority legally constituted within a State for either administrative control or direction of, or to perform a service function for, public elementary schools or secondary schools in a city, county, township, school district, or other political subdivision of a State, or of or for a combination of school districts or counties that is recognized in a State as an administrative agency for its public elementary schools or secondary schools.

(b) Administrative Control and Direction. The term includes any other public institution or agency having administrative control and direction of a public elementary school or secondary school.

(c) Bureau of Indian Education Schools. The term includes an elementary school or secondary school funded by the Bureau of Indian Education but only to the extent that including the school makes the school eligible for programs for which specific eligibility is not provided to the school in another provision of law and the school does not have a student population that is smaller than the student population of the LEA receiving assistance under the ESEA with the smallest student population, except that the school shall not be subject to the jurisdiction of any SEA (as defined in this notice) other than the Bureau of Indian Education.

(d) Educational Service Agencies. The term includes educational service agencies and consortia of those agencies.

(e) State Educational Agency. The term includes the SEA in a State in which the SEA is the sole educational agency for all public schools.

Logic model (also referred to as a theory of action) means a framework that identifies key project components of the proposed project (*i.e.,* the active ''ingredients'' that are hypothesized to be critical to achieving the relevant outcomes) and describes the theoretical and operational relationships among the key project components and relevant outcomes.

Moderate evidence means that there is evidence of effectiveness of a key project component in improving a relevant outcome for a sample that overlaps with the populations or settings proposed to receive that component, based on a relevant finding from one of the following:

(i) A practice guide prepared by the WWC using version 2.1, 3.0, 4.0, or 4.1 of the WWC Handbooks reporting a ''strong evidence base'' or ''moderate evidence base'' for the corresponding practice guide recommendation;

(ii) An intervention report prepared by the WWC using version 2.1, 3.0, 4.0, or 4.1 of the WWC Handbooks reporting a ''positive effect'' or ''potentially positive effect'' on a relevant outcome based on a ''medium to large'' extent of evidence, with no reporting of a ''negative effect'' or ''potentially negative effect'' on a relevant outcome; or

(iii) A single experimental study or quasi-experimental design study reviewed and reported by the WWC using version 2.1, 3.0, 4.0, or 4.1 of the WWC Handbooks, or otherwise assessed by the Department using version 4.1 of the WWC Handbooks, as appropriate, and that—

(A) Meets WWC standards with or without reservations;

(B) Includes at least one statistically significant and positive (*i.e.,* favorable) effect on a relevant outcome;

(C) Includes no overriding statistically significant and negative effects on relevant outcomes reported in the study or in a corresponding WWC intervention report prepared under version 2.1, 3.0, 4.0, or 4.1 of the WWC Handbooks; and

(D) Is based on a sample from more than one site (*e.g.,* State, county, city, school district, or postsecondary campus) and includes at least 350 students or other individuals across sites. Multiple studies of the same project component that each meet requirements in paragraphs (iii)(A), (B), and (C) of this definition may together satisfy the requirement in this paragraph (iii)(D).

Project component means an activity, strategy, intervention, process, product, practice, or policy included in a project. Evidence may pertain to an individual project component or to a combination of project components (*e.g.,* training teachers on instructional practices for English learners and follow-on coaching for these teachers).

Promising evidence means that there is evidence of the effectiveness of a key project component in improving a relevant outcome, based on a relevant finding from one of the following:

(i) A practice guide prepared by WWC reporting a ''strong evidence base'' or ''moderate evidence base'' for the corresponding practice guide recommendation;

(ii) An intervention report prepared by the WWC reporting a ''positive effect'' or ''potentially positive effect'' on a relevant outcome with no reporting of a ''negative effect'' or ''potentially negative effect'' on a relevant outcome; or

(iii) A single study assessed by the Department, as appropriate, that—

(A) Is an experimental study, a quasi-experimental design study, or a well-designed and well-implemented correlational study with statistical controls for selection bias (*e.g.,* a study using regression methods to account for differences between a treatment group and a comparison group); and

(B) Includes at least one statistically significant and positive (*i.e.,* favorable) effect on a relevant outcome.

Quasi-experimental design study means a study using a design that attempts to approximate an experimental study by identifying a

comparison group that is similar to the treatment group in important respects. This type of study, depending on design and implementation (*e.g.,* establishment of baseline equivalence of the groups being compared), can meet WWC standards with reservations, but cannot meet WWC standards without reservations, as described in the WWC Handbooks.

Relevant outcome means the student outcome(s) or other outcome(s) the key project component is designed to improve, consistent with the specific goals of the program.

School-based mental health services provider means a State-licensed or State-certified school counselor, school psychologist, school social worker, or other State-licensed or certified mental health professional qualified under State law to provide mental health services to children and adolescents.

State educational agency means the agency primarily responsible for the State supervision of public elementary schools and secondary schools.

Strong evidence means that there is evidence of the effectiveness of a key project component in improving a relevant outcome for a sample that overlaps with the populations and settings proposed to receive that component, based on a relevant finding from one of the following:

(i) A practice guide prepared by the WWC using version 2.1, 3.0, 4.0, or 4.1 of the WWC Handbooks reporting a ''strong evidence base'' for the corresponding practice guide recommendation;

(ii) An intervention report prepared by the WWC using version 2.1, 3.0, 4.0, or 4.1 of the WWC Handbooks reporting a ''positive effect'' on a relevant outcome based on a ''medium to large'' extent of evidence, with no reporting of a ''negative effect'' or ''potentially negative effect'' on a relevant outcome; or

(iii) A single experimental study reviewed and reported by the WWC using version 2.1, 3.0, 4.0, or 4.1 of the WWC Handbooks, or otherwise assessed by the Department using version 4.1 of the WWC Handbooks, as appropriate, and that—

(A) Meets WWC standards without reservations;

(B) Includes at least one statistically significant and positive (*i.e.,* favorable) effect on a relevant outcome;

(C) Includes no overriding statistically significant and negative effects on relevant outcomes reported in the study or in a corresponding WWC intervention report prepared under version 2.1, 3.0, 4.0, or 4.1 of the WWC Handbooks; and

(D) Is based on a sample from more than one site (*e.g.,* State, county, city, school district, or postsecondary campus) and includes at least 350 students or other individuals across sites. Multiple studies of the same project component that each meet requirements in paragraphs (iii)(A), (B), and (C) of this definition may together satisfy the requirement in this paragraph (iii)(D).

What Works Clearinghouse (WWC) Handbooks (WWC Handbooks) means the standards and procedures set forth in the WWC Standards Handbook, Versions 4.0 or 4.1, and WWC Procedures Handbook, Versions 4.0 or 4.1, or in the WWC Procedures and Standards Handbook, Version 3.0 or Version 2.1 (all incorporated by reference, see § 77.2). Study findings eligible for review under WWC standards can meet WWC standards without reservations, meet WWC standards with reservations, or not meet WWC standards. WWC practice guides and intervention reports include findings from systematic reviews of evidence as described in the WWC Handbooks documentation.

Waiver of Proposed Rulemaking: Under the Administrative Procedure Act (5 U.S.C. 553), the Department generally offers interested parties the opportunity to comment on proposed priorities, requirements, definitions, and selection criteria. Section 437(d)(1) of GEPA, however, allows the Secretary to exempt from rulemaking requirements regulations governing the first grant competition under a new or substantially revised program authority. This is the first grant competition for this program under section 4631(a)(1)(B) of the ESEA, and therefore qualifies for this exemption. In order to ensure timely grant awards, the Secretary has decided to forgo public comment on the priorities and requirements under section 437(d)(1) of GEPA. These priorities and requirements will apply to the FY 2023 grant competition and any subsequent year in which we make awards from the list of unfunded applications from this competition.

Program Authority: Section 4631(a)(1)(B) of the ESEA (20 U.S.C. 7281).

Note: Projects will be awarded and must be operated in a manner consistent with the nondiscrimination requirements contained in Federal civil rights laws.

Applicable Regulations: (a) The Education Department General Administrative Regulations in 34 CFR parts 75, 77, 79, 81, 82, 84, 86, 97, 98, and 99. (b) The Office of Management and Budget Guidelines to Agencies on Governmentwide Debarment and Suspension (Nonprocurement) in 2 CFR part 180, as adopted and amended as regulations of the Department in 2 CFR part 3485. (c) The Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards in 2 CFR part 200, as adopted and amended as regulations of the Department in 2 CFR part 3474.

Note: The regulations in 34 CFR part 86 apply to institutions of higher education only.

II. Award Information

Type of Award: Discretionary grant/cooperative agreement.

Estimated Available Funds: $2,600,000 annually for 48 months, provided that the grantee and the Department may agree to extend an additional 12 months for up to $1,300,000.

Maximum Award: We will not make an award exceeding $2,600,000 for a single budget period of 12 months.

Estimated Number of Awards: 1.

Note: The Department is not bound by any estimates in this notice.

Project Period: Up to 48 months, provided that the grantee and the Department may agree to extend an additional 12 months for a total of 60 months.

III. Eligibility Information

1. *Eligible Applicants:* Research organizations, institutions, agencies, institutions of higher education, private nonprofit organizations, and for-profit organizations, or partnerships among such entities, in each case with the demonstrated ability or capacity to carry out the activities described.

2. a. *Cost Sharing or Matching:* This program does not require cost sharing or matching.

b. *Indirect Cost Rate Information:* This program uses an unrestricted indirect cost rate. For more information regarding indirect costs, or to obtain a negotiated indirect cost rate, please see *www2.ed.gov/about/offices/list/ocfo/intro.html.*

c. *Administrative Cost Limitation:* This program does not include any program-specific limitation on administrative expenses. All administrative expenses must be reasonable and necessary and conform to Cost Principles described in 2 CFR part 200 subpart E of the Uniform Guidance.

3. *Subgrantees:* A grantee under this competition may not award subgrants to entities to directly carry out project activities described in its application.

IV. Application and Submission Information

1. *Application Submission Instructions:* Applicants are required to follow the Common Instructions for Applicants to Department of Education Discretionary Grant Programs, published in the **Federal Register** on December 7, 2022 (87 FR 75045), and available at *https://www.federalregister.gov/documents/2022/12/07/2022-26554/common-instructions-for-applicants-to-department-of-education-discretionary-grant-programs,* which contain requirements and information on how to submit an application. Please note that these Common Instructions supersede the version published on December 27, 2021.

2. *Submission of Proprietary Information:* Given the types of projects that may be proposed in applications for the MHP TA Center program, your application may include business information that you consider proprietary. In 34 CFR 5.11, we define ''business information'' and describe the process we use in determining whether any of that information is proprietary and, thus, protected from disclosure under Exemption 4 of the Freedom of Information Act (5 U.S.C. 552,as amended).

Because we plan to make successful applications available to the public, you may wish to request confidentiality of business information.

Consistent with Executive Order 12600, please designate in your application any information that you believe is exempt from disclosure under Exemption 4. In the appropriate appendix section of your application, under ''Other Attachments Form,'' please list the page number or numbers on which we can find this information. For additional information please see 34 CFR 5.11(c).

3. *Intergovernmental Review:* This program is subject to Executive Order 12372 and the regulations in 34 CFR part 79. Information about Intergovernmental Review of Federal Programs under Executive Order 12372 is in the application package for this competition.

4. *Funding Restrictions:* We reference regulations outlining funding restrictions in the *Applicable Regulations* section of this notice.

5. *Recommended Page Limit:* The application narrative is where you, the applicant, address the selection criteria that reviewers use to evaluate your application. We recommend that you (1) limit the application narrative to no more than 30 pages and (2) use the following standards:

- A ''page'' is 8.5'' x 11'', on one side only, with 1'' margins at the top, bottom, and both sides.
- Double-space (no more than three lines per vertical inch) all text in the application narrative.
- Use a font that is either 12 point or larger or no smaller than 10 pitch (characters per inch).
- Use one of the following fonts: Times New Roman, Courier, Courier New, or Arial.

The recommended page limit does not apply to the cover sheet; the budget section, including the narrative budget justification; the assurances and certifications; or the one-page abstract, the resumes, the bibliography, or the letters of support. However, the recommended page limit does apply to all of the application narrative.

6. *Notice of Intent to Apply:* The Department will be able to review grant applications more efficiently if we know the approximate number of applicants that intend to apply. Therefore, we strongly encourage each potential applicant to notify us of their intent to submit an application. To do so, please email the program contact person listed under **FOR FURTHER INFORMATION CONTACT** with the subject line ''Intent to Apply,'' and include the applicant's name and a contact person's name and email address. Applicants that do not submit a notice of intent to apply may still apply for funding; applicants that do submit a notice of intent to apply are not bound to apply or bound by the information provided.

V. Application Review Information

1. *Selection Criteria:* The selection criteria for this competition are from 34 CFR 75.210. The maximum score for all of the selection criteria is 100 points. The maximum score for each criterion is included in parentheses following the title of the specific selection criterion. Each criterion also includes the factors that reviewers will consider in determining the extent to which an applicant meets the criterion.

The selection criteria are as follows:

(a) *Quality of the project design* (up to 25 points).

The Secretary considers the quality of the design of the proposed project. In determining the quality of the design of the proposed project, the Secretary considers the following factors:

(1) The extent to which the design of the proposed project is appropriate to, and will successfully address, the needs of the target population or other identified needs. (up to 8 points)

(2) The extent to which the proposed project demonstrates a rationale (as defined in this notice). (up to 8 points)

(3) The extent to which performance feedback and continuous improvement are integral to the design of the proposed project. (up to 9 points)

(b) *Quality of project services* (up to 30 points).

The Secretary considers the quality of the project services. In determining the quality of the project services of the proposed project, the Secretary considers the following factors:

(1) The extent to which the services to be provided by the proposed project are appropriate to the needs of the intended recipients or beneficiaries of those services. (up to 15 points)

(2) The quality and sufficiency of strategies for ensuring equal access and treatment for eligible project participants who are members of groups that have traditionally been underrepresented based on race, color, national origin, gender, age, or disability. (up to 5 points)

(3) The extent to which the training or professional development services to be provided by the proposed project are of sufficient quality, intensity, and duration to lead to improvements in practice among the recipients of those services. (up to 10 points)

(c) *Quality of project personnel* (up to 20 points).

The Secretary considers the quality of the personnel who will carry out the proposed project.

(1) In determining the quality of project personnel, the Secretary considers the extent to which the applicant encourages applications for employment from persons who are members of groups that have been traditionally underrepresented based on race, color, national origin, gender, age, or disability. (up to 10 points)

(2) In addition, the Secretary considers the qualifications, including relevant training and experience, of key project personnel. (up to 10 points)

(d) *Quality of the management plan* (up to 20 points).

The Secretary considers the quality of the management plan for the proposed project. In determining the quality of the management plan for the proposed project, the Secretary considers the following factors:

(1) The adequacy of the management plan to achieve the objectives of the proposed project on time and within budget, including clearly defined responsibilities, timelines, and milestones for accomplishing project tasks. (up to 5 points)

(2) The adequacy of procedures for ensuring feedback and continuous

improvement in the operation of the proposed project. (up to 5 points)

(3) The adequacy of mechanisms for ensuring high-quality products and services from the proposed project. (up to 5 points)

(4) The extent to which the time commitments of the project director and principal investigator and other key project personnel are appropriate and adequate to meet the objectives of the proposed project. (up to 5 points)

(e) *Quality of the project evaluation* (up to 5 points).

The Secretary considers the quality of the evaluation to be conducted of the proposed project. In determining the quality of the evaluation, the Secretary considers the following factors:

(1) The extent to which the methods of evaluation will provide valid and reliable performance data on relevant outcomes. (up to 2 points)

(2) The extent to which the methods of evaluation include the use of objective performance measures that are clearly related to the intended outcomes of the project and will produce quantitative and qualitative data to the extent possible. (up to 3 points)

2. *Review and Selection Process:* We remind potential applicants that in reviewing applications in any discretionary grant competition, the Secretary may consider, under 34 CFR 75.217(d)(3), the past performance of the applicant in carrying out a previous award, such as the applicant's use of funds, achievement of project objectives, and compliance with grant conditions. The Secretary may also consider whether the applicant failed to submit a timely performance report or submitted a report of unacceptable quality.

In addition, in making a competitive grant award, the Secretary requires various assurances, including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance from the Department (34 CFR 100.4, 104.5, 106.4, 108.8, and 110.23).

3. *Risk Assessment and Specific Conditions:* Consistent with 2 CFR 200.206, before awarding grants under this competition the Department conducts a review of the risks posed by applicants. Under 2 CFR 200.208, the Secretary may impose specific conditions and, under 2 CFR 3474.10, in appropriate circumstances, high-risk conditions on a grant if the applicant or grantee is not financially stable; has a history of unsatisfactory performance; has a financial or other management system that does not meet the standards in 2 CFR part 200, subpart D; has not fulfilled the conditions of a prior grant; or is otherwise not responsible.

4. *Integrity and Performance System:* If you are selected under this competition to receive an award that over the course of the project period may exceed the simplified acquisition threshold (currently $250,000), under 2 CFR 200.206(a)(2) we must make a judgment about your integrity, business ethics, and record of performance under Federal awards—that is, the risk posed by you as an applicant—before we make an award. In doing so, we must consider any information about you that is in the integrity and performance system (currently referred to as the Federal Awardee Performance and Integrity Information System (FAPIIS)), accessible through the System for Award Management. You may review and comment on any information about yourself that a Federal agency previously entered and that is currently in FAPIIS.

Please note that, if the total value of your currently active grants, cooperative agreements, and procurement contracts from the Federal Government exceeds $10,000,000, the reporting requirements in 2 CFR part 200, appendix XII, require you to report certain integrity information to FAPIIS semiannually. Please review the requirements in 2 CFR part 200, appendix XII, if this grant plus all the other Federal funds you receive exceed $10,000,000.

5. *In General.* In accordance with the Office of Management and Budget's guidance located at 2 CFR part 200, all applicable Federal laws, and relevant Executive guidance, the Department will review and consider applications for funding pursuant to this notice inviting applications in accordance with—

(a) Selecting recipients most likely to be successful in delivering results based on the program objectives through an objective process of evaluating Federal award applications (2 CFR 200.205);

(b) Prohibiting the purchase of certain telecommunication and video surveillance services or equipment in alignment with section 889 of the National Defense Authorization Act of 2019 (Pub. L. 115–232) (2 CFR 200.216);

(c) Providing a preference, to the extent permitted by law, to maximize use of goods, products, and materials produced in the United States (2 CFR 200.322); and

(d) Terminating agreements in whole or in part to the greatest extent authorized by law if an award no longer effectuates the program goals or agency priorities (2 CFR 200.340).

VI. Award Administration Information

1. *Award Notices:* If your application is successful, we notify your U.S. Representative and U.S. Senators and send you a Grant Award Notification (GAN); or we may send you an email containing a link to access an electronic version of your GAN. We may notify you informally, also.

If your application is not evaluated or not selected for funding, we notify you.

2. *Administrative and National Policy Requirements:* We identify administrative and national policy requirements in the application package and reference these and other requirements in the *Applicable Regulations* section of this notice.

We reference the regulations outlining the terms and conditions of an award in the *Applicable Regulations* section of this notice and include these and other specific conditions in the GAN. The GAN also incorporates your approved application as part of your binding commitments under the grant.

3. *Open Licensing Requirements:* Unless an exception applies, if you are awarded a grant under this competition, you will be required to openly license to the public grant deliverables created in whole, or in part, with Department grant funds. When the deliverable consists of modifications to pre-existing works, the license extends only to those modifications that can be separately identified and only to the extent that open licensing is permitted under the terms of any licenses or other legal restrictions on the use of pre-existing works. Additionally, a grantee or subgrantee that is awarded competitive grant funds must have a plan to disseminate these public grant deliverables. This dissemination plan can be developed and submitted after your application has been reviewed and selected for funding. For additional information on the open licensing requirements please refer to 2 CFR 3474.20.

4. *Reporting:* (a) If you apply for a grant under this competition, you must ensure that you have in place the necessary processes and systems to comply with the reporting requirements in 2 CFR part 170 should you receive funding under the competition. This does not apply if you have an exception under 2 CFR 170.110(b).

(b) At the end of your project period, you must submit a final performance report, including financial information, as directed by the Secretary. If you receive a multiyear award, you must submit an annual performance report that provides the most current performance and financial expenditure

information as directed by the Secretary under 34 CFR 75.118. The Secretary may also require more frequent performance reports under 34 CFR 75.720(c). For specific requirements on reporting, please go to *www.ed.gov/fund/grant/apply/appforms/appforms.html.*

(c) Under 34 CFR 75.250(b), the Secretary may provide a grantee with additional funding for data collection analysis and reporting. In this case the Secretary establishes a data collection period.

5. *Performance Measures:* For the purposes of Department reporting under 34 CFR 75.110, we have established three performance measures for the MHP TA Center program: (1) The percentage of grantees reporting valid and reliable data on their progress as evidenced in annual performance reports; (2) The percentage of MHSP and SBMH grantees who report improvements and progress toward grant goals and objectives as evidenced in annual performance reports; and (3) The extent to which MHSP and SBMH grantees are satisfied with the quality, usefulness, and relevance of technical assistance provided as evidenced by surveys.

6. *Continuation Awards:* In making a continuation award under 34 CFR 75.253, the Secretary considers, among other things: whether a grantee has made substantial progress in achieving the goals and objectives of the project; whether the grantee has expended funds in a manner that is consistent with its approved application and budget; and, if the Secretary has established performance measurement requirements, whether the grantee has made substantial progress in achieving the performance targets in the grantee's approved application.

In making a continuation award, the Secretary also considers whether the grantee is operating in compliance with the assurances in its approved application, including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance from the Department (34 CFR 100.4, 104.5, 106.4, 108.8, and 110.23).

VII. Other Information

Accessible Format: On request to the program contact person listed under **FOR FURTHER INFORMATION CONTACT**, individuals with disabilities can obtain this document and a copy of the application package in an accessible format. The Department will provide the requestor with an accessible format that may include Rich Text Format (RTF) or text format (txt), a thumb drive, an MP3 file, braille, large print, audiotape, or compact disc, or other accessible format.

Electronic Access to This Document: The official version of this document is the document published in the **Federal Register**. You may access the official edition of the **Federal Register** and the Code of Federal Regulations at *www.govinfo.gov.* At this site you can view this document, as well as all other documents of this Department published in the **Federal Register,** in text or Portable Document Format (PDF). To use PDF, you must have Adobe Acrobat Reader, which is available free at the site.

You may also access documents of the Department published in the **Federal Register** by using the article search feature at *www.federalregister.gov.* Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

James F. Lane,

Principal Deputy Assistant Secretary, Delegated the Authority to Perform the Functions and Duties of the Assistant Secretary, Office of Elementary and Secondary Education.

[FR Doc. 2023–09412 Filed 5–2–23; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

Accrediting Agencies Currently Undergoing Review for the Purpose of Recognition by the U.S. Secretary of Education

AGENCY: Accreditation Group, Office of Postsecondary Education, U.S. Department of Education.

ACTION: Call for written third-party comments.

SUMMARY: This notice provides information to members of the public on submitting written comments for accrediting agencies currently undergoing review for the purpose of recognition by the U.S. Secretary of Education.

FOR FURTHER INFORMATION CONTACT: Herman Bounds, Director, Accreditation Group, Office of Postsecondary Education, U.S. Department of Education, 400 Maryland Avenue SW, fifth floor, Washington, DC 20202, telephone: (202) 453–7615, or email: *herman.bounds@ed.gov.*

SUPPLEMENTARY INFORMATION: This request for written third-party comments concerning the performance of accrediting agencies under review by the Secretary of Education is required by 496(n)(1)(A) of the Higher Education Act (HEA) of 1965, as amended, and pertains to the summer 2024 meeting of the National Advisory Committee on Institutional Quality and Integrity (NACIQI). The meeting date and location have not been determined but will be announced in a later **Federal Register** notice. In addition, a later **Federal Register** notice will describe how to register to provide oral comments at the meeting. Note: Written comments about the specific agencies identified below will not be accepted or provided to NACIQI members if those comments are submitted after the deadline provided in this **Federal Register** notice, which is June 5, 2023. Written comments must be submitted to the mailbox identified below. Do not submit written comments directly to Department officials or to NACIQI members.

Agencies Under Review and Evaluation: The Department requests written comments from the public on the following accrediting agencies, which are currently undergoing review and evaluation by the Accreditation Group, and which will be reviewed at the summer 2024 NACIQI meeting.

The agencies are listed by the type of application each agency has submitted. Please note, each agency's current scope of recognition is indicated below. If any agency requested to expand its scope of recognition, identified are both the current scope of recognition and the requested scope of recognition.

Applications for Renewal of Recognition

1. WASC Accrediting Commission for Community and Junior Colleges. Scope of Recognition: The accreditation and pre-accreditation (''Candidate for Accreditation'') of community and other colleges which have as a primary mission the granting of associate degrees, but which may also award certificates and other credentials, not to exceed the bachelor degree level, where the provision of such credentials is within the institution's mission and, if applicable, is authorized by their governmental authorities, and the accreditation of such programs offered via distance education and correspondence education at these colleges. This recognition also extends to the Committee on Substantive Change of the Commission, for decisions on substantive changes, and the Appeals Panel. Geographic Area of Accrediting Activities: Throughout the United States.

2. American Veterinary Medical Association, Council on Education. Scope of Recognition: The accreditation and preaccreditation (''Provisional Accreditation'') in the United States of

programs leading to professional degrees (D.V.M. or V.M.D.) in veterinary medicine. Geographic Area of Accrediting Activities: Throughout the United States.

3. Accrediting Council for Continuing Education and Training. Scope of Recognition: The accreditation throughout the United States of institutions of higher education that offer continuing education and vocational programs that confer certificates or occupational associate degrees, including those programs offered via distance education. Geographic Area of Accrediting Activities: Throughout the United States.

4. Council on Education for Public Health. Scope of Recognition: The accreditation of schools of public health and public health programs outside schools of public health, at the baccalaureate and graduate degree levels, including those offered via distance education. Geographic Area of Accrediting Activities: Throughout the United States.

5. National Association of Schools of Dance, Commission on Accreditation. Scope of Recognition: The accreditation throughout the United States of freestanding institutions that offer dance and dance-related programs (both degree and non-degree-granting), including those offered via distance education. Geographic Area of Accrediting Activities: Throughout the United States.

6. National Association of Schools of Music, Commission on Accreditation. Scope of Recognition: The accreditation throughout the United States of freestanding institutions that offer music and music related programs (both degree and non-degree-granting) including those offered via distance. This recognition also extends to the Commission on Community College Accreditation. Geographic Area of Accrediting Activities: Throughout the United States.

7. National Association of Schools of Theatre, Commission on Accreditation. Scope of Recognition: The accreditation throughout the United States of freestanding institutions that offer theatre and theatre-related programs (both degree and non-degree-granting), including those offered via distance education. Geographic Area of Accrediting Activities: Throughout the United States.

8. Puerto Rico State Agency for the Approval of Public Postsecondary Vocational, Technical Institutions and Programs. Scope of Recognition: State agency for the approval of vocational education.

9. Maryland State Board of Nursing. Scope of Recognition: State agency for the approval of nursing education.

10.New York State Board of Regents (nursing education).

Scope of Recognition: State approval agency for nursing education.

Submission of Written Comments Regarding a Specific Accrediting Agency Under Review

Written comments about the recognition of any of the accrediting agencies listed above must be received by June 5, 2023, in the *ThirdPartyComments@ed.gov* mailbox. Please include in the subject line ''Written Comments: (agency name).'' The electronic mail (email) must include the name(s), title, organization/affiliation, mailing address, email address, and telephone number of the person(s) making the comment. Comments should be submitted as a PDF, Microsoft Word document or in a medium compatible with Microsoft Word that is attached to an email or provided in the body of an email message. Comments about an agency that has submitted a petition for initial recognition, renewal of recognition, or an expansion of scope must relate to the agency's compliance with the Criteria for the recognition of Accrediting Agencies or the Criteria for the recognition of state agencies, which are available at: *https://www2.ed.gov/admins/finaid/accred/index.html.*

Only written materials submitted by the deadline to the email address listed in this notice, and in accordance with these instructions, become part of the official record concerning agencies scheduled for review and are considered by the Department and NACIQI in their deliberations. Written comments about the specific agencies identified in this **Federal Register** notice that are submitted after the deadline will not be considered by the Department or provided to NACIQI for purposes of the current cycle review. However, comments may be provided orally at the summer 2024 NACIQI meeting, which has not yet been scheduled, but which will be announced in a future **Federal Register** notice.

Electronic Access to this Document: The official version of this document is the document published in the **Federal Register**. Free internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available via the Federal Digital System at: *www.gpo.gov/fdsys.* At this site, you can view this document, as well as all other documents of the Department published in the **Federal Register**, in text or Adobe Portable Document Format (PDF). To use PDF, you must have Adobe Acrobat Reader, which is available free at the site. You may also access documents of the Department published in the **Federal Register** by using the article search feature at: *www.federalregister.gov.* Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Authority: 20 U.S.C. 1011c; 20 U.S.C. 1099b.

Annmarie Weisman,

Deputy Assistant Secretary for Policy, Planning and Innovation, Office of Postsecondary Education.

[FR Doc. 2023–09362 Filed 5–2–23; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP23–163–000]

Texas Eastern Transmission, LP; Notice of Request Under Blanket Authorization and Establishing Intervention and Protest Deadline

Take notice that on April 18, 2023, Texas Eastern Transmission, LP (Texas Eastern), 915 North Eldridge Parkway, Suite 1000, Houston, Texas 77079, filed a prior notice request in accordance with 18 CFR 157.205 and 157.216 of the Federal Energy Regulatory Commission's (Commission) regulations under the Natural Gas Act and Texas Eastern's blanket certificate issued in Docket No. CP82–535–000. Texas Eastern requests authorization to: (1) abandon in-place approximately 5.3 miles of its 12-inch-diameter Line 14–K, (2) abandon by removal the related meter and regulating station 72258, and (3) abandon by removal related ancillary facilities, all located in Pointe Coupee Parish, Louisiana. Texas Eastern states the facilities to be abandoned have not been used to provide service in over a decade.

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*www.ferc.gov/*) using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. At this time, the Commission has suspended access to the Commission's Public Reference Room. For assistance,

contact the Federal Energy Regulatory Commission at *FERCOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TTY, (202) 502–8659.

Any questions concerning this application should be directed to Estela D. Lozano, Director, Regulatory, Texas Eastern Transmission, LP, P.O. Box 1642, Houston, Texas 77251–1642, by phone at (713) 627–4522 or by email to *estela.lozano@enbridge.com.*

Pursuant to section 157.9 of the Commission's Rules of Practice and Procedure,[1] within 90 days of this Notice the Commission staff will either: complete its environmental review and place it into the Commission's public record (eLibrary) for this proceeding; or issue a Notice of Schedule for Environmental Review. If a Notice of Schedule for Environmental Review is issued, it will indicate, among other milestones, the anticipated date for the Commission staff's issuance of the final environmental impact statement (FEIS) or environmental assessment (EA) for this proposal. The filing of an EA in the Commission's public record for this proceeding or the issuance of a Notice of Schedule for Environmental Review will serve to notify federal and state agencies of the timing for the completion of all necessary reviews, and the subsequent need to complete all federal authorizations within 90 days of the date of issuance of the Commission staff's FEIS or EA.

Public Participation

There are three ways to become involved in the Commission's review of this project: you can file a protest to the project, you can file a motion to intervene in the proceeding, and you can file comments on the project. There is no fee or cost for filing protests, motions to intervene, or comments. The deadline for filing protests, motions to intervene, and comments is 5:00 p.m. Eastern Time on June 26, 2023. How to file protests, motions to intervene, and comments is explained below.

Protests

Pursuant to section 157.205 of the Commission's regulations under the NGA,[2] any person [3] or the Commission's staff may file a protest to the request. If no protest is filed within the time allowed or if a protest is filed and then withdrawn within 30 days after the allowed time for filing a protest, the proposed activity shall be deemed to be authorized effective the day after the time allowed for protest. If a protest is filed and not withdrawn within 30 days after the time allowed for filing a protest, the instant request for authorization will be considered by the Commission.

Protests must comply with the requirements specified in section 157.205(e) of the Commission's regulations,[4] and must be submitted by the protest deadline, which is June 26, 2023. A protest may also serve as a motion to intervene so long as the protestor states it also seeks to be an intervenor.

Interventions

Any person has the option to file a motion to intervene in this proceeding. Only intervenors have the right to request rehearing of Commission orders issued in this proceeding and to subsequently challenge the Commission's orders in the U.S. Circuit Courts of Appeal.

To intervene, you must submit a motion to intervene to the Commission in accordance with Rule 214 of the Commission's Rules of Practice and Procedure [5] and the regulations under the NGA [6] by the intervention deadline for the project, which is June 26, 2023. As described further in Rule 214, your motion to intervene must state, to the extent known, your position regarding the proceeding, as well as your interest in the proceeding. For an individual, this could include your status as a landowner, ratepayer, resident of an impacted community, or recreationist. You do not need to have property directly impacted by the project in order to intervene. For more information about motions to intervene, refer to the FERC website at *https://www.ferc.gov/how-intervene.*

All timely, unopposed motions to intervene are automatically granted by operation of Rule 214(c)(1). Motions to intervene that are filed after the intervention deadline are untimely and may be denied. Any late-filed motion to intervene must show good cause for being late and must explain why the time limitation should be waived and provide justification by reference to factors set forth in Rule 214(d) of the Commission's Rules and Regulations. A person obtaining party status will be placed on the service list maintained by the Secretary of the Commission and will receive copies (paper or electronic) of all documents filed by the applicant and by all other parties.

Comments

Any person wishing to comment on the project may do so. The Commission considers all comments received about the project in determining the appropriate action to be taken. To ensure that your comments are timely and properly recorded, please submit your comments on or before June 26, 2023. The filing of a comment alone will not serve to make the filer a party to the proceeding. To become a party, you must intervene in the proceeding.

How To File Protests, Interventions, and Comments

There are two ways to submit protests, motions to intervene, and comments. In both instances, please reference the Project docket number CP23–163–000 in your submission.

(1) You may file your protest, motion to intervene, and comments by using the Commission's eFiling feature, which is located on the Commission's website (*www.ferc.gov*) under the link to Documents and Filings. New eFiling users must first create an account by clicking on ''eRegister.'' You will be asked to select the type of filing you are making; first select General'' and then select ''Protest'', ''Intervention'', or ''Comment on a Filing''; or [7]

(2) You can file a paper copy of your submission by mailing it to the address below. Your submission must reference the Project docket number CP23–163–000.

To mail via USPS, use the following address: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426.

To mail via any other courier, use the following address: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852.

The Commission encourages electronic filing of submissions (option 1 above) and has eFiling staff available to assist you at (202) 502–8258 or *FercOnlineSupport@ferc.gov.*

Protests and motions to intervene must be served on the applicant either by mail or email (with a link to the document) at: Estela D. Lozano, Director, Regulatory, Texas Eastern Transmission, LP, P.O. Box 1642, Houston, Texas 77251–1642, or by email to *estela.lozano@enbridge.com.* Any subsequent submissions by an

[1] 18 CFR (Code of Federal Regulations) 157.9.

[2] 18 CFR 157.205.

[3] Persons include individuals, organizations, businesses, municipalities, and other entities. 18 CFR 385.102(d).

[4] 18 CFR 157.205(e).

[5] 18 CFR 385.214.

[6] 18 CFR 157.10.

[7] Additionally, you may file your comments electronically by using the eComment feature, which is located on the Commission's website at *www.ferc.gov* under the link to Documents and Filings. Using eComment is an easy method for interested persons to submit brief, text-only comments on a project.

intervenor must be served on the applicant and all other parties to the proceeding. Contact information for parties can be downloaded from the service list at the eService link on FERC Online.

Tracking the Proceeding

Throughout the proceeding, additional information about the project will be available from the Commission's Office of External Affairs, at (866) 208–FERC, or on the FERC website at *www.ferc.gov* using the ''eLibrary'' link as described above. The eLibrary link also provides access to the texts of all formal documents issued by the Commission, such as orders, notices, and rulemakings.

In addition, the Commission offers a free service called eSubscription which allows you to keep track of all formal issuances and submittals in specific dockets. This can reduce the amount of time you spend researching proceedings by automatically providing you with notification of these filings, document summaries, and direct links to the documents. For more information and to register, go to *www.ferc.gov/docs-filing/esubscription.asp.*

Dated: April 27, 2023.

Kimberly D. Bose,

Secretary.

[FR Doc. 2023–09376 Filed 5–2–23; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas & Oil Pipeline Rate and Refund Report filings:

Filings Instituting Proceedings

Docket Numbers: PR23–48–000.

Applicants: Spire Storage Salt Plains LLC.

Description: § 284.123(g) Rate Filing: Spire Storage Salts Plains SOC—April 2023 to be effective 4/1/2023.

Filed Date: 4/26/23.

Accession Number: 20230426–5169.

Comment Date: 5 p.m. ET 5/17/23.

Protest Date: 5 p.m. ET 6/26/23.

Docket Numbers: RP23–710–000.

Applicants: Northern Border Pipeline Company.

Description: Compliance filing: 2023 Operational Purchases and Sales Report to be effective N/A.

Filed Date: 4/26/23.

Accession Number: 20230426–5173.

Comment Date: 5 p.m. ET 5/8/23.

Docket Numbers: RP23–711–000.

Applicants: Transcontinental Gas Pipe Line Company, LLC.

Description: Compliance filing: Rate Schedule S–2 OFO Flow Through Refund Report April 2023 to be effective N/A.

Filed Date: 4/27/23.

Accession Number: 20230427–5041.

Comment Date: 5 p.m. ET 5/9/23.

Docket Numbers: RP23–712–000.

Applicants: Florida Gas Transmission Company, LLC.

Description: § 4(d) Rate Filing: New Service Agreements—Brotman II to be effective 5/1/2023.

Filed Date: 4/27/23.

Accession Number: 20230427–5085.

Comment Date: 5 p.m. ET 5/9/23.

Docket Numbers: RP23–713–000.

Applicants: Florida Gas Transmission Company, LLC.

Description: § 4(d) Rate Filing: New NRA-Denbury and Update Non-Conforming List to be effective 5/1/2023.

Filed Date: 4/27/23.

Accession Number: 20230427–5086.

Comment Date: 5 p.m. ET 5/9/23.

Docket Numbers: RP23–714–000.

Applicants: Rover Pipeline LLC.

Description: § 4(d) Rate Filing: Housekeeping Filing—Remove Surcharge-Related Language to be effective 5/27/2023.

Filed Date: 4/27/23.

Accession Number: 20230427–5174.

Comment Date: 5 p.m. ET 5/9/23.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

The filings are accessible in the Commission's eLibrary system (*https://elibrary.ferc.gov/idmws/search/fercgensearch.asp*) by querying the docket number.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: April 27, 2023.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2023–09385 Filed 5–2–23; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2790–076]

Boott Hydropower, LLC; Notice of Application Accepted for Filing and Soliciting Comments, Motions To Intervene, and Protests

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection:

a. *Application Type:* Non-capacity Amendment of License.

b. *Project No:* 2790–076.

c. *Date Filed:* April 21, 2023.[1]

d. *Applicant:* Boott Hydropower, LLC (licensee).

e. *Name of Project:* Lowell Hydroelectric Project.

f. *Location:* The project is located on the Merrimack River in the City of Lowell in Middlesex County, Massachusetts.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791a–825r.

h. *Applicant Contact:* Kevin Webb, Hydro Licensing Manager, 670 N Commercial Street, Suite 204, Manchester, NH 03101, (978) 935–6039, *kwebb@patriothydro.com* and Jim Gibson, Vice-President, 1304 Buckley Road, Syracuse, NY 13212, (315) 414–2202, *Jim.Gibson@hdrinc.com.*

i. *FERC Contact:* Jeremy Jessup, (202) 502–6779, *Jeremy.Jessup@ferc.gov.*

j. *Deadline for filing comments, motions to intervene, and protests:* May 30, 2023.

The Commission strongly encourages electronic filing. Please file comments, motions to intervene, and protests using the Commission's eFiling system at *http://www.ferc.gov/docs-filing/efiling.asp.* Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at *http://www.ferc.gov/docs-filing/ecomment.asp.* You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov,* (866) 208–3676 (toll free), or (202) 502–8659 (TTY). In lieu of electronic filing, you may submit a paper copy. Submissions sent via the U.S. Postal Service must be addressed to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Room 1A, Washington, DC 20426. Submissions sent via any other carrier

[1] The April 21, 2023 filing supersedes the May 20, 2022, July 7, 2022, and March 10, 2023 filings.

must be addressed to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852. The first page of any filing should include the docket number P–2790–076. Comments emailed to Commission staff are not considered part of the Commission record.

The Commission's Rules of Practice and Procedure require all intervenors filing documents with the Commission to serve a copy of that document on each person whose name appears on the official service list for the project. Further, if an intervenor files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency.

k. *Description of Request:* The licensee proposes to formally designate the project's current operations as run-of-river operations through revising Article 37 of the license. The licensee explains that the request is in support of renewable energy initiatives applicable to the project only if it is designated as operating in a run-of-river mode. Given the operational limits of the project's existing license, which equates to no useable storage capacity within the project's impoundment, the licensee currently operates the project in a run-of-river mode. The licensee is not proposing any changes to project facilities, existing operations, or the existing project boundary.

l. *Locations of the Application:* This filing may be viewed on the Commission's website at *http://www.ferc.gov* using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. You may also register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be notified via email of new filings and issuances related to this or other pending projects. For assistance, call 1–866–208–3676 or email *FERCOnlineSupport@ferc.gov,* for TTY, call (202) 502–8659. Agencies may obtain copies of the application directly from the applicant.

m. Individuals desiring to be included on the Commission's mailing list should so indicate by writing to the Secretary of the Commission.

n. *Comments, Protests, or Motions to Intervene:* Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, .214, respectively. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

o. *Filing and Service of Documents:* Any filing must (1) bear in all capital letters the title ''COMMENTS'', ''PROTEST'', or ''MOTION TO INTERVENE'' as applicable; (2) set forth in the heading the name of the applicant and the project number of the application to which the filing responds; (3) furnish the name, address, and telephone number of the person commenting, protesting or intervening; and (4) otherwise comply with the requirements of 18 CFR 385.2001 through 385.2005. All comments, motions to intervene, or protests must set forth their evidentiary basis. Any filing made by an intervenor must be accompanied by proof of service on all persons listed in the service list prepared by the Commission in this proceeding, in accordance with 18 CFR 385.2010.

Dated: April 27, 2023.

Kimberly D. Bose,

Secretary.

[FR Doc. 2023–09375 Filed 5–2–23; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric corporate filings:

Docket Numbers: EC23–78–000.

Applicants: Casa Mesa Wind, LLC, Chaves County Solar, LLC, Langdon Renewables, LLC, Live Oak Solar, LLC, New Mexico Wind, LLC, NextEra Energy Montezuma II Wind, LLC, River Bend Solar, LLC, NEP US SellCo, LLC, NEP US SellCo II, LLC, NextEra Energy Partners Acquisitions, LLC.

Description: Joint Application for Authorization Under Section 203 of the Federal Power Act of Casa Mesa Wind, LLC, et al.

Filed Date: 4/25/23.

Accession Number: 20230425–5335.

Comment Date: 5 p.m. ET 5/16/23.

Docket Numbers: EC23–79–000.

Applicants: Newark Energy Center LLC.

Description: Joint Application for Authorization Under Section 203 of the Federal Power Act of Newark Energy Center, LLC, et al.

Filed Date: 4/27/23.

Accession Number: 20230427–5243.

Comment Date: 5 p.m. ET 5/18/23.

Take notice that the Commission received the following exempt wholesale generator filings:

Docket Numbers: EG23–136–000.

Applicants: Elawan Pitts Dudik Solar, LLC.

Description: Elawan Pitts Dudik Solar, LLC. submits Notice of Self-Certification of Exempt Wholesale Generator Status.

Filed Date: 4/26/23.

Accession Number: 20230426–5302.

Comment Date: 5 p.m. ET 5/17/23.

Docket Numbers: EG23–137–000.

Applicants: Holtville BESS, LLC.

Description: Holtville BESS, LLC submits Notice of Self-Certification of Exempt Wholesale Generator Status.

Filed Date: 4/26/23.

Accession Number: 20230426–5307.

Comment Date: 5 p.m. ET 5/17/23.

Docket Numbers: EG23–138–000.

Applicants: Elawan Dileo Solar, LLC.

Description: Elawan Dileo Solar, LLC submits Notice of Self-Certification of Exempt Wholesale Generator Status.

Filed Date: 4/26/23.

Accession Number: 20230426–5308.

Comment Date: 5 p.m. ET 5/17/23.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER10–1819–036; ER10–1817–027; ER10–1818–034; ER10–1820–039.

Applicants: Northern States Power Company, a Wisconsin corporation, Public Service Company of Colorado, Southwestern Public Service Company, Northern States Power Company, a Minnesota corporation.

Description: Notice of Change in Status of Northern States Power Company, a Minnesota corporation, et al.

Filed Date: 4/26/23.

Accession Number: 20230426–5318.

Comment Date: 5 p.m. ET 5/17/23.

Docket Numbers: ER18–1639–023.

Applicants: Constellation Mystic Power, LLC.

Description: Compliance filing: Compliance Filing on Remand Order to be effective 6/1/2022.

Filed Date: 4/27/23.

Accession Number: 20230427–5311.

Comment Date: 5 p.m. ET 5/18/23.

Docket Numbers: ER23–982–001.

Applicants: CPV Three Rivers, LLC.

Description: Compliance filing: Reactive Service Rate Schedule Compliance Filing to be effective 4/1/2023.

Filed Date: 4/27/23.
Accession Number: 20230427–5246.
Comment Date: 5 p.m. ET 5/18/23.
Docket Numbers: ER23–1221–001.
Applicants: Duquesne Light Company, PJM Interconnection, L.L.C.
Description: Tariff Amendment: Duquesne Light Company submits tariff filing per 35.17(b): Amendment Duquesne re Beaver Valley Deactivation Trans Proj ER23–1221 to be effective 12/31/9998.
Filed Date: 4/27/23.
Accession Number: 20230427–5216.
Comment Date: 5 p.m. ET 5/18/23.
Docket Numbers: ER23–1222–001.
Applicants: Duquesne Light Company, PJM Interconnection, L.L.C.
Description: Tariff Amendment: Duquesne Light Company submits tariff filing per 35.17(b): Amendment Duquesne re Dravosburg-Elrama Exp Project ER23–1222 to be effective 12/31/9998.
Filed Date: 4/27/23.
Accession Number: 20230427–5220.
Comment Date: 5 p.m. ET 5/18/23.
Docket Numbers: ER23–1241–001; ER23–1517–001.
Applicants: IP Oberon II, LLC, IP Oberon, LLC.
Description: Supplement to April 13, 2023 IP Oberon, LLC et al. tariff filings.
Filed Date: 4/25/23.
Accession Number: 20230425–5341.
Comment Date: 5 p.m. ET 5/4/23.
Docket Numbers: ER23–1265–001.
Applicants: PJM Interconnection, L.L.C.
Description: Tariff Amendment: Amendment to GDECS Phase 7—Docket No. ER23–1265–000 to be effective 5/8/2023.
Filed Date: 4/27/23.
Accession Number: 20230427–5291.
Comment Date: 5 p.m. ET 5/18/23.
Docket Numbers: ER23–1721–000.
Applicants: Duke Energy Florida, LLC.
Description: § 205(d) Rate Filing: Annual Filing of Cost Factor Updates—2023 to be effective 5/1/2023.
Filed Date: 4/27/23.
Accession Number: 20230427–5004.
Comment Date: 5 p.m. ET 5/18/23.
Docket Numbers: ER23–1722–000.
Applicants: PJM Interconnection, L.L.C.
Description: § 205(d) Rate Filing: ISA, Original SA No. 6870; Queue No. AD1–074/AD1–075/AD1–076 to be effective 3/30/2023.
Filed Date: 4/27/23.
Accession Number: 20230427–5070.
Comment Date: 5 p.m. ET 5/18/23.
Docket Numbers: ER23–1723–000.
Applicants: PacifiCorp.
Description: Notice of Termination of Service Agreement No. 8 under PacifiCorp's FERC Electric Tariff Volume No. 6.
Filed Date: 4/25/23.
Accession Number: 20230425–5342.
Comment Date: 5 p.m. ET 5/16/23.
Docket Numbers: ER23–1724–000.
Applicants: Midcontinent Independent System Operator, Inc., Ameren Transmission Company of Illinois.
Description: § 205(d) Rate Filing: Midcontinent Independent System Operator, Inc. submits tariff filing per 35.13(a)(2)(iii: 2023–04–27_SA 4045 ATXI-Sikeston Construction Agreement to be effective 6/27/2023.
Filed Date: 4/27/23.
Accession Number: 20230427–5089.
Comment Date: 5 p.m. ET 5/18/23.
Docket Numbers: ER23–1726–000.
Applicants: Southern California Edison Company.
Description: § 205(d) Rate Filing: UFA, Rough Hat 2 (Q1799–TOT979/SA299) to be effective 4/28/2023.
Filed Date: 4/27/23.
Accession Number: 20230427–5113.
Comment Date: 5 p.m. ET 5/18/23.
Docket Numbers: ER23–1727–000.
Applicants: Southern California Edison Company.
Description: § 205(d) Rate Filing: UFA, Rough Hat Hybrid Solar (Q1650–TOT949/SA298) to be effective 4/28/2023.
Filed Date: 4/27/23.
Accession Number: 20230427–5116.
Comment Date: 5 p.m. ET 5/18/23.
Docket Numbers: ER23–1728–000.
Applicants: Midcontinent Independent System Operator, Inc.
Description: § 205(d) Rate Filing: 2023–04–27_Attachment X Continuous Improvement filing to be effective 6/27/2023.
Filed Date: 4/27/23.
Accession Number: 20230427–5148.
Comment Date: 5 p.m. ET 5/18/23.
Docket Numbers: ER23–1729–000.
Applicants: Alabama Power Company, Georgia Power Company, Mississippi Power Company.
Description: § 205(d) Rate Filing: Alabama Power Company submits tariff filing per 35.13(a)(2)(iii: Tri-State II Solar Project (Solar & Battery) LGIA Filing to be effective 4/18/2023.
Filed Date: 4/27/23.
Accession Number: 20230427–5199.
Comment Date: 5 p.m. ET 5/18/23.
Docket Numbers: ER23–1730–000.
Applicants: Pacific Gas and Electric Company.
Description: § 205(d) Rate Filing: Q1 2023 Quarterly Filing of City and County of San Francisco's WDT SA (SA 275) to be effective 3/31/2023.
Filed Date: 4/27/23.
Accession Number: 20230427–5221.
Comment Date: 5 p.m. ET 5/18/23.
Docket Numbers: ER23–1731–000.
Applicants: GSG 6, LLC.
Description: § 205(d) Rate Filing: Assignment, Co-Tenancy and Shared Facilities Agreement with Waivers to be effective 4/28/2023.
Filed Date: 4/27/23.
Accession Number: 20230427–5223.
Comment Date: 5 p.m. ET 5/18/23.
Docket Numbers: ER23–1732–000.
Applicants: Shady Oaks Wind 2, LLC.
Description: Baseline eTariff Filing: Certificate of Concurrence & Request for Waiver & Blanket Approval to be effective 4/28/2023.
Filed Date: 4/27/23.
Accession Number: 20230427–5233.
Comment Date: 5 p.m. ET 5/18/23.
Docket Numbers: ER23–1733–000.
Applicants: SFE Energy Massachusetts, Inc.
Description: Baseline eTariff Filing: Market-Based Rate Application to be effective 6/27/2023.
Filed Date: 4/27/23.
Accession Number: 20230427–5259.
Comment Date: 5 p.m. ET 5/18/23.
Docket Numbers: ER23–1734–000.
Applicants: SFE Energy, Inc.
Description: Baseline eTariff Filing: Market-Based Rate Application to be effective 6/27/2023.
Filed Date: 4/27/23.
Accession Number: 20230427–5267.
Comment Date: 5 p.m. ET 5/18/23.

Take notice that the Commission received the following public utility holding company filings:

Docket Numbers: PH23–12–000.
Applicants: Enbridge Inc.
Description: Enbridge Inc. submits FERC–65A Notice of Change in Fact to Waiver Notification.
Filed Date: 4/26/23.
Accession Number: 20230426–5322.
Comment Date: 5 p.m. ET 5/17/23.

The filings are accessible in the Commission's eLibrary system (*https://elibrary.ferc.gov/idmws/search/fercgensearch.asp*) by querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing

requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: April 27, 2023.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2023–09383 Filed 5–2–23; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2022–0223; FRL–10923–01–OCSPP]

Chlorpyrifos; Notice of Intent To Cancel Certain Pesticide Registrations and Amend Registrations To Terminate Certain Uses

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In accordance with the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), EPA is issuing a notice of receipt of requests by registrants to voluntarily cancel their registrations of certain products containing the pesticide chlorpyrifos, or to amend their chlorpyrifos registrations to terminate one or more uses. EPA intends to grant these requests at the close of the comment period for this announcement, unless the Agency receives substantive comments within the comment period that would merit its further review, or the registrant withdraws their request. If these requests are granted, any sale, distribution, or use of products listed in this notice will be permitted after the registrations have been cancelled or the uses terminated only if such sale, distribution, or use is consistent with the terms as described in the final order.

DATES: Comments must be received on or before June 2, 2023, whichever occurs later.

ADDRESSES: The docket for this action, identified under docket identification (ID) number EPA–HQ–OPP–2022–0223, is available online at *https://www.regulations.gov.* Additional instructions on visiting the docket, along with more information about dockets generally, is available at *https://www.epa.gov/dockets.* For the latest status information on EPA/DC services and docket access, visit *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Patricia Biggio, Pesticide Re-Evaluation Division (7508M), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; telephone number: (202) 566–0700; email address: *OPPChlorpyrifosInquiries@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

This action is directed to the public in general and may be of interest to a wide range of stakeholders including environmental, human health, and agricultural advocates; the chemical industry; pesticide users; and members of the public interested in the sale, distribution, or use of pesticides. Since others also may be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action.

B. What should I consider as I prepare my comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through *https://www.regulations.gov* or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD–ROM that you mail to EPA, mark the outside of the disk or CD–ROM as CBI and then identify electronically within the disk or CD–ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at *https://www.epa.gov/dockets/where-send-comments-epa-dockets.*

II. What action is the Agency taking?

This notice announces receipt by the Agency of requests from registrants to cancel certain pesticide product registrations or terminate certain uses of product registrations. These affected registrations are listed in sequence by registration number in Tables 1 and 2 of this Unit. Table 3 of this Unit includes the names and addresses of record for the registrants of the products listed in Tables 1 and 2 of this Unit, in sequence by EPA company number. This number corresponds to the first part of the EPA registration numbers of the products listed in Tables 1 and 2 of this Unit.

Unless the Agency determines that there are substantive comments that warrant further review of the requests or the registrants withdraw their requests, EPA intends to issue a final order in the **Federal Register** cancelling registrations and terminating uses as requested.

TABLE 1—CHLORPYRIFOS REGISTRATIONS WITH PENDING REQUESTS FOR TERMINATION OF SPECIFIC USES

Registration No.	Company No.	Product name	Uses to be terminated
11678–58	11678	Pyrinex Chlorpyrifos Insecticide.	Food processing plants.
66222–19	66222	Chlorpyrifos 4E AG	Food processing and food manufacturing sites.
66222–233	66222	Vulcan	Food processing and food manufacturing sites.

TABLE 1—CHLORPYRIFOS REGISTRATIONS WITH PENDING REQUESTS FOR TERMINATION OF SPECIFIC USES—Continued

Registration No.	Company No.	Product name	Uses to be terminated
85724–10	85724	Akofos 48 EC	*Food uses:* Alfalfa, apple (including apple tree trunk), asparagus, cherries, citrus fruits (calamondin, chironja, citrus citron, citrus hybrids, grapefruit, kumquat, lemons, limes, mandarin (tangerine), oranges, pummelo, Satsuma mandarin, tangelo, tangor, and other citrus fruit, small transplanted grapefruit, orange, and other citrus trees), corn, cotton, cranberries, figs, grapes, legume vegetables (legume vegetables including adzuki bean, asparagus bean, bean, blackeyed pea, broad bean (dry and succulent), catjang, chickpea, Chinese longbean, cowpea, crowder pea, dwarf pea, edible pod pea, English pea, fava bean, field bean, field pea, garbanzo bean, garden pea, grain lupin, green pea, guar, hyacinth bean, jackbean, kidney bean, lablab bean, lentil, lima bean, moth bean, mung bean, navy bean, pea, pigeon pea, pinto bean, rice bean, runner bean, snap bean, snow pea, English pea, southern pea, sugar snap pea, sweet lupin, sword bean, tepary bean, urd bean, wax bean, white lupin, white sweet lupin, yardlong bean), mint (peppermint and spearmint), nectarines, peaches, almonds, onions, peanuts, pears, sorghum grain (milo), soybeans, strawberries, sugar beets, sunflowers, sweet potatoes, tree fruits (apples, pears, plums, prunes, peaches, nectarines), tree nuts (almonds, filberts, pecans, walnuts), vegetables (rutabaga, broccoli, Brussels sprout, cabbage, cauliflower, Chinese cabbage, collards, kale, kohlrabi, turnips, radishes), wheat, and food processing plants. *Nonfood uses:* Tobacco.

TABLE 2—CHLORPYRIFOS PRODUCT REGISTRATIONS WITH PENDING REQUESTS FOR CANCELLATION

EPA registration No.	Product name	Company	Active ingredients
228–620	Nufarm Chlorpyrifos SPC 2.32% G Insecticide	NuFarm Americas, Inc	Chlorpyrifos.
228–621	Nufarm Chlorpyrifos SPC 1.0% MCB Insecticide	NuFarm Americas, Inc	Chlorpyrifos.
228–624	Nufarm Chlorpyrifos SPC 4 Insecticide	NuFarm Americas, Inc	Chlorpyrifos.
228–625	Nufarm Chlorpyrifos SPC 2 Insecticide	NuFarm Americas, Inc	Chlorpyrifos.
53883–394	CSI 16–150 Chlorpyrifos 42	Control Solutions, Inc	Chlorpyrifos.
53883–407	CSI 16–149 Chlorpyrifos 20	Control Solutions, Inc	Chlorpyrifos.
84229–25	Chlorpyrifos 4E AG	Tide International USA, Inc	Chlorpyrifos.
84229–26	Chlorpyrifos 15G	Tide International USA, Inc	Chlorpyrifos.

TABLE 3—REGISTRANTS REQUESTING VOLUNTARY CANCELLATION OR TERMINATION OF USES

EPA company No.	Company name and address
228	NuFarm, 4020 Aerial Center Pkwy., Ste. 101, Morrisville, NC 27560.
11678	ADAMA US, 3120 Highwoods Boulevard, Ste. 100, Raleigh, NC 27604.
53883	Control Solutions, Inc., 5903 Genoa Red Bluffs Rd., Pasadena, TX 77507.
66222	ADAMA US, 3120 Highwoods Boulevard, Ste. 100, Raleigh, NC 27604.
84229	Tide International USA, Inc., Agent Name: Pyxis Regulatory Consulting, Inc., 4110 136th Street Ct. NW, Gig Harbor, WA 98332.
85724	AAKO B.V., c/o Ceres International, LLC, 1087 Heartsease Dr., West Chester, PA 19382.

III. What is the Agency's authority for taking these actions?

Section 6(f)(1) of FIFRA (7 U.S.C. 136d(f)(1)) provides that a registrant of a pesticide product may at any time request that any of its pesticide registrations be cancelled or amended to terminate one or more registered uses. FIFRA further provides that, before acting on the request, EPA must publish a notice of receipt of any such request in the **Federal Register**.

Section 6(f)(1)(B) of FIFRA (7 U.S.C. 136d(f)(1)(B)) requires that before acting on a request for voluntary cancellation, EPA must provide a 30-day public comment period on the request for voluntary cancellation or use termination. In addition, FIFRA section 6(f)(1)(C) (7 U.S.C. 136d(f)(1)(C)) requires that EPA provide a 180-day comment period on a request for voluntary cancellation or termination of any minor agricultural use before granting the request, unless:

1. The registrant requests a waiver of the comment period, or

2. The EPA Administrator determines that continued use of the pesticide would pose an unreasonable adverse effect on the environment.

The registrants in Table 3 of Unit II have requested that EPA waive the 180-day comment period. Accordingly, EPA will provide a 30-day comment period on the proposed requests.

IV. Procedures for Withdrawal of Request

Registrants who choose to withdraw a request for cancellation or withdraw a request for a use termination should submit such withdrawal in writing to the person listed under **FOR FURTHER INFORMATION CONTACT**. If the products have been subject to a previous cancellation action, the effective date of cancellation and all other provisions of any earlier cancellation action are controlling.

V. Provisions for Disposition of Existing Stocks

Existing stocks are those stocks of registered pesticide products that are currently in the United States and that were packaged, labeled, and released for shipment prior to the effective date of the cancellation action.

If the requests for voluntary cancellation and amendments to terminate uses are granted, the Agency intends to publish a final cancellation order in the **Federal Register**. In any order issued in response to these requests for cancellation of product registrations and for amendments to terminate uses, EPA proposes to include the following provisions for the treatment of any existing stocks of the products listed in Tables 1 and 2 of Unit II.

All chlorpyrifos tolerances expired in the **Federal Register** on February 28, 2022 (87 FR 11222) (FRL–5993–05–OCSPP) and in the **Federal Register** on August 31, 2022 (86 FR 48315) (FRL–5993–04–OCSPP). Therefore, any food or animal feed treated with chlorpyrifos after February 28, 2022, is considered adulterated and cannot be delivered into interstate commerce. Consequently, EPA plans to prohibit existing stocks of chlorpyrifos products identified in Tables 1 and 2 of Unit 2 for food uses. Use of the products identified in Tables 1 and 2 of Unit II are permitted on non-food use sites, as long as such use is consistent with the label. EPA proposes prohibiting all sale and distribution of existing stocks of the chlorpyrifos products identified in Tables 1 and 2 of Unit II, except for export consistent with FIFRA section 17 (*7 U.S.C. 136o*) or for proper disposal in accordance with state regulations. In addition, EPA is working with Control Solutions, Inc. to develop plans for the return of existing stocks of their chlorpyrifos products. EPA will include in the final cancellation order terms allowing for distribution consistent with that return program.

List of Subjects in 40 CFR Part 180

Environmental protection, Pesticide and pests, Cancellation.

Dated: April 28, 2023.

Mary Elissa Reaves,

Director, Pesticide Re-Evaluation Division, Office of Pesticide Programs.

[FR Doc. 2023–09393 Filed 5–2–23; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–10926–01–OA]

Public Meeting of the Science Advisory Board CASTNet Review Panel

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) Science Advisory Board (SAB) Staff Office a public meeting of the Science Advisory Board CASTNet Review Panel. The purpose of the public meeting is to receive briefings from EPA on the CASTNet monitoring network, hear public comments, ask any clarifying questions, and deliberate publicly on charge questions regarding the Panel's review of the network and a report from EPA's Office of Air and Radiation. Additional information, materials, background, meeting agendas, and activities will be posted on SAB's website at: *https://sab.epa.gov.*

DATES:

Public Meetings: The Science Advisory Board CASTNet Review Panel will hold a three-day meeting on the following dates. All times listed are in eastern daylight time (EDT).

1. Wednesday, May 24, 2023, from 12:00 p.m. to 5:00 p.m.
2. Thursday, May 25, 2023, from 8:00 a.m. to 5:00 p.m.
3. Friday, May 26, 2023, from 8:00 a.m. to 12:00 p.m.

Public Comments: See the section titled ''Procedures for Providing Public Input'' under **SUPPLEMENTARY INFORMATION**

ADDRESSES: The public meeting will be held at AC Hotel by Marriott Bethesda Downtown at 4646 Montgomery Ave., Bethesda, MD 20814. Please refer to the SAB website at *https://sab.epa.gov* for details on how to access the meeting, including requesting teleconference or obtaining online simulcasting information.

FOR FURTHER INFORMATION CONTACT: Any member of the public who wants further information concerning this notice may contact Dr. Bryan Bloomer, Designated Federal Officer (DFO), via telephone (202) 564–4222, or email at *bloomer.bryan@epa.gov.* General information about the SAB, as well as any updates concerning the meetings announced in this notice can be found on the SAB website at *https://sab.epa.gov.*

SUPPLEMENTARY INFORMATION:

Background: The SAB was established pursuant to the Environmental Research, Development, and Demonstration Authorization Act (ERDDAA), codified at 42 U.S.C. 4365, to provide independent scientific and technical advice to the EPA Administrator on the scientific and technical basis for agency positions and regulations. The SAB is a Federal Advisory Committee chartered under the Federal Advisory Committee Act (FACA), 5 U.S.C., App. 2. The SAB will comply with the provisions of FACA and all appropriate SAB Staff Office procedural policies. Pursuant to FACA and EPA policy, notice is hereby given that the Science Advisory Board CASTNet Review Panel will hold a public meeting to receive a presentation of review materials, on the charge questions, to receive public comments, and to deliberate upon the charge questions regarding the CASTNet monitoring network.

Availability of Meeting Materials: All meeting materials, including the agenda, will be available on the SAB web page at *https://sab.epa.gov.*

Procedures for Providing Public Input: Public comment for consideration by EPA's federal advisory committees and panels has a different purpose from public comment provided to EPA program offices. Therefore, the process for submitting comments to a federal advisory committee is different from the process used to submit comments to an EPA program office. Federal advisory committees and panels, including scientific advisory committees, provide independent advice to the EPA. Members of the public can submit relevant comments pertaining to the committee's charge or meeting materials. Input from the public to the SAB will have the most impact if it provides specific scientific or technical information or analysis for the SAB to consider or if it relates to the clarity or accuracy of the technical information. Members of the public wishing to provide comment should follow the instruction below to submit comments.

Oral Statements: In general, individuals or groups requesting an oral presentation at an in-person meeting will be limited to five minutes. Each person making an oral statement should consider providing written comments as well as their oral statement so that the points presented orally can be expanded upon in writing. Persons interested in providing oral statements should contact the DFO, in writing (preferably via email) at the contact information noted above by May 19, 2023, to be placed on the list of registered speakers and to have the written comments posted publicly for consideration on the SAB website.

Written Statements: Written statements will be accepted throughout the advisory process; however, for timely consideration by SAB members, statements should be submitted to the DFO by May 19, 2023. Written statements should be supplied to the DFO at the contact information above. Submitters are requested to provide an unsigned version of each document because the SAB Staff Office does not publish documents with signatures on its websites. Members of the public should be aware that their personal contact information, if included in any written comments, may be posted to the SAB website. Copyrighted material will not be posted without explicit permission of the copyright holder and should be indicated as such at the time of submission.

Accessibility: For information on access or services for individuals with disabilities, please contact the DFO, at the contact information noted above, preferably at least ten days prior to the meeting, to give the EPA as much time as possible to process your request.

V. Khanna Johnston,

Deputy Director, Science Advisory Board Staff Office.

[FR Doc. 2023–09316 Filed 5–2–23; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–XXXX; FR ID 139745]

Information Collection Being Reviewed by the Federal Communications Commission

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act (PRA) of 1995, the Federal Communications Commission (FCC or the Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collection. Comments are requested concerning: whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees. The FCC may not conduct or sponsor a collection of information unless it displays a currently valid control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid Office of Management and Budget (OMB) control number.

DATES: Written PRA comments should be submitted on or before July 3, 2023. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Nicole Ongele, FCC, via email *PRA@fcc.gov* and to *nicole.ongele@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Nicole Ongele, (202) 418–2991.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–XXXX.

Title: Incarcerated People's Communications Services (IPCS) 2023 Mandatory Data Collection, WC Docket Nos. 23–62, 12–375, FCC 23–19.

Form Number(s): FCC Form 2303(a) and FCC Form 2303(b).

Type of Review: New collection.

Respondents: Business or other for-profit.

Number of Respondents and Responses: 30 respondents; 30 responses.

Estimated Time per Response: 230 hours.

Frequency of Response: One-time reporting requirement.

Obligation to Respond: Required to obtain or retain benefits. Statutory authority for this collection of information is contained in sections 1, 2, 4(i)–(j), 5(c), 201(b), 218, 220, 225, 255, 276, 403, and 716 of the Communications Act of 1934, as amended, 47 U.S.C. 151, 152,154(i)–(j), 155(c), 201(b), 218, 220, 225, 255, 276, 403, and 617, and the Martha Wright-Reed Act, Public Law 117–338, 136 Stat. 6156 (2022).

Total Annual Burden: 6,900 hours.

Total Annual Cost: No cost.

Needs and Uses: On March 17, 2023, the Commission released the *Incarcerated People's Communications Services; Implementation of the Martha Wright-Reed Act; Rates for Interstate Inmate Calling Services,* WC Docket Nos. 23–62, 12–375, Notice of Proposed Rulemaking and Order, FCC 23–19, 88 FR 20804 (Notice of Proposed Rule Making) and 88 FR 19001 (Order), in which it began the process of implementing the Martha Wright-Reed Just and Reasonable Communications Act of 2022, Public Law 117–338, 136 Stat. 6156 (the Act). The Act expands the Commission's statutory authority to encompass ''any audio or video communications service used by inmates . . . regardless of technology used.'' The Act also amends section 2(b) of the Communications Act of 1934, as amended to make clear that the Commission's jurisdiction extends to intrastate as well as interstate and international communications services used by incarcerated people.

The Act directs the Commission to ''promulgate any regulations necessary to implement'' the statutory provisions, including its mandate that the Commission establish a ''compensation plan'' ensuring that all rates and charges for IPCS ''are just and reasonable,'' not earlier than 18 months and not later than 24 months after its January 5, 2023 enactment. The Act also requires the Commission to consider, as part of its implementation, the costs of ''necessary'' safety and security measures, as well as ''differences in costs'' based on facility size, or ''other characteristics.'' It allows the Commission to ''use industry-wide average costs of telephone service and advanced communications services and the average costs of service of a communications service provider'' in determining just and reasonable rates.

To ensure that it has the data needed to meet its substantive and procedural responsibilities under the Act, the Commission delegated to the Wireline Competition Bureau (WCB) and the Office of Economics and Analytics (OEA) (collectively, WCB/OEA) authority to ''update and restructure'' the Commission's latest mandatory data collection, the Third Mandatory Data Collection (OMB Control No. 3060–1300, Inmate Calling Services (ICS) 2022 One-Time Mandatory Data Collection), ''as appropriate in light of the requirements of the new statute.'' This delegation requires WCB/OEA to collect ''data on all incarcerated people's communications services from all providers of those services now subject to'' the Commission's expanded ratemaking authority, including, but not limited to, requesting ''more recent data for additional years not covered by the most recent data collection.''

Pursuant to their delegated authority, WCB/OEA drafted proposed

instructions, a template, and a certification form for the proposed 2023 Mandatory Data Collection. See 2023 IPCS Mandatory Data Collection—Proposed Instructions, available for download at *https://www.fcc.gov/document/2023-ipcs-mandatory-data-collection-proposed-instructions.* Under WCB/OEA's proposals, IPCS providers would be required to submit the required data using a reporting template that would be filed through the Commission's electronic comment filing system. The proposed template consists of a Word document (Appendix A to the instructions) for responses requiring narrative information and Excel spreadsheets (Appendix B to the instructions) for responses that require specific numbers or information. IPCS providers would also be required to submit an audited financial statement or report for 2022, and a signed certification of truthfulness, accuracy, and completeness. The instructions, template, and certification form would simplify compliance with, and reduce the burden of, this data collection. These proposed documents will be submitted to the Office of Management and Budget as FCC Form 2303(a) and FCC Form 2303(b).

On April 28, 2023, WCB/OEA released a Public Notice seeking comment on all aspects of the proposed instructions, template, and certification form. See Proposed 2023 IPCS Mandatory Data Collection Public Notice, available for download at *https://www.fcc.gov/document/proposed-2023-ipcs-mandatory-data-collection-public-notice.* WCB/OEA will consider comments submitted in response to both the Public Notice and this notice in finalizing the proposed data collection prior to submitting the documents to the Office of Management and Budget.

Federal Communications Commission.

Katura Jackson,

Federal Register Liaison Officer.

[FR Doc. 2023–09501 Filed 5–2–23; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–XXXX; FR ID 138387]

Information Collection Requirement Being Submitted to the Office of Management and Budget for Emergency Review and Approval

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act (PRA) of 1995, the Federal Communications Commission (Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collection. Comments are requested concerning: whether the collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees. The Commission may not conduct or sponsor a collection of information unless it displays a currently valid control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid Office of Management and Budget (OMB) control number.

DATES: Written PRA comments should be submitted on or before June 2, 2023.

ADDRESSES: Comments should be sent to *http://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. Your comment must be submitted into *www.reginfo.gov* per the above instructions for it to be considered. In addition to submitting in *www.reginfo.gov* also send a copy of your comment on the information collection to Cathy Williams, FCC, via email to *PRA@fcc.gov* and to *Cathy.Williams@fcc.gov.* Include in the comments the OMB control number as shown in the **SUPPLEMENTARY INFORMATION** below.

FOR FURTHER INFORMATION CONTACT: For additional information or copies of the information collection, contact Cathy Williams at (202) 418–2918.

SUPPLEMENTARY INFORMATION: As part of its continuing effort to reduce paperwork burdens, as required by the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3520), the Commission invites the general public and other Federal Agencies to take this opportunity to comment on the following information collection. Comments are requested concerning: (a) whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's burden estimates; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology. Pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, *see* 44 U.S.C. 3506(c)(4), the Commission seeks specific comment on how it might ''further reduce the information collection burden for small business concerns with fewer than 25 employees.''

The Commission is requesting emergency OMB processing of the information collection requirement(s) contained in this notice and has requested OMB approval no later than 37 days after the collection is received at OMB. To view a copy of this information collection request (ICR) submitted to OMB: (1) go to the web page *http://www.reginfo.gov/public/do/PRAMain,* (2) look for the section of the web page called ''Currently Under Review,'' (3) click on the downward-pointing arrow in the ''Select Agency'' box below the ''Currently Under Review'' heading, (4) select ''Federal Communications Commission'' from the list of agencies presented in the ''Select Agency'' box, (5) click the ''Submit'' button to the right of the ''Select Agency'' box, (6) when the list of Commission ICRs currently under review appears, look for the Title of this ICR and then click on the ICR Reference Number. A copy of the Commission's submission to OMB will be displayed.

OMB Control No.: 3060–xxxx.

Title: Reporting On Foreign Ownership of International Section 214 Authorization Holders.

Form Number: N/A.

Type of Review: New information collection.

Respondents: Business or other for-profit.

Number of Respondents: 1,500 respondents; 1,500 responses.

Estimated Time per Response: 6 hours.

Frequency of Response: One time reporting requirement.

Obligation To Respond: Required to obtain or retain benefits. Statutory authority for this information collection is contained in sections 218, 219, and

403 of the Communications Act of 1934, as amended, 47 U.S.C. 218, 219, and 403.

Total Annual Burden: 4,500 hours.

Annual Cost Burden: $1,350,000.

Needs and Uses: The Federal Communications Commission (Commission) is requesting that the Office of Management and Budget (OMB) to approve OMB Control No. 3060–xxxx—Reporting On Foreign Ownership of International Section 214 Authorization Holders. The Commission established a new one-time information collection in the *Review of International Section 214 Authorizations to Assess Evolving National Security, Law Enforcement, Foreign Policy, and Trade Policy Risks, IB Docket No. 23–119; Amendment of the Schedule of Application Fees Set Forth in Sections 1.1102 through 1.1109 of the Commission's Rules, MD Docket No. 23–134,* Order and Notice of Proposed Rulemaking (*Evolving Risks Order and Notice*), FCC 23–28. Each international section 214 authorization holder is required to identify its 10% or greater direct or indirect foreign interest holders (reportable foreign ownership) as of thirty (30) days prior to the filing deadline. Additionally, the filer will be required to certify as to the accuracy of the information provided. The filer must submit its information based on the categories below.

(1) Reportable Foreign.

(2) Ownership—Foreign Adversary—China (including Hong Kong), Cuba, Iran, North Korea, Russia, Maduro Regime. Where there are interest holders that are entities and individuals that are a government organization or citizen of a ''foreign adversary'' country, an authorization holder must identify its 10% or greater direct or indirect foreign interest holders, including any 10% or greater direct or indirect foreign interest holders outside the foregoing ''foreign adversary'' countries. A ''foreign adversary'' country is defined in the Department of Commerce's rule, 15 CFR 7.4. The authorization holder must:

- identify each interest holder and the foreign country or countries, including countries that are not foreign adversary countries;
- disclose whether any interest holder has dual or more citizenships and identify all countries where citizenship is held; and
- certify to the truth and accuracy of all information.

(3) Reportable Foreign Ownership—No Foreign Adversary. Where there are no interest holders that are entities or individuals that are a government organization or citizen of any foreign country that is a ''foreign adversary'' country defined in the Department of Commerce's rule, 15 CFR 7.4, an authorization holder must identify its 10% or greater direct or indirect foreign interest holders. The authorization holder must:

- identify each interest holder and the foreign country or countries;
- disclose whether any interest holder has dual or more citizenships and identify all the countries where citizenship is held; and
- certify to the truth and accuracy of all information.

(4) No Reportable Foreign Ownership. An authorization holder that has no reportable foreign ownership must certify to the truth and accuracy of this information.

Federal Communications Commission.

Marlene Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2023–09371 Filed 5–2–23; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–1256; FR ID 138984]

Information Collection Being Submitted for Review and Approval to Office of Management and Budget

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, as required by the Paperwork Reduction Act (PRA) of 1995, the Federal Communications Commission (FCC or the Commission) invites the general public and other Federal Agencies to take this opportunity to comment on the following information collection. Pursuant to the Small Business Paperwork Relief Act of 2002, the FCC seeks specific comment on how it might ''further reduce the information collection burden for small business concerns with fewer than 25 employees.'' The Commission may not conduct or sponsor a collection of information unless it displays a currently valid Office of Management and Budget (OMB) control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid OMB control number.

DATES: Written comments and recommendations for the proposed information collection should be submitted on or before June 2, 2023.

ADDRESSES: Comments should be sent to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. Your comment must be submitted into *www.reginfo.gov* per the above instructions for it to be considered. In addition to submitting in *www.reginfo.gov* also send a copy of your comment on the proposed information collection to Nicole Ongele, FCC, via email to *PRA@fcc.gov* and to *Nicole.Ongele@fcc.gov.* Include in the comments the OMB control number as shown in the **SUPPLEMENTARY INFORMATION** below.

FOR FURTHER INFORMATION CONTACT: For additional information or copies of the information collection, contact Nicole Ongele at (202) 418–2991. To view a copy of this information collection request (ICR) submitted to OMB: (1) go to the web page *http://www.reginfo.gov/public/do/PRAMain,* (2) look for the section of the web page called ''Currently Under Review,'' (3) click on the downward-pointing arrow in the ''Select Agency'' box below the ''Currently Under Review'' heading, (4) select ''Federal Communications Commission'' from the list of agencies presented in the ''Select Agency'' box, (5) click the ''Submit'' button to the right of the ''Select Agency'' box, (6) when the list of FCC ICRs currently under review appears, look for the Title of this ICR and then click on the ICR Reference Number. A copy of the FCC submission to OMB will be displayed.

SUPPLEMENTARY INFORMATION: As part of its continuing effort to reduce paperwork burdens, as required by the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3520), the FCC invited the general public and other Federal Agencies to take this opportunity to comment on the following information collection. Comments are requested concerning: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's burden estimates; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology. Pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, see 44 U.S.C. 3506(c)(4), the FCC seeks specific comment on how

it might ''further reduce the information collection burden for small business concerns with fewer than 25 employees.''

OMB Control Number: 3060–1256.

Title: Application for Connect America Fund Phase II and Rural Digital Opportunity Fund Auction Support.

Form Number: FCC Form 683.

Type of Review: Revision of a currently approved collection.

Respondents: Business or other for-profit entities, Not-for-profit institutions, and State, Local or Tribal governments.

Number of Respondents and Responses: 530 respondents and 930 responses.

Estimated Time per Response: 2–12 hours (on average).

Frequency of Response: Annual reporting requirements, on occasion reporting requirement.

Obligation to Respond: Required to obtain or retain benefits. Statutory authority for this information collection *47 U.S.C. 154, 214, 254* and *303(r)* of the Communications Act of 1934, as amended.

Total Annual Burden: 5,860 hours.

Total Annual Cost: No Cost.

Needs and Uses:

Connect America Fund Phase II Auction

The Commission is requesting the Office of Management and Budget (OMB) approval for this revised information collection. On November 18, 2011, the Commission released the *USF/ICC Transformation Order and Further Notice of Proposed Rulemaking,* WC Docket No. 10–90 et al., FCC 11–161 (*USF/ICC Transformation Order and/or FNPRM*), which comprehensively reformed and modernized the high-cost program within the universal service fund to focus support on networks capable of providing voice and broadband services. Among other things, the Commission created the Connect America Fund (CAF) and concluded that support in price cap areas would be provided through a combination of ''a new forward-looking model of the cost of constructing modern multi-purpose networks'' and a competitive bidding process (CAF Phase II auction or Auction 903). The Commission also sought comment in the accompanying *USF/ICC Transformation FNPRM* on proposed rules governing the CAF Phase II auction, including basic auction design and the application process.

In the CAF Phase II auction, service providers competed to receive support of up to $1.98 billion over 10 years to offer voice and broadband service in unserved high-cost areas. The information collection requirements reported under this collection are the result of several Commission decisions to implement the reform adopted in the *USF/ICC Transformation Order* and move forward with conducting the CAF Phase II auction. In the *April 2014 Connect America Order,* WC Docket No. 10–90 et al., FCC 14–54, the Commission adopted various rules regarding participation in the CAF Phase II auction, the term of support, and the eligible telecommunications carrier (ETC) designation process. In the *Phase II Auction Order,* WC Docket No. 10–90 et al., FCC 16–64, the Commission adopted rules to govern the CAF Phase II auction, including the adoption of a two-stage application process, which includes a pre-auction short-form application to be submitted by parties interested in bidding in the CAF Phase II auction and a post-auction long-form application that must be submitted by winning bidders seeking to become authorized to receive CAF Phase II auction support. The Commission concluded, based on its experience with auctions and consistent with the record, that this two-stage application process balances the need to collect information essential to conducting a successful auction and authorizing CAF Phase II support with administrative efficiency.

On January 30, 2018, the Commission adopted a public notice that established the final procedures for the CAF Phase II auction, including the long-form application disclosure and certification requirements for winning bidders seeking to become authorized to receive CAF Phase II auction support. *See Phase II Auction Procedures Public Notice,* WC Docket No. 17–182 et al., FCC 18–6. The Commission also adopted the *Phase II Auction Order on Reconsideration,* WC Docket No. 10–90 et al., FCC 18–5, which modified the Commission's letter of credit rules to provide some additional relief for CAF Phase II auction support recipients by reducing the costs of maintaining a letter of credit. On January 19, 2023, WCB released a public notice announcing that the Commission had concluded its review of CAF Phase II auction long-form applications. *See WCB Concludes CAF II Application Review, Long-Forms Made Public,* AU Docket No. 17–182 et al., DA 23–49.

The Commission proposes to eliminate the information collection requirements related to the CAF Phase II auction FCC Form 683 now that the Commission's review of CAF Phase II auction long-form applications has concluded. All other information collection requirements remain unchanged.

Rural Digital Opportunity Fund Auction

On February 7, 2020 the Commission released the *Rural Digital Opportunity Fund Order,* WC Docket Nos. 19–126, 10–90, FCC 20–5 which will commit up to $20.4 billion over the next decade to support up to gigabit speed broadband networks in rural America. The funding was allocated through a multi-round, reverse, descending clock auction that favored faster services with lower latency and encouraged intermodal competition in order to ensure that the greatest possible number of Americans will be connected to the best possible networks, all at a competitive cost.

To implement the Rural Digital Opportunity Fund auction (or Auction 904), the Commission adopted new rules for the Rural Digital Opportunity Fund auction, including the adoption of a two-stage application process. Like with the CAF Phase II auction, this process includes a pre-auction short-form application to be submitted by parties interested in bidding in the Rural Digital Opportunity Fund auction (FCC Form 183) and a post-auction long-form application that must be submitted by winning bidders (or their designees) seeking to become authorized to receive Rural Digital Opportunity Fund support (FCC Form 683). The Commission received approval for the short-form application (FCC Form 183) in a separate collection under the OMB control number 3060–1252.

This information collection includes the disclosures and certifications adopted by the Commission that must be made by winning bidders seeking to become authorized for Rural Digital Opportunity Fund support and the requirement that Rural Digital Opportunity Fund support recipients maintain a letter of credit. Any additional revisions or new collections for OMB review that address other reforms adopted in the Order will be submitted at a later date.

The Commission therefore proposes to revise this information collection to maintain these Rural Digital Opportunity Fund requirements.

Federal Communications Commission.

Marlene Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2023–09407 Filed 5–2–23; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–0920; FR ID 139313]

Information Collections Being Reviewed by the Federal Communications Commission

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act of 1995 (PRA), the Federal Communications Commission (FCC or Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collections. Comments are requested concerning: whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees. The FCC may not conduct or sponsor a collection of information unless it displays a currently valid Office of Management and Budget (OMB) control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid OMB control number.

DATES: Written PRA comments should be submitted on or before July 3, 2023. If you anticipate that you will be submitting comments but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Cathy Williams, FCC, via email to *PRA@fcc.gov* and to *Cathy.Williams@fcc.gov*.

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Cathy Williams at (202) 418–2918.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–0920.

Title: Form 2100, Schedule 318—Low Power FM Station Construction Permit Application; Report and Order in MM Docket No. 99–25 Creation of Low Power Radio Service; Sections 73.801, 73.807, 73.809, 73.810, 73.816, 73.827, 73.850, 73.865, 73.870, 73.871, 73.872, 73.877, 73.878, 73.318, 73.1030, 73.1207, 73.1212, 73.1300, 73.1350, 73.1610, 73.1620, 73.1750, 73.1943, 73.3525, 73.3550, 73.3598, 11.61(ii).

Form No.: Form 2100, Schedule 318.

Type of Review: Extension of a currently approved collection.

Respondents: Not-for-profit institutions; State, local or Tribal governments.

Number of Respondents and Responses: 24,606 respondents with multiple responses; 31,324 responses.

Estimated Time per Response: .0025–12 hours.

Frequency of Response: Recordkeeping requirement; On occasion reporting requirement; Monthly reporting requirement; Third party disclosure requirement.

Obligation To Respond: Required to obtain or retain benefits. The statutory authority for this collection of information is contained in sections 154(i), 303, 308 and 325(a) of the Communications Act of 1934, as amended.

Total Annual Burden: 52,889 hours.

Total Annual Costs: $1,229,370.

Needs and Uses: Form 2100, Schedule 318, Low Power FM (LPFM) Station Construction Permit Application (Schedule 318), is used to: (1) apply to construct a new Low Power FM (LPFM) broadcast station; (2) make changes to an authorized LPFM broadcast station; (3) amend a pending LPFM construction permit application; or (4) propose mandatory time-sharing.

Schedule 318's Online Notice (third party disclosure) Requirement: 47 CFR 73.3580, as amended in the Commission's 2020 Public Notice Second Report and Order, discussed below, requires local public notice of the filing of all applications to construct a new LPFM broadcast station. Notice is given by an applicant posting notice of the application filing on its station website, its licensee website, its parent entity website, or on a publicly accessible, locally targeted website, for 30 consecutive days beginning within five business days of acceptance of the application for filing. The online notice must link to a copy of the application as filed in the Commission's LMS licensing database. In the 2020 Public Notice Second Report and Order, the Commission also clarified LPFM stations' obligations to provide local public notice, and amended section 73.801 of the rules to indicate that the local public notice rule, 47 CFR 73.3580, applies to the LPFM service.

FCC staff uses the data to determine whether an applicant meets basic statutory and regulatory requirements to become a Commission licensee and to ensure that the public interest would be served by grant of the application. In addition, the information contained within this information collection ensures that (1) the integrity of the FM spectrum is not compromised, (2) unacceptable interference will not be caused to existing radio services, (3) statutory requirements are met, and (4) the stations operate in the public interest.

Federal Communications Commission.

Marlene Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2023–09404 Filed 5–2–23; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–XXXX, OMB 3060–0400; FR ID 138566]

Information Collections Being Submitted for Review and Approval to Office of Management and Budget

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, as required by the Paperwork Reduction Act (PRA) of 1995, the Federal Communications Commission (FCC or the Commission) invites the general public and other Federal Agencies to take this opportunity to comment on the following information collection. Pursuant to the Small Business Paperwork Relief Act of 2002, the FCC seeks specific comment on how it might ''further reduce the information collection burden for small business concerns with fewer than 25 employees.'' The Commission may not conduct or sponsor a collection of information unless it displays a currently valid Office of Management and Budget (OMB) control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid OMB control number.

DATES: Written comments and recommendations for the proposed information collection should be submitted on or before June 2, 2023.

ADDRESSES: Comments should be sent to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. Your comment must be submitted into *www.reginfo.gov* per the above instructions for it to be considered. In addition to submitting in *www.reginfo.gov* also send a copy of your comment on the proposed information collection to Nicole Ongele, FCC, via email to *PRA@fcc.gov* and to *Nicole.Ongele@fcc.gov.* Include in the comments the OMB control number as shown in the **SUPPLEMENTARY INFORMATION** below.

FOR FURTHER INFORMATION CONTACT: For additional information or copies of the information collection, contact Nicole Ongele at (202) 418–2991. To view a copy of this information collection request (ICR) submitted to OMB: (1) go to the web page *http://www.reginfo.gov/public/do/PRAMain,* (2) look for the section of the web page called ''Currently Under Review,'' (3) click on the downward-pointing arrow in the ''Select Agency'' box below the ''Currently Under Review'' heading, (4) select ''Federal Communications Commission'' from the list of agencies presented in the ''Select Agency'' box, (5) click the ''Submit'' button to the right of the ''Select Agency'' box, (6) when the list of FCC ICRs currently under review appears, look for the Title of this ICR and then click on the ICR Reference Number. A copy of the FCC submission to OMB will be displayed.

SUPPLEMENTARY INFORMATION: As part of its continuing effort to reduce paperwork burdens, as required by the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3520), the FCC invited the general public and other Federal Agencies to take this opportunity to comment on the following information collection. Comments are requested concerning: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's burden estimates; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology. Pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, see 44 U.S.C. 3506(c)(4), the FCC seeks specific comment on how it might ''further reduce the information collection burden for small business concerns with fewer than 25 employees.''

OMB Control Number: 3060–XXXX.

Title: Freedom of Information/Privacy Act Request.

Form Number: N/A.

Type of Review: New information collection.

Respondents: Individuals or Households, Business or other for-profit, and Not-for-profit institutions, Federal Government, State, Local or Tribal Government.

Number of Respondents and Responses: 770 respondents; 770 responses.

Estimated Time per Response: 0.08 hours.

Frequency of Response: On occasion reporting requirement.

Obligation to Respond: Voluntary. The statutory authority for this collection of information is contained in 5 U.S.C 552 and 552a.

Total Annual Burden: 62 hours.

Total Annual Cost: $5,124.00.

Needs and Uses: The online form is used to collect information necessary to process a proper FOIA request relating to a subject matter provided by the requester. Freedom of Information Act, 5 U.S.C. 552, details what makes a proper FOIA request. A proper request must include: (1) a reasonable description of the record and (2) is made in accordance with published agency rules stating time, place, fees (if any) and procedures to be followed.

Respondents can request records at any time. The request must describe each requested record in sufficient detail to enable the FCC staff to locate the record. The online form is used to collect requester's information (address, contact information, etc.) and a detailed description of the records sought. The FOIA requester is asked to provide information that would assist the FCC in locating responsive records (if they exist). This information is essential to the accurate search and retrieval of records responsive to FOIA/PA requests. Additionally, the requester may include information, if applicable, about fee categories, fee waivers, and expedited processing.

This form will enhance the quality, utility, and clarity of the information to be collected; and minimize the burden of the collection of information on those responding.

OMB Control Number: 3060–0400.

Title: Part 61, Tariff Review Plan (TRP).

Form Number: N/A.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit.

Number of Respondents and Responses: 2,747 respondents; 4,148 responses.

Estimated time per response: 0.5–53 hours.

Frequency of Response: One-time, on occasion, annual or biennial reporting requirements, and certification requirement.

Obligation To Respond: Required to obtain or retain benefits. Statutory Authority for this information collection is contained in 47 U.S.C. 201, 202, 203, and 251(b)(5) of the Communications Act of 1934, as amended. See 47 U.S.C. 201, 202 and 203, and 251(b)(5).

Total Annual Burden: 60,576 hours.

Total Annual Cost: No cost.

Needs and Uses: The Commission has developed standardized Tariff Review Plans (TRPs) that set forth the summary material that incumbent LECs (ILECs) file to support revisions to the rates in their interstate access service tariffs. The TRPs display basic data on rate development in a consistent manner, thereby facilitating review of the ILEC rate revisions by the Commission and interested parties. The TRPs have served this purpose effectively in past years.

Federal Communications Commission.

Marlene Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2023–09405 Filed 5–2–23; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–0633; FR ID 139067]

Information Collection Being Reviewed by the Federal Communications Commission

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act of 1995 (PRA), the Federal Communications Commission (FCC or Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collections. Comments are requested concerning: whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's

burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees. The FCC may not conduct or sponsor a collection of information unless it displays a currently valid Office of Management and Budget (OMB) control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid OMB control number.

DATES: Written PRA comments should be submitted on or before July 3, 2023. If you anticipate that you will be submitting comments but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Cathy Williams, FCC, via email to *PRA@fcc.gov* and to *Cathy.Williams@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Cathy Williams at (202) 418–2918.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–0633.

Title: Sections 74.165, 74.432 and 74.832, Filing of Station Licenses.

Form Number: N/A.

Type of Review: Revision of a currently approved collection.

Respondents: Business or other for-profit entities, Not-for-profit institutions and State, local or Tribal Government.

Number of Respondents and Responses: 1,000 respondents and 1,000 responses.

Estimated Hours per Response: 0.083 hours.

Frequency of Response: Recordkeeping requirement.

Obligation to Responds: Required to obtain or retain benefits. The statutory authority for this collection of information is contained in section 154(i) of the Communications Act of 1934, as amended.

Total Annual Burden: 83 hours.

Total Annual Cost: No cost.

Needs and Uses: The Commission released a Report and Order, Amendment of Parts 0, 1, 5, 73, and 74 of the Commission's Rules Regarding Posting of Station Licenses and Related Information, MB Docket No. 18–121, FCC 18–174, on December 11, 2018. In this Report and Order, the Commission eliminated rule sections 47 CFR 73.1230, 74.564, 74.664, 74.765 and 74.1265 to remove the posting information requirements from the Commission's rules. This collection is being revised to remove these rule sections from this information collection. Also, the posting information requirements are being removed from Sections 74.432 and 74.832 with this revision to the Office of Management and Budget. The remaining information collection requirements for this collection are as follows:

47 CFR 74.165 requires that the instrument of authorization for an experimental broadcast station be available at the transmitter site.

47 CFR 74.432(j) requires that the license of a remote pickup broadcast/low power auxiliary station shall be retained in the licensee's files and the address shown on the authorization.

47 CFR 74.832(j) (low power auxiliary stations) requires that the license shall be retained in the licensee's files at the address shown on the authorization.

Federal Communications Commission.

Marlene Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2023–09408 Filed 5–2–23; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL DEPOSIT INSURANCE CORPORATION

[OMB No. 3064–0057; –0061; –0087]

Agency Information Collection Activities: Proposed Collection Renewal; Comment Request

AGENCY: Federal Deposit Insurance Corporation (FDIC).

ACTION: Notice and request for comment.

SUMMARY: The FDIC, as part of its obligations under the Paperwork Reduction Act of 1995 (PRA), invites the general public and other Federal agencies to take this opportunity to comment on the renewal of the existing information collections described below (OMB Control No. 3064–0057; –0061; –0087).

DATES: Comments must be submitted on or before July 3, 2023.

ADDRESSES: Interested parties are invited to submit written comments to the FDIC by any of the following methods:

- *Agency Website: https://www.fdic.gov/resources/regulations/federal-register-publications/.*
- *Email: comments@fdic.gov.* Include the name and number of the collection in the subject line of the message.
- *Mail:* Manny Cabeza (202–898–3767), Regulatory Counsel, MB–3128, Federal Deposit Insurance Corporation, 550 17th Street NW, Washington, DC 20429.
- *Hand Delivery:* Comments may be hand-delivered to the guard station at the rear of the 17th Street NW building (located on F Street NW), on business days between 7:00 a.m. and 5:00 p.m.

All comments should refer to the relevant OMB control number. A copy of the comments may also be submitted to the OMB desk officer for the FDIC: Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Manny Cabeza, Regulatory Counsel, 202–898–3767, *mcabeza@fdic.gov,* MB–3128, Federal Deposit Insurance Corporation, 550 17th Street NW, Washington, DC 20429.

SUPPLEMENTARY INFORMATION:

Proposal to renew the following currently approved collection of information:

1. *Title:* Certified Statement for Semiannual Deposit Insurance Assessment.

OMB Number: 3064–0057.

Forms: None.

Affected Public: FDIC-insured depository institutions.

Burden Estimate:

SUMMARY OF ESTIMATED ANNUAL BURDEN

[OMB No. 3064–0057]

Information collection (obligation to respond)	Type of burden (frequency of response)	Number of respondents	Number of responses per respondent	Time per response (HH:MM)	Annual burden (hours)
1. Quarterly Certified Statement Invoice for Deposit Insurance Assessment, 12 CFR Part 327 (Mandatory).	Reporting (Quarterly)	4,755	4	00:20	6,340
Total Annual Burden (Hours)	.....	.....	.....	.....	6,340

Source: FDIC.

General Description of Collection: The FDIC collects deposit insurance assessments on a quarterly basis. Each quarterly assessment is based on an insured depository institution's quarterly report of condition for the prior calendar quarter. The FDIC collects the quarterly assessment payments by means of direct debits through the Automated Clearing House network. The information collection consists of the reporting requirement associated with certifying the review by officials of the insured institutions to confirm that the assessment data are accurate and, in cases of inaccuracy, submission of corrected data. There is no change in the substance or methodology of this information collection. The change in burden is due solely to the decrease in the estimated number of respondents by 671 from the estimated 7,011 annual respondents in the currently-approved information collection to the current estimate of 6,340. The decrease in estimated respondents is the result of the drop in the total number of insured depository institutions.

2. *Title:* Summary of Deposits.

OMB Number: 3064–0061.

Forms: None.

Affected Public: FDIC-insured depository institutions.

Burden Estimate:

SUMMARY OF ESTIMATED ANNUAL BURDEN

[OMB No. 3064–0061]

Information collection (obligation to respond)	Type of burden (frequency of response)	Number of respondents	Number of responses per respondent	Time per response (HH:MM)	Annual burden (hours)
1. Summary of Deposits (Mandatory)	Recordkeeping (Annual)	3,870	1	3:00	11,610
Total Annual Burden (Hours)	.....	.....	.....	.....	11,610

General Description of Collection: The Summary of Deposits (SOD) is the annual survey of branch office deposits as of June 30 for all FDIC-insured institutions, including insured U.S. branches of foreign banks. All FDIC-insured institutions that operate a main office and one or more branch locations (including limited service drive-thru locations) as of June 30 each year are required to file the SOD Survey. Insured branches of foreign banks are also required to file. All data collected on the SOD submission are available to the public. The survey data provides a basis for measuring the competitive impact of bank mergers and has additional use in research on banking. There is no change in the substance or methodology of this information collection. The change in burden is due solely to the decrease in the estimated number of respondents by 429 from the estimated 4,299 annual respondents in the currently-approved information collection to the current estimate of 3,870.

3. *Title:* Procedures for Monitoring Bank Secrecy Act Compliance.

OMB Number: 3064–0087.

Forms: None.

Affected Public: Insured State Nonmember Banks and Savings Associations..

Burden Estimate:

SUMMARY OF ESTIMATED ANNUAL BURDEN

[OMB No. 3064–0087]

Information collection (obligation to respond)	Type of burden (frequency of response)	Number of respondents	Number of responses per respondent	Time per response (HH:MM)	Annual burden (hours)
1. Procedures for monitoring BSA compliance, small institutions (<$500 million in total assets), 12 CFR 326.8(b)(1) and (c) (Mandatory).	Recordkeeping (Annual)	2,013	1	35:00	70,455
2. Procedures for monitoring BSA compliance, medium institutions ($500 million to $10 billion in total assets), 12 CFR 326.8(b)(1) and (c)(Mandatory).	Recordkeeping (Annual)	964	1	250:00	241,000

SUMMARY OF ESTIMATED ANNUAL BURDEN—Continued

[OMB No. 3064–0087]

Information collection (obligation to respond)	Type of burden (frequency of response)	Number of respondents	Number of responses per respondent	Time per response (HH:MM)	Annual burden (hours)
3. Procedures for monitoring BSA compliance, large institutions (>$10 billion in total assets), 12 CFR 326.8(b)(1) and (c) (Mandatory).	Recordkeeping (Annual)	61	1	450:00	27,450
Total Annual Burden (Hours)	.....	.....	.....	.....	338,905

Source: FDIC.

General Description of Collection: Respondents must establish and maintain procedures designed to monitor and ensure their compliance with the requirements of the Bank Secrecy Act and the implementing regulations promulgated by the Department of Treasury at 31 CFR chapter X. Respondents must also keep records evidencing that they have provided training for appropriate personnel. There is no change in the method or substance of the collection. The overall increase in burden hours is a result of economic fluctuation. In particular, the total number of respondents has increased while the hours per response remain the same.

Request for Comment: Comments are invited on: (a) Whether the collections of information are necessary for the proper performance of the FDIC's functions, including whether the information has practical utility; (b) the accuracy of the estimates of the burden of the information collections, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collections of information on respondents, including through the use of automated collection techniques or other forms of information technology. All comments will become a matter of public record.

Federal Deposit Insurance Corporation.

Dated at Washington, DC, on April 27, 2023.

James P. Sheesley,

Assistant Executive Secretary.

[FR Doc. 2023–09319 Filed 5–2–23; 8:45 am]

BILLING CODE 6714–01–P

FEDERAL MARITIME COMMISSION

[Docket No. 23–02]

Bed Bath & Beyond Inc. Complainant v. Orient Overseas Container Line Limited and OOCL (EUROPE) LIMITED, Respondents; Notice of Filing of Complaint and Assignment

Notice is given that a complaint has been filed with the Federal Maritime Commission (Commission) by Bed Bath & Beyond Inc., hereinafter ''Complainant,'' against Orient Overseas Container Line Limited and OOCL (Europe) Limited (hereinafter ''Respondents.'') Complainant states that it is a corporation existing under the laws of New York with a principal place of business in New Jersey. Complainant identifies Orient Overseas Container Line Limited as an ocean common carrier existing under the laws of Hong Kong with a principal place of business in Hong Kong, as well as a ''controlled carrier'' of the People's Republic of China. Complainant identifies OOCL (Europe) Limited as an ocean common carrier existing under the laws of United Kingdom with a principal place of business in the United Kingdom, as well as a ''controlled carrier'' of the People's Republic of China. Complainant further alleges that both companies act in the United States by and through their agent, OOCL (USA) Inc. (''OOCL (USA)''), a company existing under the laws of the State of New York with its principal place of business located in Utah.

Complainant alleges that Respondent violated 46 U.S.C. 41102(c), 41104(a)(2), and 41104(a)(10), as well as 46 CFR 545.5, regarding its practices and the billing and payment of costs and charges on the shipments of cargo, including demurrage and detention, as well as systematically failing to meet its service commitments to Complainant under Service Contracts, and by coercing Complainant to pay Peak Season Surcharges (PSS) and enter into premium rate contracts. An answer to the complaint is due to be filed with the Commission within twenty-five (25) days after the date of service. The full text of the complaint can be found in the Commission's Electronic Reading Room at *https://www2.fmc.gov/readingroom/proceeding/23-02/*. This proceeding has been assigned to Office of Administrative Law Judges. The initial decision of the presiding officer in this proceeding shall be issued by April 29, 2024, and the final decision of the Commission shall be issued by November 12, 2024.

Served: April 27, 2023.

William Cody,

Secretary.

[FR Doc. 2023–09374 Filed 5–2–23; 8:45 am]

BILLING CODE P

FEDERAL MARITIME COMMISSION

Notice of Agreements Filed

The Commission hereby gives notice of filing of the following agreements under the Shipping Act of 1984. Interested parties may submit comments, relevant information, or documents regarding the agreements to the Secretary by email at *Secretary@fmc.gov,* or by mail, Federal Maritime Commission, 800 North Capitol Street, Washington, DC 20573. Comments will be most helpful to the Commission if received within 12 days of the date this notice appears in the **Federal Register**, and the Commission requests that comments be submitted within 7 days on agreements that request expedited review. Copies of agreements are available through the Commission's website (*www.fmc.gov*) or by contacting the Office of Agreements at (202)–523–5793 or *tradeanalysis@fmc.gov.*

Agreement No.: 010071–048.

Agreement Name: Cruise Lines International Association.

Parties: Aida Cruises, American Crusine Lines, Inc., Atlas Ocean Voyages; Australian Pacific Touring Pty

Ltd; Azamara Cruises; Carnival Cruise Lines; Celebrity Cruises, Inc.; Costa Cruise Lines; Crystal Cruises; Cunard Line; Disney Cruise Line; Emerald Cruises; Explora SA; Hapag-Lloyd Kreuzfahrten GmbH; Heritage Expeditions; Holland America Line; Marella Cruise; MSC Cruises; NCL Corporation; Oceania Cruises; P&O Cruises; Pearl Seas Cruises; Ponant Yacht Cruises & Expeditions; Princess Cruises; Regent Seves Seas Cruises; Royal Caribbean International; Sea Cloud Cruises GmbH; Seabourn Cruise Line; Seadream Yacht Club, Ltd.; Star Cruises (HK) Limited; Swan Hellenic; Virgin Voyages; and Windstar Cruises.

Filing Party: Marissa Rivera, Cruise Lines International Association.

Synopsis: The amendment updates the membership of the agreement and revises the agreement to divide Global Members between Global Holding Members and Global Operating Members and specifies the difference between them.

Proposed Effective Date: 6/11/2023.

Location: https://www2.fmc.gov/FMC.Agreements.Web/Public/AgreementHistory/999.

Dated: April 28, 2023.

JoAnne O'Bryant,

Program Analyst.

[FR Doc. 2023–09387 Filed 5–2–23; 8:45 am]

BILLING CODE 6730–02–P

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisitions of Shares of a Bank or Bank Holding Company

The notificants listed below have applied under the Change in Bank Control Act (Act) (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire shares of a bank or bank holding company. The factors that are considered in acting on the applications are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The public portions of the applications listed below, as well as other related filings required by the Board, if any, are available for immediate inspection at the Federal Reserve Bank(s) indicated below and at the offices of the Board of Governors. This information may also be obtained on an expedited basis, upon request, by contacting the appropriate Federal Reserve Bank and from the Board's Freedom of Information Office at *https://www.federalreserve.gov/foia/request.htm.* Interested persons may express their views in writing on the standards enumerated in paragraph 7 of the Act.

Comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors, Ann E. Misback, Secretary of the Board, 20th Street and Constitution Avenue NW, Washington, DC 20551–0001, not later than May 18, 2023.

A. Federal Reserve Bank of Kansas City (Jeffrey Imgarten, Assistant Vice President) One Memorial Drive, Kansas City, Missouri 64198. Comments can also be electronically to *KCApplicationComments@kc.frb.org:*

1. *Steven R. Niemack, individually, and as trustee of the Steven R. Niemack Revocable Living Trust dated 3–25–2021 and the Steven R. Niemack Family Irrevocable Trust dated 1–31–2011, all of Lawrence, Kansas;* to form the Niemack Family Group, a group acting in concert, to retain voting shares of Maple Hill Bancshares, Inc., and thereby indirectly retain voting shares of Stockgrowers State Bank, both of Maple Hill, Kansas.

Board of Governors of the Federal Reserve System.

Michele Taylor Fennell,

Deputy Associate Secretary of the Board.

[FR Doc. 2023–09368 Filed 5–2–23; 8:45 am]

BILLING CODE P

FEDERAL TRADE COMMISSION

Horseracing Integrity and Safety Act: Anti-Doping and Medication Control Rule

AGENCY: Federal Trade Commission.

ACTION: Notice of Horseracing Integrity and Safety Authority (HISA) final rule; delay of effectiveness.

SUMMARY: The Federal Trade Commission modifies the Horseracing Integrity and Safety Authority's Anti-Doping and Medication Control Rule by extending its date of effectiveness until May 22, 2023.

DATES: As of May 3, 2023, the date of effectiveness for the Horseracing Integrity and Safety Authority's Anti-Doping and Medication Control Rule is delayed to May 22, 2023.

FOR FURTHER INFORMATION CONTACT: John H. Seesel (202–326–2702), Attorney, Office of the General Counsel, Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington, DC 20580.

SUPPLEMENTARY INFORMATION:

I. Reason for Delay of HISA's Final Rule

The Horseracing Integrity and Safety Act of 2020, 15 U.S.C. 3051–3060 (''Act''), tasks a self-regulatory nonprofit organization, the Horseracing Integrity and Safety Authority (''Authority''), with developing proposed rules on a variety of subjects. *See* 15 U.S.C. 3053(a). Those proposed rules take effect only if approved by the Federal Trade Commission, *see* 15 U.S.C. 3053(b)(2), which must approve the proposed rules if it finds that they are consistent with the Act and with applicable rules approved by the Commission, *see* 15 U.S.C. 3053(c)(2). The Commission, however, may by rule abrogate, add to, or modify the Authority's rules ''as the Commission finds necessary or appropriate to ensure the fair administration of the Authority, to conform the rules of the Authority'' to the Act's requirements or applicable rules approved by the Commission, ''or otherwise in furtherance of the purposes of this Act.'' *Id.* sec. 3053(e).

On March 27, 2023, the Commission issued an Order (''Order'') approving the Authority's proposed Anti-Doping and Medication Control (''ADMC'') Rule. Pursuant to that Order, the ADMC Rule took effect immediately upon the Commission's approval, *i.e.,* on March 27, 2023.[1]

On March 31, 2023, however, the United States District Court for the Northern District of Texas determined that the Commission had violated the Administrative Procedure Act by declaring the ADMC Rule effective immediately upon the issuance of the Commission's Order approving the Rule. Viewing the Commission's March 27 Order as tantamount to an agency's issuance of a substantive rule, the court found that the Commission should have delayed the date of effectiveness for the ADMC Rule for 30 days following approval. The court accordingly enjoined implementation or enforcement of the ADMC Rule until May 1, 2023.[2]

The district court's March 31 order has given rise to substantial uncertainty regarding the criteria and procedures under which anti-doping and medication control protocols will be implemented as the Thoroughbred horseracing industry nears the Triple Crown events of May 6 (Kentucky Derby), May 20 (Preakness Stakes), and June 10 (Belmont Stakes). With the date of effectiveness for the Authority's nationally applicable ADMC Rule

[1] *See* Fed. Trade Comm'n, Order Approving the Anti-Doping and Medication Control Rule Proposed by the Horseracing Integrity & Safety Auth. (Mar. 27, 2023), *https://www.ftc.gov/system/files/ftc_gov/pdf/P222100CommissionOrderAntiDopingMedication.pdf.*

[2] *Nat'l Horsemen's Benevolent & Protective Ass'n et al.* v. *Jerry Black et al.,* No. 5:21–CV–071–H, 2023 WL 2753978 (N.D. Tex. Mar. 31, 2023).

suspended by the district court until May 1, the conduct of anti-doping and medication control will remain under the jurisdiction of the various state racing authorities until that date, with the Authority's jurisdiction resuming only five days before the Kentucky Derby and nineteen days before the Preakness. Because the ADMC Rule governs the treatment of horses weeks before a covered race, some affected parties who are treating horses in a manner consistent with state requirements may find it difficult to come into compliance in the five days between the ADMC Rule's scheduled date of effectiveness and the Kentucky Derby on May 6.[3] Even in the absence of conflicts between the ADMC Rule and applicable state regulations, implementing new testing requirements just days before the start of the Triple Crown creates an appreciable risk of errors, confusion, and inconsistent treatment of similarly situated horses—harms that could frustrate the purposes of the Act.

In light of these policy concerns, the Commission finds it necessary to modify HISA's ADMC Rule, pursuant to the recently revised 15 U.S.C. 3053(e), to ensure the ''fair administration of the Authority'' and otherwise in furtherance of the Act's purposes. Accordingly, pursuant to the authority granted to the Commission by 15 U.S.C. 3053(e), the Commission issues this document delaying the date of effectiveness for the Horseracing Integrity and Safety Authority's Anti-Doping and Medication Control Rule until May 22, 2023.

II. Administrative Procedure Act

As noted above, the Act authorizes the Commission to abrogate, add to, or modify the Authority's rules for specified reasons, including ''to ensure the fair administration of the Authority.'' 15 U.S.C. 3053(e). This provision authorizes Commission rulemaking pursuant to section 553 of Title 5, the Administrative Procedure Act (APA). The APA typically provides for notice-and-comment rulemaking, but under section 553(b)(3)(B) of the APA, general notice and the opportunity for public comment are not required with respect to a rulemaking when an ''agency for good cause finds (and incorporates the finding and a brief statement of reasons therefor in the rules issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest.'' [4]

Here, the Commission finds, for good cause, that notice and comment is impracticable and unnecessary with respect to the document. Given the short time remaining before commencement of the Triple Crown races, providing advance notice would delay the effect of HISA's final rule until after the Kentucky Derby, defeating the rule's purpose. Obtaining comments after issuance of the rule is unnecessary because the full effect of the Commission's rule—which merely provides for a brief delay in the date of effectiveness for the ADMC Rule—will have occurred prior to the Commission's collection and consideration of any comments.

For these reasons, the Commission finds that there is good cause consistent with the public interest to issue the document without notice and comment.[5] The Commission therefore issues the document without prior notice and comment.

The APA also requires a 30-day delayed effective date, except for ''(1) substantive rules which grant or recognize an exemption or relieve a restriction; (2) interpretative rules and statements of policy; or (3) as otherwise provided by the agency for good cause.'' [6] For the same reasons noted with regard to notice and comment, and because extending the date of effectiveness for the ADMC Rule relieves a restriction, the Commission finds there is good cause for its document to take effect immediately.

III. Paperwork Reduction Act

In accordance with the requirements of the Paperwork Reduction Act (PRA), an agency may not conduct or sponsor, and a respondent is not required to respond to, an information collection unless it displays a currently valid Office of Management and Budget control number. This document issued by the Commission—which addresses solely the date of effectiveness for the Authority's ADMC Rule—does not involve any collection of information pursuant to the PRA.

IV. Regulatory Flexibility Act and Congressional Review Act

The Regulatory Flexibility Act (RFA), 5 U.S.C. 601–612, requires that the Commission provide an Initial Regulatory Flexibility Analysis (IRFA) with a proposed rule and a Final Regulatory Flexibility Analysis (FRFA), if any, with a final rule. However, this obligation does not apply when an agency for good cause determines that a rulemaking is not subject to notice and comment. *See, e.g., Or. Trollers Ass'n* v. *Gutierrez,* 452 F.3d 1104, 1123–24 (9th Cir. 2006). The Commission finds that good cause exists for adopting this document without advance public notice or an opportunity for public comment. Because notice and comment are not statutorily required, the requirement to publish an analysis under the RFA does not apply to this document.

Pursuant to the Congressional Review Act (5 U.S.C. 801 through 808), the Office of Information and Regulatory Affairs has said that it would presumptively treat the type of rulemaking that the Commission announces today as not a ''major rule'' (as defined in 5 U.S.C. 804(2)). The Commission occasionally extends a compliance date for a new rule or rule amendment to give entities additional time to prepare for compliance. For example, in 2010, the FTC extended the compliance date for its Energy Labeling Rule (16 CFR part 305) (formerly, Appliance Labeling Rule) to give regulated entities additional time to incorporate new labeling requirements for light bulbs into product packaging. *See* 75 FR 81943 (Dec. 29, 2010); 76 FR 20233 (Apr. 12, 2011). The Office of Management and Budget has previously designated such extensions as ''not major.'' Because such amendments merely defer the expected economic effects of a previously adopted rule, any costs and benefits associated with the compliance date extension should be incremental to those already considered in connection with the promulgation of the underlying rule. For similar reasons, the relief should not result in major cost increases or significant adverse effects on competition, investment, or innovation. In addition, for purposes of this category, presumptively ''not major'' rules would be those in which the compliance date extension is limited to not more than one year, which will further serve to limit the economic impact of such extensions. The three-week extension of the ADMC Rule's date of effectiveness satisfies this criterion.

For the reasons stated above, the Federal Trade Commission extends the date of effectiveness for the Horseracing Integrity and Safety Authority's Anti-Doping and Medication Control Rule to May 22, 2023.

[3] *Compare, e.g.,* ADMC Rule 4222 (prohibiting all intra-articular injections within fourteen days of post time) *with* Kentucky Horse Racing Commission Withdrawal Guidelines: Thoroughbred; Standardbred; Quarter Horse, Appaloosa, and Arabian, KHRC 8–020–2 (04/2020) (prohibiting intra-articular injection of specified substances within fourteen days of post time), *available at https://khrc.ky.gov/Documents/8-020-2-Withdrawal%20Guidelines%20%20Copy.pdf.*

[4] 5 U.S.C. 553(b)(3)(B).

[5] *Id.*

[6] *Id.* at 553(d).

By direction of the Commission.

April J. Tabor,

Secretary.

[FR Doc. 2023–09247 Filed 5–2–23; 8:45 am]

BILLING CODE 6750–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10174]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (the PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by July 3, 2023.

ADDRESSES: When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to *http://www.regulations.gov.* Follow the instructions for ''Comment or Submission'' or ''More Search Options'' to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number: ____, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, please access the CMS PRA website by copying and pasting the following web address into your web browser: *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.*

FOR FURTHER INFORMATION CONTACT: William N. Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS–10174 Collection of Prescription Drug Data from MA–PD, PDP and Fallout Plans/Sponsors for Medicare Part D Payments

Under the PRA (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term ''collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

Information Collection

1. *Type of Information Collection Request:* Revision of the currently approved collection; *Title of Information Collection:* Collection of Prescription Drug Data from MA–PD, PDP and Fallout Plans/Sponsors for Medicare Part D Payments; *Use:* The PDE data is used in the Payment Reconciliation System to perform the annual Part D payment reconciliation, any PDE data within the Coverage Gap Phase of the Part D benefit is used for invoicing in the CGDP, and the data are part of the report provided to the Secretary of the Treasury for Section 9008.

The information users will be pharmacy benefit managers (PBMs), third party administrators and pharmacies, and the PDPs, MA–PDs, Fallbacks, and other plans that offer coverage of outpatient prescription drugs under the Medicare Part D benefit to Medicare beneficiaries. The statutorily required data is used primarily for payment and is used for claim validation as well as for other legislated functions such as quality monitoring, program integrity and oversight. In addition, the PDE data are used to support operations and program development.

CMS has used PDE data to create summarized dashboards and tools, including the Medicare Part D Drug Spending Dashboard & Data, the Part D Manufacturer Rebate Summary Report, and the Medicare Part D Opioid Prescribing Mapping Tool. The data are also used in the Medicare Trustees Report. Due to the market sensitive nature of PDE data, external uses of the data are subject to significant limitations. However, CMS does analyze the data on a regular basis to determine drug cost and utilization patterns in order to inform programmatic changes and to develop informed policy in the Part D program. *Form Number:* CMS–10174 (OMB control number: 0938–0982); *Frequency:* Monthly; *Affected Public:* Private Sector, Federal Government; *Number of Respondents:* 856; *Total Annual Responses:* 1,499,065,636; *Total Annual Hours:* 62,918. (For policy questions regarding this collection contact Shelly Winston at (443) 934–3621.)

Dated: April 28, 2023.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2023–09398 Filed 5–2–23; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–0623]

Antimicrobial Drugs Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of a public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Antimicrobial Drugs Advisory Committee. The general function of the committee is to provide advice and recommendations to FDA on regulatory issues. The meeting will be open to the public. FDA is establishing a docket for public comment on this document.

DATES: The meeting will be held virtually on June 8, 2023, from 9:30 a.m. to 5 p.m. Eastern Time.

ADDRESSES: Please note that due to the impact of COVID–19, all meeting participants will be joining this advisory committee meeting via an online teleconferencing platform. Answers to commonly asked questions about FDA advisory committee meetings may be accessed at: *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.*

FDA is establishing a docket for public comment on this meeting. The docket number is FDA–2023–N–0623. Please note that late, untimely filed comments will not be considered. The docket will close on June 7, 2023. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of June 7, 2023. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Comments received on or before May 24, 2023, will be provided to the committee. Comments received after that date will be taken into consideration by FDA. In the event that the meeting is cancelled, FDA will continue to evaluate any relevant applications or information, and consider any comments submitted to the docket, as appropriate.

You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2023–N–0623 for ''Antimicrobial Drugs Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments.'' Received comments, those filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' FDA will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify the information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: She-Chia Jankowski, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 240–402–5343, email: *AMDAC@fda.hhs.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last-minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check FDA's website at *https://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: The meeting presentations will be heard, viewed, captioned, and recorded through an online teleconferencing platform. The committee will discuss biologics license application (BLA) 761328, for nirsevimab, a long-acting respiratory syncytial virus (RSV) F protein inhibitor monoclonal antibody for intramuscular use, submitted by AstraZeneca AB. The proposed indication is prevention of RSV lower respiratory tract disease in:

- Neonates and infants born during or entering their first RSV season.
- Children up to 24 months of age who remain vulnerable to severe RSV

disease through their second RSV season.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available on FDA's website at the time of the advisory committee meeting. Background material and the link to the online teleconference meeting room will be available at *https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm*. Scroll down to the appropriate advisory committee meeting link. The meeting will include slide presentations with audio components to allow the presentation of materials in a manner that most closely resembles an in-person advisory committee meeting.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. All electronic and written submissions submitted to the Docket (see **ADDRESSES**) on or before May 24, 2023, will be provided to the committee. Oral presentations from the public will be scheduled between approximately 1:30 p.m. and 2:30 p.m. Eastern Time. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before May 16, 2023. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by May 17, 2023.

For press inquiries, please contact the Office of Media Affairs at *fdaoma@fda.hhs.gov* or 301–796–4540.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact She-Chia Jankowski (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: April 27, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–09321 Filed 5–2–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–1619]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by June 2, 2023.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0606. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements—21 CFR Part 111

OMB Control Number 0910–0606—Extension

The Dietary Supplement Health and Education Act (Pub. L. 103–417) added section 402(g) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 342(g)), which provides, in part, that the Secretary of Health and Human Services may, by regulation, prescribe good manufacturing practice for dietary supplements. Section 402(g) of the FD&C Act also stipulates that such regulations will be modeled after Current Good Manufacturing Practice (CGMP) regulations for food and may not impose standards for which there are no current, and generally available, analytical methodology. Section 402(g)(1) of the FD&C Act states that a dietary supplement is adulterated if it has been prepared, packed, or held under conditions that do not meet current good manufacturing practice regulations.

Accordingly, we have issued regulations in part 111 (21 CFR part 111) establishing minimum CGMP requirements pertaining to the manufacturing, packaging, labeling, or holding of dietary supplements to ensure their quality. Included among the requirements is recordkeeping, documenting, planning, control, and improvement processes of a quality control system. Implementation of these processes in a manufacturing operation serves as the backbone to CGMP. The records must show what is being manufactured and whether the controls in place ensure the product's identity, purity, strength, and composition and that limits on contaminants and measures to prevent adulteration are effective. Further, records must show whether and what deviations from control processes occurred, facilitate evaluation and corrective action concerning these deviations (including, where necessary, whether associated batches of product should be recalled from the marketplace), and enable a manufacturer to assure that the corrective action was effective. We believe the regulations in part 111 establish the minimum manufacturing practices necessary to ensure that dietary supplements are manufactured, packaged, labeled, or held in a manner

that will ensure the quality of the dietary supplements during manufacturing, packaging, labeling, or holding operations.

Specifically, the recordkeeping requirements of the regulations in part 111 include establishing written procedures and maintaining records pertaining to: (1) personnel; (2) sanitation; (3) calibration of instruments and controls; (4) calibration, inspection, or checks of automated, mechanical, or electronic equipment; (5) maintaining, cleaning, and sanitizing equipment and utensils and other contact surfaces; (6) water used that may become a component of the dietary supplement; (7) production and process controls; (8) quality control; (9) components, packaging, labels, and product received for packaging and labeling; (10) master manufacturing and batch production; (11) laboratory operations; (12) manufacturing operations; (13) packaging and labeling operations; (14) holding and distributing operations; (15) returned dietary supplements; and (16) product complaints.

Section 111.75(a)(1) (21 CFR 111.75(a)(1)) reflects FDA's determination that manufacturers that test or examine 100 percent of the incoming dietary ingredients for identity can be assured of the identity of the ingredient. However, we recognize that it may be possible for a manufacturer to demonstrate, through various methods and processes in use over time for its particular operation, that a system of less than 100 percent identity testing would result in no material diminution of assurance of the identity of the dietary ingredient as compared to the assurance provided by 100 percent identity testing. Section 111.75(a)(1) provides an opportunity for a manufacturer to make such a showing and reduce the frequency of identity testing of components that are dietary ingredients from 100 percent to some lower frequency. Section 111.75(a)(1) also sets forth the information a manufacturer is required to submit for an exemption from the requirement of 100 percent identity testing when a manufacturer petitions the Agency for such an exemption to 100 percent identity testing under 21 CFR 10.30 and the Agency grants such exemption.

Description of Respondents: Respondents to this collection of information include manufacturers, packagers and repackagers, labelers and re-labelers, holders, distributors, warehousers, exporters, importers, large businesses, and small businesses engaged in the dietary supplement industry. Respondents are from the private sector (for-profit businesses).

In the **Federal Register** of October 14, 2022 (87 FR 62429), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR section; activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
111.14; records of personnel practices, including documentation of training	15,000	4	60,000	1	60,000
111.23; records of physical plant sanitation practices, including pest control and water quality.	15,000	1	15,000	0.2 (12 minutes)	3,000
111.35; records regarding equipment and utensils, including calibration and sanitation practices.	400	1	400	12.5	5,000
111.95; records of production and process control systems	250	1	250	45	11,250
111.140; records that quality control personnel must make and keep	240	1,163	279,120	1	279,120
111.180; records associated with components, packaging, labels, and product received for packaging and labeling as a dietary supplement.	240	1,163	279,120	1	279,120
111.210; requirements for what the master manufacturing record must include.	240	1	240	2.5	600
111.260; requirements for what the batch production record must include	145	1,408	204,160	1	204,160
111.325; records that quality control personnel must make and keep for laboratory operations.	120	1	120	15	1,800
111.375; records of the written procedures established for manufacturing operations.	260	1	260	2	520
111.430; records of the written procedures for packaging and labeling operations.	50	1	50	12.6	630
111.475; records of product distribution and procedures for holding and distributing operations.	15,000	1	15,000	0.4 (24 minutes)	6,000
111.535; records for returned dietary supplements	110	4	440	13.5	5,940
111.570; records regarding product complaints	240	600	144,000	0.5 (30 minutes)	72,000
Total					929,140

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section; activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
111.75; petition for exemption from 100% identity testing	1	1	1	8	8

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate. We base our estimates for the recordkeeping and reporting burdens on our experience with the recordkeeping and petition activities.

Dated: April 28, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–09411 Filed 5–2–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–D–2870]

Decentralized Clinical Trials for Drugs, Biological Products, and Devices; Draft Guidance for Industry, Investigators, and Other Stakeholders; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry, investigators, and other stakeholders entitled ''Decentralized Clinical Trials for Drugs, Biological Products, and Devices.'' This draft guidance provides recommendations for sponsors, investigators, and other stakeholders regarding the implementation of decentralized clinical trials (DCTs) for drugs, biological products, and devices. In this draft guidance, a DCT refers to a clinical trial where some or all of the trial-related activities occur at locations other than traditional clinical trial sites.

DATES: Submit either electronic or written comments on the draft guidance by August 1, 2023 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2022–D–2870 for ''Decentralized Clinical Trials for Drugs, Biological Products, and Devices.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002; the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002; or the Office of Policy, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Ryan Robinson, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 3342, Silver Spring, MD 20993, 240–402–9756; Diane Maloney, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993, 240–402–7911; Soma Kalb, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. G318, Silver Spring, MD 20993–0002, 301–796–6359; or Paul Kluetz, Oncology Center of Excellence, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 2223, Silver Spring, MD 20993, 301–796–9567.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry, investigators, and other stakeholders entitled ''Decentralized Clinical Trials for Drugs, Biological Products, and Devices.'' This guidance fulfills the requirements set forth in section

3606(a)(1) of the Food and Drug Omnibus Reform Act (FDORA). The content described in section 3606(b) of FDORA is further addressed through this guidance's reference to FDA's draft guidance for industry, investigators, and other stakeholders entitled ''Digital Health Technologies for Remote Data Acquisition in Clinical Investigations'' (December 2021). In this draft guidance, a DCT refers to a clinical trial where some or all of the trial-related activities occur at locations other than traditional clinical trial sites. These trial-related activities may take place at the location of trial participants or in local healthcare facilities that are close to trial participants' locations.

DCTs may involve different levels of decentralization. In fully decentralized clinical trials, all activities take place at locations other than traditional trial sites. In hybrid DCTs, some activities involve in-person visits by trial participants to traditional clinical trial sites, and other visits or activities are conducted at locations other than traditional clinical trial sites. FDA's regulatory requirements are the same for DCTs and traditional site-based clinical trials.

DCTs may include the use of local healthcare providers and local clinical laboratory facilities in the management of trial participants and the use of telehealth and digital health technologies to remotely acquire data. By allowing remote participation and reducing the need to travel for face-to-face visits, DCTs may enhance convenience for study participants, facilitate research on diseases affecting populations with limited mobility, and reduce the burden on caregivers.

The investigator in a DCT is responsible for the conduct of the DCT and oversight of individuals delegated to perform trial-related activities. In a DCT, the investigator still ensures that appropriate informed consent is obtained, the investigational product is appropriately administered in accordance with the protocol, and other required safety and efficacy assessments are done with appropriate documentation. Specific issues related to the feasibility, design, implementation, or analysis of a DCT should be discussed with the relevant FDA review division.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Decentralized Clinical Trials for Drugs, Biological Products, and Devices.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 11 have been approved under OMB control number 0910–0303; the collections of information in 21 CFR part 312, including Form FDA 1572, have been approved under OMB control number 0910–0014; the collections of information in 21 CFR part 812 and 812.140 have been approved under OMB control number 0910–0078; and the collections of information in 21 CFR parts 50 and 56 have been approved under OMB control number 0910–0130.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: April 28, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–09399 Filed 5–2–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–P–2060]

Determination That Levitra (Vardenafil Hydrochloride) Oral Tablets, 5 Milligrams, 10 Milligrams, and 20 Milligrams, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) has determined that Levitra (vardenafil hydrochloride) oral tablets, 5 milligrams (mg), 10 mg, and 20 mg, were not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to these drug products, and it will allow FDA to continue to approve ANDAs that refer to these products as long as they meet relevant legal and regulatory requirements.

FOR FURTHER INFORMATION CONTACT: Daniel Ritterbeck, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6219, Silver Spring, MD 20993–0002, 301–796–4673, *Daniel.Ritterbeck@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(j)) allows the submission of an ANDA to market a generic version of a previously approved drug product. To obtain approval, the ANDA applicant must show, among other things, that the generic drug product: (1) has the same active ingredient(s), dosage form, route of administration, strength, conditions of use, and (with certain exceptions) labeling as the listed drug, which is a version of the drug that was previously approved, and (2) is bioequivalent to the listed drug. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

Section 505(j)(7) of the FD&C Act requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is known generally as the ''Orange Book.'' Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

Levitra (vardenafil hydrochloride) oral tablets, 5 mg, 10 mg and 20 mg, are

the subject of NDA 021400, held by Bayer HealthCare Pharmaceuticals, Inc., and initially approved on August 19, 2003. Levitra is a phosphodiesterase 5 inhibitor indicated for the treatment of erectile dysfunction.

In letters dated September 26, 2019, September 24, 2020, and September 20, 2021, Bayer HealthCare Pharmaceuticals, Inc. notified FDA that Levitra (vardenafil hydrochloride) oral tablets, 5 mg, 10 mg and 20 mg, respectively, were being discontinued, and FDA moved the drug products to the ''Discontinued Drug Product List'' section of the Orange Book.

Respira Therapeutics, Inc. submitted a citizen petition dated August 29, 2022 (Docket No. FDA–2022–P–2060), under 21 CFR 10.30, requesting that the Agency determine whether Levitra (vardenafil hydrochloride) oral tablets, 20 mg, were withdrawn from sale for reasons of safety or effectiveness. Although the citizen petition did not address the 5 mg and 10 mg strengths, those strengths have also been discontinued. On our own initiative, we have also determined whether those strengths were withdrawn for safety or effectiveness reasons.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that Levitra (vardenafil hydrochloride) oral tablets, 5 mg, 10 mg, and 20 mg, were not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that these drug products were withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of Levitra (vardenafil hydrochloride) oral tablets, 5 mg, 10 mg, and 20 mg, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have reviewed the available evidence and determined that these drug products were not withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list Levitra (vardenafil hydrochloride) oral tablets, 5 mg, 10 mg, and 20 mg, in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. FDA will not begin procedures to withdraw approval of approved ANDAs that refer to these drug products. Additional ANDAs for these drug products may also be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for these drug products should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: April 28, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–09365 Filed 5–2–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection; Public Comment Request; Application and Other Forms Used by the National Health Service Corps Scholarship Program, the NHSC Students to Service Loan Repayment Program, and the Native Hawaiian Health Scholarship Program

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, HRSA submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period. OMB may act on HRSA's ICR only after the 30-day comment period for this notice has closed.

DATES: Comments on this ICR should be received no later than June 2, 2023.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments,'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email Samantha Miller, the Acting HRSA Information Collection Clearance Officer, at *paperwork@hrsa.gov* or call 301–594–4394.

SUPPLEMENTARY INFORMATION: *Information Collection Request Title:* Application and Other Forms Used by the National Health Service Corps (NHSC) Scholarship Program (SP), the NHSC Students to Service Loan Repayment Program (S2S LRP), and the Native Hawaiian Health Scholarship Program (NHHSP), OMB No. 0915–0146-Revision.

Abstract: Administered by HRSA's Bureau of Health Workforce, the NHSC SP, NHSC S2S LRP, and the NHHSP provide scholarships or loan repayment to qualified students who are pursuing primary care health professions education and training. In return, students agree to provide primary health care services in underserved communities located in federally designated Health Professional Shortage Areas once they are fully trained and licensed health professionals. Awards are made to applicants who demonstrate the greatest potential for successful completion of their education and training as well as commitment to provide primary health care services to communities of greatest need. The information from program applications, forms, and supporting documentation is used to select the best qualified candidates for these competitive awards, and to monitor program participants' enrollment in school, postgraduate training, and compliance with program requirements.

Although some program forms vary from program to program (see program-specific burden charts below), required forms generally include: a program application, academic and non-academic letters of recommendation, the authorization to release information, and the acceptance/verification of good academic standing report. The NHHSP is not seeking to change or add any forms or documentation.

A 60-day notice published in the **Federal Register** on February 14, 2023, 88 FR 9525–26. There were no public comments.

Need and Proposed Use of the Information: The NHSC SP, S2S LRP, and NHHSP applications, forms, and supporting documentation are used to collect necessary information from applicants and schools that enable HRSA to make selection determinations for the competitive awards and monitor compliance (via training programs and sites) with program requirements.

Likely Respondents: Qualified students who are pursuing education and training in primary care health professions and are interested in working in health professional shortage areas and schools at which such students are enrolled.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose, or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

Total Estimated Annualized Burden—Hours

NHSC Scholarship Program Application

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
NHSC Scholarship Program Application	2,575	1	2,575	2.00	5150.00
Letters of Recommendation	2,575	2	5,150	1.00	5150.00
Authorization to Release Information	2,575	1	2,575	.10	257.50
Acceptance/Verification of Good Standing Report	2,575	1	2,575	.25	643.75
Verification of Disadvantaged Background Status	615	1	615	.25	153.75
Total	*2,575		13,490		11,355.00

*Certain documents are submitted by a subset of respondents consistent with program requirements.

NHSC Awardees/Schools/Post Graduate Training Programs/Sites

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Data Collection Worksheet	400	1	400	1.00	400
Post Graduate Training Verification Form	100	1	100	.50	50
Enrollment Verification Form	600	2	1,200	.50	600
Total	*600		1,700		1,050

*Please note that the same group of respondents may complete each form as necessary.

NHSC Students to Service Loan Repayment Program Application

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
NHSC Students to Service Loan Repayment Program Application	284	1	284	2.00	568.00
Letters of Recommendation	284	1	284	2.00	568.00
Authorization to Release Information	284	1	284	.10	28.40
Acceptance/Verification of Good Standing Report	284	1	284	.25	71.00
Verification of Disadvantaged Background Status	84	1	84	.25	21.00
Total	*284		1,220		1,256.40

*Certain documents are submitted by a subset of respondents consistent with program requirements.

Native Hawaiian Health Scholarship Program Application

Form name	Number of respondents	Number of responses per respondent	Total Responses	Average burden per response (in hours)	Total burden hours
Native Hawaiian Health Scholarship Program Application	310	1.00	310	2.00	620.00
Letters of Recommendation	310	2.00	620	.25	155.00
Authorization to Release Information	310	1.00	310	.25	77.50
Acceptance/Verification of Good Standing Report	40	1.00	40	.25	10.00
Scholar Enrollment Verification Form	40	7.50	300	.50	150.00
Change in Program Curriculum Form	40	2.00	80	.25	20.00
NHHSP Graduation Documentation Form	40	1.00	40	.25	10.00
Total	*310		1,700		1,042.50

*Certain documents are submitted by a subset of respondents consistent with program requirements.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2023–09356 Filed 5–2–23; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Findings of Research Misconduct

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: Findings of research misconduct have been made against Johnny J. He, Ph.D. (Respondent), who is a Professor, Department of Microbiology and Immunology, Rosalind Franklin University of Medicine and Science (RFUMS). Respondent engaged in research misconduct in research reported in grant applications submitted for U.S. Public Health Service (PHS) funds, specifically U01 DA056010–01 and DP1 DA056160–01 submitted to the National Institute on Drug Abuse (NIDA), National Institutes of Health (NIH), R01 AG078019–01 submitted to the National Institute on Aging (NIA), NIH, and R35 NS127233–01 submitted to the National Institute of Neurological Disorders and Stroke (NINDS), NIH. The administrative actions, including supervision for a period of three (3) years, were implemented beginning on April 17, 2023, and are detailed below.

FOR FURTHER INFORMATION CONTACT: Sheila Garrity, JD, MPH, MBA, Director, Office of Research Integrity, 1101 Wootton Parkway, Suite 240, Rockville, MD 20852, (240) 453–8200.

SUPPLEMENTARY INFORMATION: Notice is hereby given that the Office of Research Integrity (ORI) has taken final action in the following case:

Johnny J. He, Ph.D., Rosalind Franklin University of Medicine and Science: Based on the report of an investigation conducted by RFUMS, an admission by Respondent, and analysis conducted by ORI in its oversight review, ORI found that Johnny J. He, Ph.D., Professor, Department of Microbiology and Immunology, RFUMS, engaged in research misconduct in research reported in grant applications submitted for PHS funds, specifically U01 DA056010–01 and DP1 DA056160–01 submitted to NIDA, NIH, R01 AG078019–01 submitted to NIA, NIH, and R35 NS127233–01 submitted to NINDS, NIH.

ORI found that Respondent engaged in research misconduct by intentionally, knowingly, or recklessly falsifying, fabricating, and plagiarizing experimental data and text that described the research from one (1) preprint and four (4) published papers and represented the data and/or ideas as his own under different experimental conditions in four (4) NIH grant applications and in one research record. The falsified, fabricated, and plagiarized research data and text appeared in the following NIH grant applications:

- NIA, NIH, grant R01 AG078019–01, ''iTat mice to model HIV-impaired neurogenesis and accelerated aging,'' submitted on September 7, 2021
- NIDA, NIH, grant U01 DA056010–01, ''Single cell and spatial transcriptomic changes of cocaine use in the iTat HAND model,'' submitted on July 20, 2021
- NIDA, NIH, grant DP1 DA056160–01, ''Targeting epigenetic changes to understand and treat CUD in people living with HAND,'' submitted on August 13, 2021
- NINDS, NIH, grant R35 NS127233–01, ''HIV-associated neurocognitive disorder: from mechanisms to therapeutics,'' submitted on July 13, 2021

The sources of the plagiarized images and text were:

- *Clin Transl Med.* 2017 June 8;6(1):20. doi: 10.1186/s40169–017–0150–9 (hereafter referred to as ''*Clin Trans Med* 2017'')
- *Sci Adv.* 2019 October 16;5(10):eaax1532. doi: 10.1126/sciadv.aax1532 (hereafter referred to as ''*Sci Adv* 2019'')
- *BioRxiv.* March 5, 2020. doi:10.1101/2020.02.29.970558v2 (hereafter referred to as ''*BioRxiv* 2020''). *BioRxiv* 2020 is a preprint version of *Nature.* 2021 October 6;598(7879):103–110. doi: 10.1038/s41586–021–03500–8
- *Biosci Biotechnol Biochem.* 2020 May;84(5):919–926. doi:10.1080/09168451.2020.1714420 (hereafter referred to as ''*BBB* 2020'')
- *Front Oncol.* 2021 January 19;10:607349. doi: 10.3389/fonc.2020.607349 (hereafter referred to as ''*Front Onc* 2021'')

Specifically, ORI found that Respondent knowingly, intentionally, or recklessly:

- falsified, fabricated, and plagiarized research data and the text that described the research by:

—using Figures 1A and 1B of *BBB* 2020, representing wild-type and APP23 mice at 6 and 24 months, as the Respondent's own data in Figures 5A and 5B of U01 DA056010–01 and Figures 7A and 7B of R01 AG78019–01, representing wild-type and iTat mice at 6 and 12 months

—using Figures 3c and 3d of *BioRxiv* 2020, representing results in 60 days old *Snap25–IRES2–Cre* mice crossed to *Ai14* mice, as the Respondent's own data in Figure 6 of U01 DA056010–01 and Figure 8 of R01 AG078019–01, representing results in 12-weeks old iTat mice

—using, cropping, and splicing Figures 5g–5i of *BioRxiv* 2020, representing cell type transcription factors networks signature of the regulatory genome in neurons isolated from the brains of *Snap25–IRES2–Cre* mice crossed to *Ai14* mice, as the Respondent's own data in one research record intended for use in preparing figures for incorporation in U01 DA056010–01, representing spatiotemporal atlas of gene regulatory networks and biological pathways in the brain during neurogenesis and aging altered by Tat expression and HIV infection

- fabricated and plagiarized research data and text that described the research by:

—using Figure 3 of *Front Onc* 2021 as the Respondent's own data in Figure 8 of U01 DA056010–01 and Figure 10 of R01 AG078019–01

- plagiarized text by:

—using a paragraph from *Sci Adv* 2019 as the Respondent's own text describing cocaine use disorder in the section titled ''The problem description and a new therapeutic strategy for CUD in people living with HAND'' of DP1 DA056160–01

—using a paragraph from *Clin Trans Med* 2017 as the Respondent's own text describing single cell sequencing in Specific Aim 2 of both U01 DA056010–01 and R01 AG078019–01

Dr. He entered into a Voluntary Settlement Agreement (Agreement) and voluntarily agreed to the following:

(1) Respondent will have his research supervised for a period of three (3) years beginning on April 17, 2023 (the ''Supervision Period''). Prior to the submission of an application for PHS support for a research project on which Respondent's participation is proposed and prior to Respondent's participation in any capacity in PHS-supported research, Respondent will submit a plan for supervision of Respondent's duties to ORI for approval. The supervision plan must be designed to ensure the integrity of Respondent's research. Respondent will not participate in any PHS-supported research until such a supervision plan is approved by ORI. Respondent will comply with the agreed-upon supervision plan.

(2) The requirements for Respondent's supervision plan are as follows:

i. A committee of 2–3 senior faculty members at the institution who are familiar with Respondent's field of research, but not including Respondent's supervisor or collaborators, will provide oversight and guidance for a period of three (3) years from the effective date of the Agreement. The committee will review primary data from Respondent's laboratory on a quarterly basis and submit a report to ORI at six (6)-month intervals setting forth the committee meeting dates and Respondent's compliance with appropriate research standards and confirming the integrity of Respondent's research.

ii. The committee will conduct an advance review of each application for PHS funds, or report, manuscript, or abstract involving PHS-supported research in which Respondent is involved. The review will include a discussion with Respondent of the primary data represented in those documents and will include a certification to ORI that the data presented in the proposed application, report, manuscript, or abstract are supported by the research record.

(3) During the Supervision Period, Respondent will ensure that any institution employing him submits, in conjunction with each application for PHS funds, or report, manuscript, or abstract involving PHS-supported research in which Respondent is involved, a certification to ORI that the data provided by Respondent are based on actual experiments or are otherwise legitimately derived and that the data, procedures, and methodology are accurately reported and not plagiarized in the application, report, manuscript, or abstract.

(4) If no supervision plan is provided to ORI, Respondent will provide certification to ORI at the conclusion of the Supervision Period that his participation was not proposed on a research project for which an application for PHS support was submitted and that he has not participated in any capacity in PHS-supported research.

(5) During the Supervision Period, Respondent will exclude himself voluntarily from serving in any advisory or consultant capacity to PHS including, but not limited to, service on any PHS advisory committee, board, and/or peer review committee.

Dated: April 28, 2023.

Sheila Garrity,

Director, Office of Research Integrity, Office of the Assistant Secretary for Health.

[FR Doc. 2023–09355 Filed 5–2–23; 8:45 am]

BILLING CODE 4150–31–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Community Health Aide Program: Tribal Planning & Implementation

Announcement Type: New.

Funding Announcement Number: HHS–2023–IHS–TPI–0001.

Assistance Listing (Catalog of Federal Domestic Assistance or CFDA) Number: 93.382.

Key Dates

Application Deadline Date: August 1, 2023.

Earliest Anticipated Start Date: September 15, 2023.

I. Funding Opportunity Description

Statutory Authority

The Indian Health Service (IHS) is accepting applications for grants for the Community Health Aide Program (CHAP) Tribal Planning and Implementation (TPI) program. The CHAP is authorized under the Snyder Act, 25 U.S.C. 13; the Transfer Act, 42 U.S.C. 2001(a); and the Indian Health Care Improvement Act, 25 U.S.C. 1616l. The Assistance Listings section of SAM.gov (*https://sam.gov/content/home*) describes this program under 93.382.

Background

The national CHAP will provide a network of health aides trained to support licensed health professionals while providing direct health care, health promotion, and disease prevention services. These providers will work within a referral relationship under the supervision of licensed clinical providers that includes clinics, service units, and hospitals. The program will increase access to direct health services, including inpatient and outpatient visits.

The Alaska CHAP has become a model for efficient and high quality health care delivery in rural Alaska providing approximately 300,000 patient encounters per year and responding to emergencies 24 hours a day, 7 days a week. Specialized providers in dental and behavioral health were later introduced to respond to the needs of patients and address the health disparities in oral health and mental health amongst American Indians and Alaska Natives.

The national CHAP is a workforce model that includes three different provider types that act as extenders of licensed clinical supervisors. The national CHAP currently includes a behavioral health aide, community health aide, and dental health aide. Each of the health aide categories operate in a tiered level practice system. The national CHAP model provides an opportunity for increased access to care through the extension of primary care, dental, and behavioral health clinicians.

In 2010, under the permanent reauthorization of the Indian Health Care Improvement Act (IHCIA), Congress provided the Secretary of Health and Human Services, acting through the IHS, the authority to expand the Alaska CHAP program. In 2016, the IHS initiated Tribal Consultation on expanding the CHAP to the contiguous 48 states. In 2018, the IHS formed the CHAP Tribal Advisory Group (TAG) and began developing the program. In 2020, the IHS announced the national CHAP policy, which formally created the national CHAP.

Purpose

The purpose of the TPI program is to support the planning and implementation for Tribes and Tribal Organizations (T/TO) positioned to begin operating a CHAP or support a growing CHAP in the contiguous 48 states. The program is designed to support the regional flexibility required to implement a CHAP unique to the needs of individual Tribal communities across the country through the identification of feasibility factors. The focus of the program is to:

1. Develop clinical supervisor support for primary care, behavioral health, and dental health clinicians providing both direct and indirect supervision of prospective health aides;

2. Identify area and community-specific health care needs of patients that can be addressed by the health aides;

3. Identify and develop a technology infrastructure plan for the mobility and success of health aides in anticipation of providing services;

4. Develop a training plan to include partners across the T/TO's geographic region to enhance the training opportunities available to prospective health aides to include continuing education and clinical practice;

5. Identify best practices for integrating a CHAP workforce into an existing Tribal health system;

6. Address social determinants of health that impact the recruitment and retention of prospective health aides; and

7. Identify the total cost of full implementation of a CHAP within an existing Tribal health system.

II. Award Information

Funding Instrument—Grant

Estimated Funds Available

The total funding identified for fiscal year (FY) 2023 is approximately $3,000,000. Individual award amounts are anticipated to be between $900,000 and $1,000,000. The funding available for competing and subsequent continuation awards issued under this announcement is subject to the availability of appropriations and budgetary priorities of the Agency. The IHS is under no obligation to make awards that are selected for funding under this announcement.

Anticipated Number of Awards

Approximately three to five awards will be issued under this program announcement. The IHS intends to award no more than one grant per IHS area.

Period of Performance

The period of performance is 2 years.

I. Eligibility Information

1. Eligibility

To be eligible for this funding opportunity, an applicant must be one of the following as defined under 25 U.S.C. 1603:

- A federally recognized Indian Tribe as defined by 25 U.S.C. 1603(14). The term ''Indian Tribe'' means any Indian Tribe, band, nation, or other organized group or community, including any Alaska Native village or group, or regional or village corporation, as defined in or established pursuant to the Alaska Native Claims Settlement Act (85 Stat. 688) [43 U.S.C. 1601 *et seq.*], which is recognized as eligible for the special programs and services provided by the United States (U.S.) to Indians because of their status as Indians.
- A Tribal organization as defined by 25 U.S.C. 1603(26). The term ''Tribal organization'' has the meaning given the term in Section 4 of the Indian Self-Determination and Education Assistance Act (25 U.S.C. 5304(l)): ''Tribal organization'' means the recognized governing body of any Indian Tribe; any legally established organization of Indians which is controlled, sanctioned, or chartered by such governing body or which is democratically elected by the adult members of the Indian community to be served by such organization and which includes the maximum participation of Indians in all phases of its activities: provided that, in any case where a contract is let or grant made to an organization to perform services benefiting more than one Indian Tribe, the approval of each such Indian Tribe shall be a prerequisite to the letting or making of such contract or grant. Applicant shall submit letters of support and/or Tribal Resolutions from the Tribes to be served.

The Division of Grants Management (DGM) will notify any applicants deemed ineligible.

2. Additional Information on Eligibility

The IHS does not fund concurrent projects. If an applicant is successful under this announcement, any subsequent applications in response to other TPI announcements from the same applicant will not be funded. Applications on behalf of individuals (including sole proprietorships) and foreign organizations are not eligible and will be disqualified from competitive review and funding under this funding opportunity.

Specifically, an applicant may not apply to both this opportunity, TPI, and the CHAP Tribal Assessment and Planning (TAP) opportunity (number HHS–2023–IHS–TAP–0001).

An organization currently carrying out a CHAP in the U.S. in accordance with 25 U.S.C. 1616l through an Indian Self-Determination and Education Assistance Act (ISDEAA) agreement is eligible to apply, but may not utilize the funds to carry out a CHAP.

Note: Please refer to Section IV.2 (Application and Submission Information/ Subsection 2, Content and Form of Application Submission) for additional proof of applicant status documents required, such as Tribal Resolutions, proof of non-profit status, etc.

3. Cost Sharing or Matching

The IHS does not require matching funds or cost sharing for grants or cooperative agreements.

4. Other Requirements

Applications with budget requests that exceed the highest dollar amount outlined under Section II Award Information, Estimated Funds Available, or exceed the period of performance outlined under Section II Award Information, Period of Performance, are considered not responsive and will not be reviewed. The DGM will notify the applicant.

Additional Required Documentation

Tribal Resolution

The DGM must receive an official, signed Tribal Resolution prior to issuing a Notice of Award (NoA) to any T/O selected for funding. An applicant that is proposing a project affecting another Indian Tribe must include resolutions from all affected Tribes to be served. However, if an official signed Tribal Resolution cannot be submitted with the application prior to the application deadline date, a draft Tribal Resolution must be submitted with the application by the deadline date in order for the application to be considered complete and eligible for review. The draft Tribal Resolution is not in lieu of the required signed resolution but is acceptable until a signed resolution is received. If an application without a signed Tribal Resolution is selected for funding, the applicant will be contacted by the Grants Management Specialist (GMS) listed in this funding announcement and given 90 days to submit an official signed Tribal Resolution to the GMS. If the signed Tribal Resolution is not received within 90 days, the award will be forfeited.

Applicants organized with a governing structure other than a Tribal council may submit an equivalent document commensurate with their governing organization.

Proof of Nonprofit Status

Organizations claiming nonprofit status must submit a current copy of the 501(c)(3) Certificate with the application.

IV. Application and Submission Information

Grants.gov uses a Workspace model for accepting applications. The Workspace consists of several online forms and three forms in which to upload documents—Project Narrative, Budget Narrative, and Other Documents. Give your files brief descriptive names. The filenames are key in finding specific documents during the objective review and in processing awards. Upload all requested and optional documents individually, rather than combining them into a single file. Creating a single file creates confusion when trying to find specific documents. Such confusion can contribute to delays in processing awards, and could lead to lower scores during the objective review.

1. Obtaining Application Materials

The application package and detailed instructions for this announcement are available on *https://www.Grants.gov.*

Please direct questions regarding the application process to *DGM@ihs.gov.*

2. Content and Form Application Submission

Mandatory documents for all applicants include:

- Application forms:

1. SF–424, Application for Federal Assistance.

2. SF–424A, Budget Information—Non-Construction Programs.

3. SF–424B, Assurances—Non-Construction Programs.

4. Project Abstract Summary form.

- Project Narrative (not to exceed 15 pages). See Section IV.2.A Project Narrative for instructions.

1. Background information on the organization.

2. Proposed scope of work, objectives, and activities that provide a description of what the applicant plans to accomplish.

- Budget Justification and Narrative (not to exceed 5 pages). See Section IV.2.B Budget Narrative for instructions.
- One-page Timeframe Chart.
- Tribal Resolution(s).
- Letters of Support from organization's Board of Directors (if applicable).
- 501(c)(3) Certificate.
- Biographical sketches for all Key Personnel.
- Contractor/Consultant resumes or qualifications and scope of work.
- Disclosure of Lobbying Activities (SF–LLL), if applicant conducts reportable lobbying.
- Certification Regarding Lobbying (GG-Lobbying Form).
- Copy of current Negotiated Indirect Cost rate (IDC) agreement (required in order to receive IDC).
- Organizational Chart (optional).
- Documentation of current Office of Management and Budget (OMB) Financial Audit (if applicable).

Acceptable forms of documentation include:

1. Email confirmation from Federal Audit Clearinghouse (FAC) that audits were submitted; or

2. Face sheets from audit reports. Applicants can find these on the FAC website at *https://facdissem.census.gov/.*

Public Policy Requirements

All Federal public policies apply to IHS grants and cooperative agreements. Pursuant to 45 CFR 80.3(d), an individual shall not be deemed subjected to discrimination by reason of their exclusion from benefits limited by Federal law to individuals eligible for benefits and services from the IHS. See *https://www.hhs.gov/grants/grants/grants-policies-regulations/index.html.*

Requirements for Project and Budget Narratives

A. *Project Narrative:* This narrative should be a separate document that is no more than 15 pages and must: (1) have consecutively numbered pages; (2) use black font 12 points or larger; (3) be single-spaced; and (4) be formatted to fit standard letter paper (8½ × 11 inches). Do not combine this document with any others.

Be sure to succinctly answer all questions listed under the evaluation criteria (refer to Section V.1, Evaluation Criteria) and place all responses and required information in the correct section noted below or they will not be considered or scored. If the narrative exceeds the page limit, the reviewers will be directed to ignore any content beyond the page limit. The 15-page limit for the project narrative does not include the work plan, standard forms, Tribal Resolutions, budget, budget narratives, and/or other items. Page limits for each section within the project narrative are guidelines, not hard limits.

There are three parts to the project narrative: Part 1—Program Information; Part 2—Program Planning; Part 3—Program Evaluation; and Part 4—Program Report. See below for additional details about what must be included in the narrative.

The page limits below are for each narrative and budget submitted.

Part 1: Program Information (limit—4 pages)

Section 1: Community Profile

Describe the demographics of the community including but not limited to geography, languages, age, and socioeconomic status. The community profile should include data specific to the community that would benefit from the implementation of the CHAP. Include a brief summary of information obtained through use of a Tribal and Assessment Planning Grant if applicable.

Section 2: Health & Infrastructure Needs

Describe the community's current health disparities related to primary, behavioral, and oral health care. The needs section should provide facts and evidence related to infrastructure barriers (*e.g.,* recruitment, retention, and access to facilities). Include a brief summary of information obtained through use of a Tribal and Assessment Planning Grant if applicable.

Section 3: Organizational Capacity

Describe the T/TO's current health program activities, how long it has been operating, and what programs or services are currently being provided. Describe in full the organization's infrastructure and its ability to assess the feasibility of implementing a CHAP and identifying significant barriers that could prohibit the implementation. Include a brief summary of any information obtained through use of a Tribal Assessment and Planning Grant.

Part 2: Program Planning and Evaluation (limit—6 pages)

Section 1: Program Plans

Describe in full the direction the T/TO plans to take in the CHAP TPI. The program plan should identify the plan, including how all aspects of the implementation will be based in Tribal culture and how the program plan will address Tribal infrastructure needs specific to:

- Clinical infrastructure and clinical operations.
- Workforce development including supervision plans for CHAP providers that address community and region specific needs.
- Training infrastructure (including continuing education).
- Technology infrastructure.
- System integration.
- Implementation cost.

Section 2: Program Activities

Describe in full how the applicant will develop a robust clinical infrastructure to support clinical operations specific to CHAP providers. The activities should include how the applicant will correlate the community health needs with the CHAP program needs, including specific cultural elements. Include how the applicant will develop position descriptions, the scope of work of health aides, policy development, and a detailed plan of how to adjust the clinical operations to incorporate CHAP providers. Describe how CHAP providers will be trained, specific to the regional resources, include continuing education training plans. Describe how the CHAP providers will be supervised including staffing plans for CHAP provider supervision. List the available technology and detail how the current technology infrastructure will be utilized to support the CHAP providers, including aiding in provider mobility or how it will be built specific to the needs of the CHAP program, both at the provider and the clinic level. Detail how the CHAP program will be integrated with the current system to provide maximization of provider and program to improve community health, including cultural components the program is uniquely positioned or

designed to address. Provide a detailed plan of how the award funds will be used by the applicant to implement the CHAP program, specific to the above implementation components.

Section 3: Staffing Plan

Describe key staff tasked with carrying out the program activities carried out in Section 2. Applicants are highly encouraged to partner with other key stakeholders within the T/TO's region for a robust understanding of the needs and implications of implementing a CHAP into their respective communities.

Section 4: Timeline

Describe a timeline not to exceed 2 years for the completion of the program plan, activities, and evaluation plan. Provide a timeline chart depicting a realistic timeline that details all major activities, milestones, and applicable staffing plans. The timeline should include the projected progress report due at the midpoint of the project period. The timeline chart should not exceed one page.

Part 3: Program Evaluation

Section 1: Evaluation Plan

Please identify and describe significant program activities and achievements associated with the delivery of quality health services. Provide a plan to provide a comparison of the actual accomplishments to the goals established for the project period, or if applicable, provide justification for the lack of progress. The evaluation plan should address major categories related to (See Logic Model in Appendix):

- Clinical infrastructure and clinical operations. Describe how clinical infrastructure and operations have changed to incorporate and integrate the CHAP program. Include any data on referrals to CHAP providers, number of clinic providers making referrals to CHAP providers and demonstrated increases in health promotion and disease prevention efforts.
- Workforce development including supervision plans for CHAP providers that address community and region specific needs. Include data on outreach and recruiting activities, number of CHAP applications received, supervisors trained for each provider type.
- Training infrastructure (including continuing education). Describe where the training for each CHAP discipline will be provided and whether it will be delivered in person, virtually or hybrid. Summarize how oversight will be maintained to assure a high-quality training is achieved. Detail how each aspiring or advancing CHAP provider will be supported and supervised throughout any hands-on training. Include data on each item if available.
- Technology infrastructure. Describe what technology will be used and how it supports the CHAP program. Detail any changes made to existing technology infrastructure to incorporate CHAP providers. Include how CHAP provider charting will be integrated into electronic health records. List specific technology purchased or transferred to the CHAP program to support CHAP providers. Include information on network accessibility, specifically any barriers to accessibility and how this can be overcome.
- System integration. Describe in detail what barriers to integration have been overcome and how. List patient outreach and education, trainings provided to clinic staff, trainings specific to providers on how CHAP providers will integrate and extend licensed providers to achieve best practices and health benefits. Describe specific populations where CHAP may be focused such as prenatal, child vaccination, dental sealant placement, substance abuse screening, hospital discharge follow up, etc., and how the CHAP providers integrate their visits with existing clinic systems. Include any data that supports system integration changes.
- Implementation cost. Provide details on budgeted items, explaining any overages and what happened that created overages. Explain how any excess funds were re-allocated to fully utilize all grant funds.

Part 4: Program Report (limit—5 pages)

Section 1: Describe your organization's significant program activities and accomplishments over the past 5 years associated with the goals of this announcement. Please identify and describe significant program activities and achievements associated with the planning and implementation of the CHAP program. Provide a comparison of the actual accomplishments to the goals established for the project period, or if applicable, provide justification for the lack of progress.

B. Budget Narrative (limit—5 pages)

Provide a budget narrative that explains the amounts requested for each line item of the budget from the SF–424A (Budget Information for Non-Construction Programs) for the first year of the project. The applicant can submit with the budget narrative a more detailed spreadsheet than is provided by the SF–424A (the spreadsheet will not be considered part of the budget narrative). The budget narrative should specifically describe how each item would support the achievement of proposed objectives. Be very careful about showing how each item in the ''Other'' category is justified. Do NOT use the budget narrative to expand the project narrative.

3. Submission Dates and Times

Applications must be submitted through *Grants.gov* by 11:59 p.m. Eastern Time on the Application Deadline Date. Any application received after the application deadline will not be accepted for review. *Grants.gov* will notify the applicant via email if the application is rejected.

If technical challenges arise and assistance is required with the application process, contact *Grants.gov* Customer Support (see contact information at *https://www.Grants.gov*). If problems persist, contact Mr. Paul Gettys, Deputy Director, DGM, by email at *DGM@ihs.gov.* Please be sure to contact Mr. Gettys at least 10 days prior to the application deadline. Please do not contact the DGM until you have received a *Grants.gov* tracking number. In the event you are not able to obtain a tracking number, call the DGM as soon as possible.

The IHS will not acknowledge receipt of applications.

4. Intergovernmental Review

Executive Order 12372 requiring intergovernmental review is not applicable to this program.

5. Funding Restrictions

- Pre-award costs are allowable up to 90 days before the start date of the award provided the costs are otherwise allowable if awarded. Pre-award costs are incurred at the risk of the applicant.
- The available funds are inclusive of direct and indirect costs.
- Only one grant may be awarded per applicant.

6. Electronic Submission Requirements

All applications must be submitted via *Grants.gov*. Please use the *https://www.Grants.gov* website to submit an application. Find the application by selecting the ''Search Grants'' link on the homepage. Follow the instructions for submitting an application under the Package tab. No other method of application submission is acceptable.

If you cannot submit an application through *Grants.gov*, you must request a waiver prior to the application due date. You must submit your waiver request by email to *DGM@ihs.gov.* Your waiver request must include clear justification for the need to deviate from the required

application submission process. The IHS will not accept any applications submitted through any means outside of *Grants.gov* without an approved waiver.

If the DGM approves your waiver request, you will receive a confirmation of approval email containing submission instructions. You must include a copy of the written approval with the application submitted to the DGM. Applications that do not include a copy of the waiver approval from the DGM will not be reviewed. The Grants Management Officer of the DGM will notify the applicant via email of this decision. Applications submitted under waiver must be received by the DGM no later than 5:00 p.m. Eastern Time on the Application Deadline Date. Late applications will not be accepted for processing. Applicants that do not register for both the System for Award Management (SAM) and *Grants.gov* and/or fail to request timely assistance with technical issues will not be considered for a waiver to submit an application via alternative method.

Please be aware of the following:

- Please search for the application package in *https://www.Grants.gov* by entering the Assistance Listing number or the Funding Opportunity Number. Both numbers are located in the header of this announcement.
- If you experience technical challenges while submitting your application, please contact *Grants.gov* Customer Support (see contact information at *https://www.Grants.gov*).
- Upon contacting *Grants.gov*, obtain a tracking number as proof of contact. The tracking number is helpful if there are technical issues that cannot be resolved and a waiver from the agency must be obtained.
- Applicants are strongly encouraged not to wait until the deadline date to begin the application process through *Grants.gov* as the registration process for SAM and *Grants.gov* could take up to 20 working days.
- Please follow the instructions on *Grants.gov* to include additional documentation that may be requested by this funding announcement.
- Applicants must comply with any page limits described in this funding announcement.
- After submitting the application, you will receive an automatic acknowledgment from *Grants.gov* that contains a *Grants.gov* tracking number. The IHS will not notify you that the application has been received.

System for Award Management

Organizations that are not registered with the System for Award Management (SAM) must access the SAM online registration through the SAM home page at *https://sam.gov.* Organizations based in the U.S. will also need to provide an Employer Identification Number from the Internal Revenue Service that may take an additional 2–5 weeks to become active. Please see *SAM.gov* for details on the registration process and timeline. Registration with the SAM is free of charge but can take several weeks to process. Applicants may register online at *https://sam.gov.*

Unique Entity Identifier

Your *SAM.gov* registration now includes a Unique Entity Identifier (UEI), generated by *SAM.gov*, which replaces the DUNS number obtained from Dun and Bradstreet. *SAM.gov* registration no longer requires a DUNS number.

Check your organization's *SAM.gov* registration as soon as you decide to apply for this program. If your *SAM.gov* registration is expired, you will not be able to submit an application. It can take several weeks to renew it or resolve any issues with your registration, so do not wait.

Check your *Grants.gov* registration. Registration and role assignments in *Grants.gov* are self-serve functions. One user for your organization will have the authority to approve role assignments, and these must be approved for active users in order to ensure someone in your organization has the necessary access to submit an application.

The Federal Funding Accountability and Transparency Act of 2006, as amended (''Transparency Act''), requires all HHS awardees to report information on sub-awards. Accordingly, all IHS awardees must notify potential first-tier sub-awardees that no entity may receive a first-tier sub-award unless the entity has provided its UEI number to the prime awardee organization. This requirement ensures the use of a universal identifier to enhance the quality of information available to the public pursuant to the Transparency Act.

Additional information on implementing the Transparency Act, including the specific requirements for SAM, are available on the DGM Grants Management, Policy Topics web page at *https://www.ihs.gov/dgm/policytopics/.*

V. Application Review Information

Possible points assigned to each section are noted in parentheses. The project narrative and budget narrative should include only the first year of activities. The project narrative should be written in a manner that is clear to outside reviewers unfamiliar with prior related activities of the applicant. It should be well organized, succinct, and contain all information necessary for reviewers to fully understand the project. Attachments requested in the criteria do not count toward the page limit for the narratives. Points will be assigned to each evaluation criteria adding up to a total of 100 possible points. Points are assigned as follows:

1. Evaluation Criteria

A. Introduction and Need for Assistance (10 points)

Identify the proposed project and plans to fully implement a CHAP within their community. The needs should clearly identify the existing health system and how the CHAP will be integrated to meet the health needs of the community in the fields of behavioral, oral, and primary health care.

B. Project Objective(s), Work Plan, and Approach (30 points)

The work plan should be comprised of two key parts: Program Information and Program Plan. Provide information related to three key sections: community profile; health and infrastructure; and organizational capacity. The Program Information part should demonstrate a robust community profile that highlights the existing health system, demographical data of community members and user population, and a detailed description of the T/TO carrying out the proposed activity. An acceptable Program Plan expecting to receive full points should include details of the applicants plan to address the program objective. The Program Plan should address at a minimum key activities related to clinical supervisor support, scope of work, technology infrastructure, training infrastructure, integration best practices, and auxiliary support to health aides that address social determinants.

C. Program Evaluation (30 points)

The program evaluation should be comprised of two key sections: evaluation plan and outcome report. The evaluation plan should address major categories related to clinical supervisor support, enhanced scope of work, technology infrastructure, training infrastructure, integration best practices, auxiliary support, and full implementation costs (See Sample Logic Model in Appendix). The evaluation plan should identify how the T/TO plans to fully integrate CHAP. The evaluation should include total implementation costs based on the implementation plan and program plan identified including any significant

implementation barriers. List measurable and attainable goals with explicit timelines that detail expectation of findings. The Outcome Report should describe in full the findings of the program plan, evaluation, determination on stage of readiness for implementation and implementation activities. The outcome report should organize the findings into at least five of the six categories:

1. Clinical infrastructure and clinical operations.
2. Workforce development including supervision plans for CHAP providers that address community and region specific needs.
3. Training infrastructure (including continuing education).
4. Technology infrastructure.
5. System integration.
6. Implementation cost.

Applicants are encouraged to identify additional categories above these six and may choose to develop subcategories that best fit the program plan.

D. Organizational Capabilities, Key Personnel, and Qualifications (10 points)

Provide a detailed biographical sketch of each member of key personnel assigned to carry out the objectives of the program plan. The sketches should detail the qualifications and expertise of identified staff.

E. Categorical Budget and Budget Justification (20 points)

Provide a detailed budget of each expenditure directly related to the identified program activities.

Additional documents can be uploaded as Other Attachments in *Grants.gov*. These can include:

- Work plan, logic model, and/or timeline for proposed objectives.
- Position descriptions for key staff.
- Resumes of key staff that reflect current duties.
- Consultant or contractor proposed scope of work and letter of commitment (if applicable).
- Current Indirect Cost Rate Agreement.
- Organizational chart.
- Map of area identifying project location(s).
- Additional documents to support narrative (*i.e.* data tables, key news articles, etc.).

2. Review and Selection

Each application will be prescreened for eligibility and completeness as outlined in this funding announcement. Applications that meet the eligibility criteria shall be reviewed for merit by the Review Committee (RC) based on the evaluation criteria. Incomplete applications and applications that are not responsive to the administrative thresholds (budget limit, period of performance limit) will not be referred to the RC and will not be funded. The DGM will notify the applicant of this determination.

Applicants must address all program requirements and provide all required documentation.

3. Notifications of Disposition

All applicants will receive an Executive Summary Statement from the IHS Office of Clinical and Preventive Services within 30 days of the conclusion of the RC outlining the strengths and weaknesses of their application. The summary statement will be sent to the Authorizing Official identified on the face page (SF–424) of the application.

A. Award Notices for Funded Applications

The NoA is the authorizing document for which funds are dispersed to the approved entities and reflects the amount of Federal funds awarded, the purpose of the award, the terms and conditions of the award, the effective date of the award, the budget period, and period of performance. Each entity approved for funding must have a user account in GrantSolutions in order to retrieve the NoA. Please see the Agency Contacts list in Section VII for the systems contact information.

B. Approved but Unfunded Applications

Approved applications not funded due to lack of available funds will be held for 1 year. If funding becomes available during the course of the year, the application may be reconsidered.

Note: Any correspondence other than the official NoA executed by an IHS grants management official announcing to the project director that an award has been made to their organization is not an authorization to implement their program on behalf of the IHS.

VI. Award Administration Information

1. Administrative Requirements

Awards issued under this announcement are subject to, and are administered in accordance with, the following regulations and policies:

A. The criteria as outlined in this program announcement.

B. *Administrative Regulations for Grants:*

- Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards currently in effect or implemented during the period of award, other Department regulations and policies in effect at the time of award, and applicable statutory provisions. At the time of publication, this includes 45 CFR part 75, at *https://www.govinfo.gov/content/pkg/CFR-2021-title45-vol1/pdf/CFR-2021-title45-vol1-part75.pdf.*
- Please review all HHS regulatory provisions for Termination at 45 CFR 75.372, at the time of this publication located at *https://www.govinfo.gov/content/pkg/CFR-2021-title45-vol1/pdf/CFR-2021-title45-vol1-sec75-372.pdf.*

C. *Grants Policy:*

- HHS Grants Policy Statement, Revised January 2007, at *https://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf.*

D. *Cost Principles:*

- Uniform Administrative Requirements for HHS Awards, ''Cost Principles,'' at 45 CFR part 75 subpart E, at the time of this publication located at *https://www.govinfo.gov/content/pkg/CFR-2021-title45-vol1/pdf/CFR-2021-title45-vol1-part75-subpartE.pdf.*

E. *Audit Requirements:*

- Uniform Administrative Requirements for HHS Awards, ''Audit Requirements,'' at 45 CFR part 75 subpart F, at the time of this publication located at *https://www.govinfo.gov/content/pkg/CFR-2021-title45-vol1/pdf/CFR-2021-title45-vol1-part75-subpartF.pdf.*

F. As of August 13, 2020, 2 CFR part 200 was updated to include a prohibition on certain telecommunications and video surveillance services or equipment. This prohibition is described in 2 CFR part 200.216. This will also be described in the terms and conditions of every IHS grant and cooperative agreement awarded on or after August 13, 2020.

2. Indirect Costs

This section applies to all recipients that request reimbursement of IDC in their application budget. In accordance with HHS Grants Policy Statement, Part II–27, the IHS requires applicants to obtain a current IDC rate agreement and submit it to the DGM prior to the DGM issuing an award. The rate agreement must be prepared in accordance with the applicable cost principles and guidance as provided by the cognizant agency or office. A current rate covers the applicable award activities under the current award's budget period. If the current rate agreement is not on file with the DGM at the time of award, the IDC portion of the budget will be restricted. The restrictions remain in

place until the current rate agreement is provided to the DGM.

Per 2 CFR 200.414(f) Indirect (F&A) costs,

> any non-Federal entity (NFE) [*i.e.,* applicant] that does not have a current negotiated rate, . . . may elect to charge a de minimis rate of 10 percent of modified total direct costs which may be used indefinitely. As described in Section 200.403, costs must be consistently charged as either indirect or direct costs, but may not be double charged or inconsistently charged as both. If chosen, this methodology once elected must be used consistently for all Federal awards until such time as the NFE chooses to negotiate for a rate, which the NFE may apply to do at any time.

Electing to charge a de minimis rate of 10 percent can be used by applicants that have received an approved negotiated indirect cost rate from HHS or another cognizant Federal agency. Applicants awaiting approval of their indirect cost proposal may request the 10 percent de minimis rate. When the applicant chooses this method, costs included in the indirect cost pool must not be charged as direct costs to the award.

Available funds are inclusive of direct and appropriate indirect costs. Approved indirect funds are awarded as part of the award amount, and no additional funds will be provided.

Generally, IDC rates for IHS recipients are negotiated with the Division of Cost Allocation at *https://rates.psc.gov/* or the Department of the Interior (Interior Business Center) at *https://ibc.doi.gov/ICS/tribal.* For questions regarding the indirect cost policy, please write to *DGM@ihs.gov.*

3. Reporting Requirements

The recipient must submit required reports consistent with the applicable deadlines. Failure to submit required reports within the time allowed may result in suspension or termination of an active award, withholding of additional awards for the project, or other enforcement actions such as withholding of payments or converting to the reimbursement method of payment. Continued failure to submit required reports may result in the imposition of special award provisions and/or the non-funding or non-award of other eligible projects or activities. This requirement applies whether the delinquency is attributable to the failure of the recipient organization or the individual responsible for preparation of the reports. Per DGM policy, all reports must be submitted electronically by attaching them as a ''Grant Note'' in GrantSolutions. Personnel responsible for submitting reports will be required to obtain a login and password for GrantSolutions. Please use the form under the Recipient User section of *https://www.grantsolutions.gov/home/getting-started-request-a-user-account/.* Download the Recipient User Account Request Form, fill it out completely, and submit it as described on the web page and in the form.

The reporting requirements for this program are noted below.

A. Progress Reports

Program progress reports are required annually. The progress reports are due within 90 days after the budget period ends (specific dates will be listed in the NoA Terms and Conditions). These reports must include a brief comparison of actual accomplishments to the goals established for the period, a summary of progress to date or, if applicable, provide sound justification for the lack of progress, and other pertinent information as required. A final report must be submitted within 120 days of expiration of the period of performance.

B. Financial Reports

Federal Financial Reports are due 90 days after the end of each budget period, and a final report is due 120 days after the end of the period of performance. Recipients are responsible and accountable for reporting accurate information on all required reports: the Progress Reports and the Federal Financial Report.

Failure to submit timely reports may result in adverse award actions blocking access to funds.

C. Data Collection and Reporting

At the conclusion of the program period, the outcome report should detail how the T/TO plans to completely integrate CHAP into their Tribal health system and list major barriers that could potentially impact full integration. The Outcome Report should describe in full the findings of the program plan and evaluation, and plans for implementation. The outcome report should organize the findings of the key categories:

1. Clinical Supervisor Support.
2. Scope of Practice.
3. Technology Infrastructure.
4. Training Plan.
5. System Integration.
6. Auxiliary Support to Address Social Determinants.

Based on the findings and measureable outcomes of the categories, the applicant should explicitly identify the implementation plan and projected cost associated with full implementation.

D. Federal Sub-Award Reporting System (FSRS)

This award may be subject to the Transparency Act sub-award and executive compensation reporting requirements of 2 CFR part 170.

The Transparency Act requires the OMB to establish a single searchable database, accessible to the public, with information on financial assistance awards made by Federal agencies. The Transparency Act also includes a requirement for recipients of Federal awards to report information about first-tier sub-awards and executive compensation under Federal assistance awards.

The IHS has implemented a Term of Award into all IHS Standard Terms and Conditions, NoAs, and funding announcements regarding the FSRS reporting requirement. This IHS Term of Award is applicable to all IHS grant and cooperative agreements issued on or after October 1, 2010, with a $25,000 sub-award obligation threshold met for any specific reporting period.

For the full IHS award term implementing this requirement and additional award applicability information, visit the DGM Grants Management website at *https://www.ihs.gov/dgm/policytopics/.*

E. Non-Discrimination Legal Requirements for Awardees of Federal Financial Assistance (FFA)

The recipient must administer the project in compliance with Federal civil rights laws, where applicable, that prohibit discrimination on the basis of race, color, national origin, disability, age, and comply with applicable conscience protections. The recipient must comply with applicable laws that prohibit discrimination on the basis of sex, which includes discrimination on the basis of gender identity, sexual orientation, and pregnancy. Compliance with these laws requires taking reasonable steps to provide meaningful access to persons with limited English proficiency and providing programs that are accessible to and usable by persons with disabilities. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. See *https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html* and *https://www.hhs.gov/civil-rights/for-individuals/nondiscrimination/index.html.*

- Recipients of FFA must ensure that their programs are accessible to persons with limited English proficiency. For guidance on meeting your legal obligation to take reasonable steps to

ensure meaningful access to your programs or activities by limited English proficiency individuals, see *https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html* and *https://www.lep.gov.*

- For information on your specific legal obligations for serving qualified individuals with disabilities, including reasonable modifications and making services accessible to them, see *https://www.hhs.gov/civil-rights/for-individuals/disability/index.html.*
- HHS funded health and education programs must be administered in an environment free of sexual harassment. See *https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html.*
- For guidance on administering your program in compliance with applicable Federal religious nondiscrimination laws and applicable Federal conscience protection and associated anti-discrimination laws, see *https://www.hhs.gov/conscience/conscience-protections/index.html* and *https://www.hhs.gov/conscience/religious-freedom/index.html.*
- Pursuant to 45 CFR 80.3(d), an individual shall not be deemed subjected to discrimination by reason of their exclusion from benefits limited by Federal law to individuals eligible for benefits and services from the IHS.

F. Federal Awardee Performance and Integrity Information System (FAPIIS)

The IHS is required to review and consider any information about the applicant that is in the FAPIIS at *https://www.fapiis.gov/fapiis/#/home* before making any award in excess of the simplified acquisition threshold (currently $250,000) over the period of performance. An applicant may review and comment on any information about itself that a Federal awarding agency previously entered. The IHS will consider any comments by the applicant, in addition to other information in FAPIIS, in making a judgment about the applicant's integrity, business ethics, and record of performance under Federal awards when completing the review of risk posed by applicants, as described in 45 CFR 75.205.

As required by 45 CFR part 75 Appendix XII of the Uniform Guidance, NFEs are required to disclose in FAPIIS any information about criminal, civil, and administrative proceedings, and/or affirm that there is no new information to provide. This applies to NFEs that receive Federal awards (currently active grants, cooperative agreements, and procurement contracts) greater than $10 million for any period of time during the period of performance of an award/project.

Mandatory Disclosure Requirements

As required by 2 CFR part 200 of the Uniform Guidance, and the HHS implementing regulations at 45 CFR part 75, the IHS must require an NFE or an applicant for a Federal award to disclose, in a timely manner, in writing to the IHS or pass-through entity all violations of Federal criminal law involving fraud, bribery, or gratuity violations potentially affecting the Federal award. All applicants and recipients must disclose in writing, in a timely manner, to the IHS and to the HHS Office of Inspector General all information related to violations of Federal criminal law involving fraud, bribery, or gratuity violations potentially affecting the Federal award. 45 CFR 75.113.

Disclosures must be sent in writing to:

U.S. Department of Health and Human Services, Indian Health Service, Division of Grants Management, ATTN: Marsha Brookins, Director, 5600 Fishers Lane, Mail Stop: 09E70, Rockville, MD 20857, (Include ''Mandatory Grant Disclosures'' in subject line), Office: (301) 443–5204, Fax: (301) 594–0899, Email: *DGM@ihs.gov*.

and

U.S. Department of Health and Human Services, Office of Inspector General, ATTN: Mandatory Grant Disclosures, Intake Coordinator, 330 Independence Avenue SW, Cohen Building, Room 5527, Washington, DC 20201, URL: *https://oig.hhs.gov/fraud/report-fraud/*, (Include ''Mandatory Grant Disclosures'' in subject line,), Fax: (202) 205–0604 (Include ''Mandatory Grant Disclosures'' in subject line) or Email: *MandatoryGranteeDisclosures@oig.hhs.gov*.

Failure to make required disclosures can result in any of the remedies described in 45 CFR 75.371. Remedies for noncompliance, including suspension or debarment (see 2 CFR part 180 and 2 CFR part 376).

VII. Agency Contacts

1. Questions on the programmatic issues may be directed to: Donna E. Enfield, Public Health Advisor, Office of Clinical and Preventive Services, 5600 Fishers Lane, Mail Stop: 08N34A, Rockville, MD 20857, Phone: (301) 526–6966, Fax: (301) 594–6213, Email: *IHSCHAP@ihs.gov*.

2. Questions on grants management and fiscal matters may be directed to: Indian Health Service, Division of Grants Management, 5600 Fishers Lane, Mail Stop: 09E70, Rockville, MD 20857, Email: *DGM@ihs.gov*.

3. For technical assistance with *Grants.gov*, please contact the *Grants.gov* help desk at (800) 518–4726, or by email at *support@grants.gov.*

4. For technical assistance with GrantSolutions, please contact the GrantSolutions help desk at (866) 577–0771, or by email at *help@grantsolutions.gov.*

VIII. Other Information

The Public Health Service strongly encourages all grant, cooperative agreement, and contract recipients to provide a smoke-free workplace and promote the non-use of all tobacco products. In addition, Public Law 103–227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of the facility) in which regular or routine education, library, day care, health care, or early childhood development services are provided to children. This is consistent with the HHS mission to protect and advance the physical and mental health of the American people.

Roselyn Tso,

Director, Indian Health Service.

BILLING CODE 4165–16–P

Appendix

SAMPLE CHAP Tribal Planning and Implementation (TPI) Grant LOGIC MODEL			
Category	Assess	Solution for Implementation	Data
Clinical Supervisor Support	- CHAP integration will require two additional clinicians at the largest health care facility - Supervisory functions will account for 25 percent of the clinical staff job functions requiring a restructure	- Develop a Memorandum of Understanding (MOU) to share licensed clinicians across the facilities where 1 day a week clinicians serve as clinical supervisors - Reassess the clinic workload to evenly distribute the clinical supervision load amongst licensed staff - Develop training for licensed clinician on supervising paraprofessionals	- Number of clinics with eligible clinicians for supervision duties - Quantify the number of staff working within a care team in primary care, behavioral health, and dental health - Number of trainings by workforce on care team
Scope of Practice	- Instances of suicide ideation are 4x times higher in the community requiring additional training such as QPR for providers	- Partner with the local IHS facility and the Area office to recommend an additional 30 hours of training in suicide prevention	- Number of appropriate suicide prevention models that are culturally appropriate - Number of hours for training requirements above National Standards and Procedures

Technology Infrastructure	- Aim to station a behavioral health aide at the local school and a community health aide at the local community center, but there is a lack of internet or mobile technology for field notes	- Develop an MOU with non-clinical sites for space specific to providing health services. - Purchase tablets for the clinic to assign to health aides so they may enter field notes regardless of where they see patients.	- Number of non-clinical sites appropriate to station a behavioral, community, and dental health aide - Number of applicable level of health BHA, CHA, and DHA for each identified site - Projected costs for tablets for health aides - Projected cost for mobile internet for health aides
Training Infrastructure	- Tribe currently operates a training facility that needs to have an updated curriculum to align with the standards and procedures for training - The closest training facility for EMS is over 200 miles away - Tribe operates virtual continuing education that can be used for health aides with additional resources	- Develop an updated training curriculum and partnership plan to secure instructors to enhance the Tribe's current training facility. - Plan and indicate total costs to develop a local EMS training program through partnership with other Area Tribes to share across the region - Expand the topics for continuing education to make health aides eligible for CEs.	- Number of traditional practices appropriate (as determined by the Tribe) for primary care, behavioral health, and dental health to be including in training - Number of current training courses in comparison to the standards and procedures identified by either the Alaska CHAP Standards and Procedures or the National Standards and Procedures - Number of current on demand courses available for CEs

System Integration	- The existing care team is not aware of how to divide responsibilities in standards of care with the integration of CHAP	- Clearly plan and delineate duties with the integration of health aides - Reassess job duties for care team based on newly hired health aides predicated on scope of work - Develop on demand training for entire care team on the role of health aides to specify duties/limitations	- List of all the duties by care team members compared to duties for a health aide - Number of duties that overlap across the team that can be reassigned -
Support to Address SDOH	- Students graduating high school have expressed interest in studying oral health but there are no dental training options local to the community. - The local Tribal College that offers a mental health training associates degree has seen a decline in enrollment due to costs associated with textbooks, lack of childcare, and transportation support	- Begin planning to recruit local students into the field by clearly communicating time commitment for training, salary potential, and benefits - Develop stipends for childcare - Partner with the transportation system to provide discounted tickets using identified route to get from town to training	- Number of graduating students eligible for training - Number of potential training sites for partnership - Number of potential childcare sites for partnership for students - Cost to develop a distance delivered training program -

[FR Doc. 2023–09363 Filed 5–2–23; 8:45 am]
BILLING CODE 4165–16–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; R13 Conference Grant Applications.

Date: June 29, 2023.

Time: 10:00 a.m. to 12:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Democracy II, 6707 Democracy Blvd., Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Jian Yang, Ph.D., Scientific Review Officer, NIDDK/Scientific Review Branch, National Institutes of Health, 2 Democracy Plaza, Room 7011, 6707 Democracy Blvd., Bethesda, MD 20892–5452, (301) 594–7799, *jian.yang@nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: April 27, 2023.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023–09378 Filed 5–2–23; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; Notice of Closed Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Aging Special Emphasis Panel; Clinical Research Support.

Date: June 2, 2023.

Time: 10:00 a.m. to 3:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health, National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Greg Bissonette, Ph.D., Scientific Review Officer, National Institute on Aging, National Institutes of Health, Gateway Building, Suite 2W200, 7201 Wisconsin Avenue, Bethesda, MD 20892, 301–402–1622, *bissonettegb@mail.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: April 27, 2023.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023–09380 Filed 5–2–23; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of General Medical Sciences; Notice of Closed Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: NIGMS Initial Review Group; Training and Workforce Development Study Section—B Review of Pre-doctoral T32 Applications (TWD–B).

Date: June 20–21, 2023.

Time: 9:30 a.m. to 5:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, National Institute of General Medical Sciences, Natcher Building, 45 Center Drive, Bethesda, Maryland 20892 (Virtual Meeting).

Contact Person: Latarsha J. Carithers, Ph.D., Scientific Review Officer, Office of Scientific Review, National Institute of General Medical Sciences, National Institutes of Health, 45 Center Drive, Room 3AN12C, Bethesda, Maryland 20892, 301–594–4859, *latarsha.carithers@nih.gov*.

Information is also available on the Institute's/Center's home page: *www.nigms.nih.gov/,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program No. 93.859, Biomedical Research and Research Training, National Institutes of Health, HHS)

Dated: April 27, 2023.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023–09382 Filed 5–2–23; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; Notice of Closed Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Aging Special Emphasis Panel; AD Drug Development.

Date: June 20, 2023.

Time: 12:00 p.m. to 3:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Alicia Mariel Jais, Ph.D. Scientific Review Officer, Scientific Review Branch, National Institute on Aging, National Institutes of Health, Gateway Building

2W200, 7201 Wisconsin Avenue, RM 2E400, Bethesda, MD 20892, (301) 594–2614, *mariel.jais@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: April 27, 2023.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023–09377 Filed 5–2–23; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; 30-Day Comment Request; Early Career Reviewer Program Online Application and Vetting System—Center for Scientific Review (CSR)

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below.

DATES: Comments regarding this information collection are best assured of having their full effect if received within 30 days of the date of this publication.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Dr. Hope Cummings, Project Clearance Liaison, Center for Scientific Review, NIH, Room 907–M, 6701 Rockledge Drive, Bethesda, Maryland 20892 or call non-toll-free number (301) 402–4706 or Email your request, including your address to: *hope.cummings@nih.gov.* Formal requests for additional plans and instruments must be requested in writing.

SUPPLEMENTARY INFORMATION: This proposed information collection was previously published in the **Federal Register** on February 14, 2023, pages 9528–9529 (88 FR 30) and allowed 60 days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The Center for Scientific Review (CSR), National Institutes of Health, may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

In compliance with Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below.

Proposed Collection Title: Early Career Reviewer Program Online Application and Vetting System—0925–0695, REVISION—expiration date 06/30/2023, Center for Scientific Review (CSR), National Institutes of Health (NIH).

Need and Use of Information Collection: The Center for Scientific Review (CSR) is the portal for NIH grant applications and their review for scientific merit. Our mission is to see that all NIH grant applications receive fair, independent, expert, and timely reviews—free from inappropriate influences—so NIH can fund the most promising research. To accomplish this goal, Scientific Review Officers (SRO) form study sections consisting of scientists who have the technical and scientific expertise to evaluate the merit of grant applications. Study section members are generally scientists who have established independent programs of research as demonstrated by their publications and their grant award experiences.

The CSR Early Career Reviewer program was developed to identify and train qualified scientists who are early in their scientific careers and who have not had prior CSR review experience. The goals of the program are to expose these early career scientists to the peer review experience so that they become more competitive as applicants as well as to enrich the existing pool of NIH reviewers. Currently, the online application software, the Early Career Reviewer Application and Vetting System, is accessed online by applicants to the Early Career Reviewer Program who provide information such as their name, contact information, a description of their areas of expertise, their study section preferences, and their professional Curriculum Vitae. This Information Collection Request (ICR) is to revise the Early Career Reviewer Application and Vetting System by removing several optional socio-demographic questions.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 555.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Number of respondents	Number of responses per respondent	Average time per response (in hours)	Total annual burden hour
Research scientists	1,332	1	25/60	555
Total		1,332		555

Hope M. Cummings,

Project Clearance Liaison, Center for Scientific Review (CSR), National Institutes of Health.

[FR Doc. 2023–09386 Filed 5–2–23; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Center for Scientific Review Special Emphasis Panel.

Date: May 26, 2023.

Time: 10:00 a.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Mark P. Rubert, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5218, MSC 7852, Bethesda, MD 20892, 301–806–6596, *rubertm@csr.nih.gov*.

Name of Committee: Risk, Prevention and Health Behavior Integrated Review Group; Biobehavioral Medicine and Health Outcomes Study Section.

Date: June 5–6, 2023.

Time: 9:30 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Mark A. Vosvick, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3110, Bethesda, MD 20892, (301) 402–4128 *mark.vosvick@nih.gov*.

Name of Committee: Biology of Development and Aging Integrated Review Group; Mechanisms of Cancer Therapeutics A Study Section.

Date: June 12–13, 2023.

Time: 9:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Careen K. Tang-Toth, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6214, MSC 7804, Bethesda, MD 20892, (301) 435–3504, *tothct@csr.nih.gov*.

Name of Committee: Surgical Sciences, Biomedical Imaging and Bioengineering Integrated Review Group; Surgery, Anesthesiology and Trauma Study Section.

Date: June 14–15, 2023.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency, Bethesda, One Metro Center, 7400 Wisconsin Avenue Bethesda, MD 20814.

Contact Person: Weihua Luo, MD, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5114, MSC 7854, Bethesda, MD 20892, (301) 435–1170, *luow@csr.nih.gov*.

Name of Committee: Cardiovascular and Respiratory Sciences Integrated Review Group; Therapeutic Development and Preclinical Studies Study Section.

Date: June 14–15, 2023.

Time: 9:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Richard D. Schneiderman, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4138, Bethesda, MD 20817, 301–402–3995, *richard.schneiderman@nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: April 27, 2023.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023–09379 Filed 5–2–23; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Digestive, Kidney and Urological Systems Integrated Review Group; Environmental Determinants of Disease Study Section (EDD).

Date: June 8–9, 2023.

Time: 9:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Jodie Michelle Fleming, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 812R, Bethesda, MD 20892, (301) 867–5309, *flemingjm@csr.nih.gov*.

Name of Committee: Biology of Development and Aging Integrated Review Group; Radiation Therapeutics and Biology Study Section.

Date: June 12–13, 2023.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency, Bethesda, One Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Bo Hong, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6194, MSC 7804, Bethesda, MD 20892, 301–996–6208, *hongb@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR Panel: International and Cooperative Projects.

Date: June 12, 2023.

Time: 10:00 a.m. to 2:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Lauren Penney, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 496–1968, *penneyls@csr.nih.gov*.

Name of Committee: Bioengineering Sciences & Technologies Integrated Review Group; Modeling and Analysis of Biological Systems Study Section.

Date: June 13–14, 2023.

Time: 8:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Place: The Bethesdan Hotel, Tapestry Collection by Hilton, 8120 Wisconsin Ave., Bethesda, MD 20814.

Contact Person: Zarana Patel, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 496–9295, *zarana.patel@nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: April 27, 2023.

David W. Freeman,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023–09381 Filed 5–2–23; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Fiscal Year (FY) 2023 Notice of Supplemental Funding Opportunity

AGENCY: Substance Abuse and Mental Health Services Administration, Department of Health and Human Services (HHS).

ACTION: Notice of intent to award supplemental funding.

SUMMARY: This notice is to inform the public the Substance Abuse and Mental Health Services Administration (SAMHSA) is supporting a supplement in scope of the original award for the one grant recipient funded in fiscal year (FY) 2018 under the Clinical Support System for Serious Mental Illness (CSS–SMI) Notice of Funding Opportunity (NOFO) SM–18–020. The grant recipient may receive up to $2,846,283. The grant recipient's project period will be extended by 12 months until July 8, 2024. The supplemental funding will be used to maintain a national center that provides technical assistance to providers, programs, and communities across the nation to address evidence-based treatment and recovery support programs for individuals living with serious mental illness (SMI).

FOR FURTHER INFORMATION CONTACT: Kimberly E. Reynolds, MPA, MEd, Public Health Advisor and Project Officer, Substance Abuse and Mental Health Services Administration, 5600 Fishers Lane, Rockville, MD 20857, telephone (240) 276–2825; email: *Kimberly.Reynolds@samhsa.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Funding Opportunity Title: FY 2018 Clinical Support System for Serious Mental Illness Cooperative Agreement SM–18–020.

Assistance Listing: 93.243.

Authority: Section 520A of the Public Health Service Act as amended.

Justification: Eligibility for this supplemental funding is limited to the American Psychiatric Association which was funded in FY 2018 under NOFO SM–18–020. The American Psychiatric Association is uniquely qualified and has the required special expertise to address the implementation and provision of evidence-based treatment and recovery support programs for individuals living with SMI.

This is not a formal request for application. Assistance will only be provided to the sole CSS–SMI grant recipient funded in FY2018 under the Clinical Support System for Serious Mental Illness (CSS–SMI) SM–18–020 based on the receipt of a satisfactory application and associated budget that is approved by a review group.

Dated: April 27, 2023.

Ann Ferrero,

Public Health Analyst.

[FR Doc. 2023–09317 Filed 5–2–23; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2023–0246]

Area Maritime Security Advisory Committee (AMSC), Eastern Great Lakes, Northwest Pennsylvania Sub-Committee Vacancy

AGENCY: Coast Guard, DHS.

ACTION: Notice of availability of committee vacancy; solicitation for membership.

SUMMARY: The Coast Guard requests individuals interested in serving on the Area Maritime Security Committee, Eastern Great Lakes, Northwest Pennsylvania Region sub-committee submit their applications for membership to the U.S. Coast Guard Captain of the Port, Buffalo. The Committee assists the Captain of the Port as the Federal Maritime Security Coordinator, Buffalo, in developing, reviewing, and updating the Area Maritime Security Plan for their area of responsibility.

DATES: Requests for membership should reach the Captain of the Port, Buffalo, by 22 May 2023.

ADDRESSES: Applications for membership should be submitted to the Captain of the Port at the following address: Captain of the Port, Buffalo, Attention: LCDR Katherine Peet, 1 Fuhrmann Boulevard, Buffalo, NY 14203–3189.

FOR FURTHER INFORMATION CONTACT: For questions about submitting an application, or about the AMSC in general, contact Mr. John Kelly, Northwest Pennsylvania Region Sub-Committee Executive Coordinator, at 716–843–9574 or *John.K.Kelly@uscg.mil.*

SUPPLEMENTARY INFORMATION:

Basis and Purpose

Section 102 of the Maritime Transportation Security Act (MTSA) of 2002 (Pub. L. 107–295) added section 70112 to Title 46 of the U.S. Code and authorized the Secretary of the Department in which the Coast Guard is operating to establish Area Maritime Security Advisory Committees (ASMC) for any port area of the United States. (See 33 U.S.C. 1226; 46 U.S.C.; 33 CFR 1.05–1, 6.01; Department of Homeland Security Delegation No. 0170.1). The MTSA includes a provision exempting these AMSCs from the Federal Advisory Committee Act (FACA), Public Law 92–436, 86 Stat. 470 (5 U.S.C. App. 2). The AMSCs shall assist the Federal Maritime Security Coordinator (FMSC) in the development, review, update, and exercising of the Area Maritime Security Plan (AMSP) for their area of responsibility. Such matters may include, but are not limited to, the following:

(1) Identifying critical port infrastructure and operations; Identifying risks (threats, vulnerabilities, and consequences).

(2) Determining mitigation strategies and implementation methods.

(3) Developing strategies to facilitate the recovery of the Maritime Transportation System after a Transportation Security Incident.

(4) Developing and describing the process to continually evaluate overall port security by considering consequences and vulnerabilities, how they may change over time, and what additional mitigation strategies can be applied; and

(5) Providing advice to and assisting the Federal Maritime Security Coordinator in developing and maintaining the Area Maritime Security Plan.

AMSC Membership

Members of the AMSC should have at least five years of experience related to maritime or port security operations. We are seeking to fill one (1) Sub-Committee vacancies with this solicitation, an Executive Board member to serve as Vice-Chairperson; the position will serve concurrently as a member of the Eastern Great Lakes AMSC when so convened by the FMSC.

Applicants may be required to pass an appropriate security background check prior to appointment to the committee. Applicants must register with and remain active as a Coast Guard Homeport user if appointed. Member's term of office will be for five years; however, a member is eligible to serve

additional terms of office. Members will not receive any salary or other compensation for their service on an AMSC. In accordance with 33 CFR 103, members may be selected from Federal, Territorial, or Tribal governments; State government and political subdivisions of the State; local public safety, crisis management, and emergency response agencies; law enforcement and security organizations; maritime industry, including labor; other port stakeholders having a special competence in maritime security; and port stakeholders affected by security practices and policies.

The Department of Homeland Security does not discriminate in selection of committee members on the basis of race, color, religion, sex, national origin, political affiliation, sexual orientation, gender identity, marital status, disability, and genetic information, age, membership in an employee organization, or any other non-merit factor. The Department of Homeland Security strives to achieve a widely diverse candidate pool for all of its recruitment actions.

Request for Applications

Those seeking membership are not required to submit formal applications to the local Captain of the Port, however, because we do have an obligation to ensure that a specific number of members have the prerequisite maritime security experience, we encourage the submission of resumes highlighting experience in the maritime and security industries.

Dated: April 17, 2023.

Mark I. Kuperman,

Captain, U.S. Coast Guard, Captain of the Port & Federal Maritime Security Coordinator, Buffalo.

[FR Doc. 2023–09309 Filed 5–2–23; 8:45 am]

BILLING CODE 9110–15–P

DEPARTMENT OF THE INTERIOR

Office of the Secretary

[XXXD5198NI DS61100000 DNINR0000.000000 DX61104]

Notice To Reopen the Call for Nominations to the Exxon Valdez Oil Spill Public Advisory Committee

AGENCY: Office of the Secretary, Interior.

ACTION: Notice to reopen a call for nominations.

SUMMARY: A request for nominations was published by the Department of the Interior in the **Federal Register** on January 26, 2023, for specific positions on the *Exxon Valdez* Oil Spill Public Advisory Committee (Committee). The nomination period ended on March 13, 2023. This notice reopens the nomination period until June 20, 2023.

DATES: The nomination period for the notice published on January 26, 2023, at 88 FR 5035, is reopened. Nominations for the vacant positions are due by June 20, 2023.

ADDRESSES: Send nomination packages by hard copy or via email to Shiway Wang, Executive Director, *Exxon Valdez* Oil Spill Trustee Council, 4230 University Drive, Suite 220, Anchorage, Alaska, 99508–4650, or at *shiway.wang@alaska.gov.* Also please copy Joy Maglaqui, Executive Assistant, on any email correspondence at *joy.maglaqui@alaska.gov.*

FOR FURTHER INFORMATION CONTACT: Grace Cochon, Department of the Interior, Office of Environmental Policy and Compliance, telephone number: (907) 786–3620; email: *grace_cochon@ios.doi.gov.*

SUPPLEMENTARY INFORMATION: The Committee was created pursuant to Paragraph V.A.4 of the Memorandum of Agreement and Consent Decree entered into by the United States of America and the State of Alaska on August 27, 1991, and approved by the United States District Court for the District of Alaska in settlement of *United States of America* v. *State of Alaska,* Civil Action No. A91–081 CV. The Committee advises the *Exxon Valdez* Oil Spill Trustee Council on matters relating to decisions on injury assessment, restoration activities, or other use of natural resource damage recoveries obtained by the government due to the T/V *Exxon Valdez* oil spill of March 1989. The Trustee Council consists of representatives of the U.S. Department of the Interior, U.S. Department of Agriculture, National Oceanic and Atmospheric Administration, Alaska Department of Fish and Game, Alaska Department of Environmental Conservation, and Alaska Department of Law.

The Committee consists of 10 members to reflect balanced representation from each of the following principal interests: aquaculture/mariculture, commercial tourism, conservation/environmental, recreation, subsistence use, commercial fishing, native landownership, sport hunting/fishing, science/technology, and public-at-large.

We are soliciting nominations for three positions that represent sport hunting/fishing, conservation/environmental, and science/technology interests. The Committee members will be selected and appointed by the Secretary of the Interior to serve a four-year term.

Nomination Process: Nominations for membership may be submitted by any source. Nominations should include a résumé providing an adequate description of the nominee's qualifications, including information that would enable the Department of the Interior to evaluate the nominee's ability to meet Committee membership requirements and to contact a potential member.

Authority: 5 U.S.C. 10.

Lisa M. Fox,

Regional Environmental Officer, Office of Environmental Policy and Compliance.

[FR Doc. 2023–09323 Filed 5–2–23; 8:45 am]

BILLING CODE 4334–63–P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 701–TA–689 and 731–TA–1618 (Preliminary)]

Non-Refillable Steel Cylinders From India; Institution of Anti-Dumping and Countervailing Duty Investigations and Scheduling of Preliminary Phase Investigations

AGENCY: United States International Trade Commission.

ACTION: Notice.

SUMMARY: The Commission hereby gives notice of the institution of investigations and commencement of preliminary phase antidumping and countervailing duty investigation nos. 701–TA–689 and 731–TA–1618 (Preliminary) pursuant to the Tariff Act of 1930 (''the Act'') to determine whether there is a reasonable indication that an industry in the United States is materially injured or threatened with material injury, or the establishment of an industry in the United States is materially retarded, by reason of imports of non-refillable steel cylinders from India, provided for in heading 7311.00.00 of the Harmonized Tariff Schedule of the United States, that are alleged to be sold in the United States at less than fair value and alleged to be subsidized by the Government of India. Unless the Department of Commerce (''Commerce'') extends the time for initiation, the Commission must reach a preliminary determination in antidumping and countervailing duty investigations in 45 days, or in this case by June 9, 2023. The Commission's views must be transmitted to Commerce within five business days thereafter, or by June 20, 2023.

DATES: April 27, 2023.

FOR FURTHER INFORMATION CONTACT: Peter Stebbins (205–2039), Office of Investigations, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000. General information concerning the Commission may also be obtained by accessing its internet server (*https://www.usitc.gov*). The public record for these investigations may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.*

SUPPLEMENTARY INFORMATION:

Background.—These investigations are being instituted, pursuant to sections 703(a) and 733(a) of the Tariff Act of 1930 (19 U.S.C. 1671b(a) and 1673b(a)), in response to petitions filed on April 27, 2023, by Worthington Industries, Columbus, Ohio.

For further information concerning the conduct of these investigations and rules of general application, consult the Commission's Rules of Practice and Procedure, part 201, subparts A and B (19 CFR part 201), and part 207, subparts A and B (19 CFR part 207).

Participation in the investigations and public service list.—Persons (other than petitioners) wishing to participate in the investigations as parties must file an entry of appearance with the Secretary to the Commission, as provided in §§ 201.11 and 207.10 of the Commission's rules, not later than seven days after publication of this notice in the **Federal Register**. Industrial users and (if the merchandise under investigation is sold at the retail level) representative consumer organizations have the right to appear as parties in Commission antidumping duty and countervailing duty investigations. The Secretary will prepare a public service list containing the names and addresses of all persons, or their representatives, who are parties to these investigations upon the expiration of the period for filing entries of appearance.

Limited disclosure of business proprietary information (BPI) under an administrative protective order (APO) and BPI service list.—Pursuant to § 207.7(a) of the Commission's rules, the Secretary will make BPI gathered in these investigations available to authorized applicants representing interested parties (as defined in 19 U.S.C. 1677(9)) who are parties to the investigations under the APO issued in the investigations, provided that the application is made not later than seven days after the publication of this notice in the **Federal Register**. A separate service list will be maintained by the Secretary for those parties authorized to receive BPI under the APO.

Conference.—The Office of Investigations will hold a staff conference in connection with the preliminary phase of these investigations beginning at 9:30 a.m. on May 18, 2023. Requests to appear at the conference should be emailed to *preliminaryconferences@usitc.gov* (DO NOT FILE ON EDIS) on or before May 16, 2023. Please provide an email address for each conference participant in the email. Information on conference procedures, format, and virtual witness attendance, if relevant, will be available on the Commission's Public Calendar. A nonparty who has testimony that may aid the Commission's deliberations may request permission to participate by submitting a short statement.

Please note the Secretary's Office will accept only electronic filings during this time. Filings must be made through the Commission's Electronic Document Information System (EDIS, *https://edis.usitc.gov*). No in-person paper-based filings or paper copies of any electronic filings will be accepted until further notice.

Written submissions.—As provided in §§ 201.8 and 207.15 of the Commission's rules, any person may submit to the Commission on or before May 23, 2023, a written brief containing information and arguments pertinent to the subject matter of the investigations. Parties shall file written testimony and supplementary material in connection with their presentation at the conference no later than noon on May 17, 2023. All written submissions must conform with the provisions of § 201.8 of the Commission's rules; any submissions that contain BPI must also conform with the requirements of §§ 201.6, 207.3, and 207.7 of the Commission's rules. The Commission's *Handbook on Filing Procedures,* available on the Commission's website at *https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf,* elaborates upon the Commission's procedures with respect to filings.

In accordance with §§ 201.16(c) and 207.3 of the rules, each document filed by a party to the investigations must be served on all other parties to the investigations (as identified by either the public or BPI service list), and a certificate of service must be timely filed. The Secretary will not accept a document for filing without a certificate of service.

Certification.—Pursuant to § 207.3 of the Commission's rules, any person submitting information to the Commission in connection with these investigations must certify that the information is accurate and complete to the best of the submitter's knowledge. In making the certification, the submitter will acknowledge that any information that it submits to the Commission during these investigations may be disclosed to and used: (i) by the Commission, its employees and Offices, and contract personnel (a) for developing or maintaining the records of these or related investigations or reviews, or (b) in internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission including under 5 U.S.C. Appendix 3; or (ii) by U.S. government employees and contract personnel, solely for cybersecurity purposes. All contract personnel will sign appropriate nondisclosure agreements.

Authority: These investigations are being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to § 207.12 of the Commission's rules.

By order of the Commission.

Issued: April 28, 2023.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2023–09364 Filed 5–2–23; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 701–TA–686–688 and 731–TA–1612–1617 (Preliminary)]

Brass Rod From Brazil, India, Israel, Mexico, South Africa, and South Korea; Institution of Antidumping and Countervailing Duty Investigations and Scheduling of Preliminary Phase Investigations

AGENCY: United States International Trade Commission.

ACTION: Notice.

SUMMARY: The Commission hereby gives notice of the institution of investigations and commencement of preliminary phase antidumping and countervailing duty investigation Nos. 701–TA–686–688 and 731–TA–1612–1617 (Preliminary) pursuant to the Tariff Act of 1930 (''the Act'') to determine whether there is a reasonable indication that an industry in the United States is materially injured or threatened with

material injury, or the establishment of an industry in the United States is materially retarded, by reason of imports of brass rod from Brazil, India, Israel, Mexico, South Africa, and South Korea, provided for in statistical reporting numbers 7407.21.1500, 7407.21.3000, 7407.21.7000, and 7407.21.9000 of the Harmonized Tariff Schedule of the United States, that are alleged to be sold in the United States at less than fair value and alleged to be subsidized by the Government of India, Israel, and South Korea. Unless the Department of Commerce (''Commerce'') extends the time for initiation, the Commission must reach a preliminary determination in antidumping and countervailing duty investigations in 45 days, or in this case by June 12, 2023. The Commission's views must be transmitted to Commerce within five business days thereafter, or by June 20, 2023.

DATES: April 27, 2023.

FOR FURTHER INFORMATION CONTACT: Julie Duffy ((202) 708–2579), Office of Investigations, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000. General information concerning the Commission may also be obtained by accessing its internet server (*https://www.usitc.gov*). The public record for these investigations may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.*

SUPPLEMENTARY INFORMATION:

Background.—These investigations are being instituted, pursuant to sections 703(a) and 733(a) of the Tariff Act of 1930 (19 U.S.C. 1671b(a) and 1673b(a)), in response to a petition filed on April 27, 2023, by the American Brass Rod Fair Trade Coalition, Washington, District of Columbia; Mueller Brass Co., Port Huron, Michigan, and Wieland Chase LLC, Montpelier, Ohio.

For further information concerning the conduct of these investigations and rules of general application, consult the Commission's Rules of Practice and Procedure, part 201, subparts A and B (19 CFR part 201), and part 207, subparts A and B (19 CFR part 207).

Participation in the investigations and public service list.—Persons (other than petitioners) wishing to participate in the investigations as parties must file an entry of appearance with the Secretary to the Commission, as provided in §§ 201.11 and 207.10 of the Commission's rules, not later than seven days after publication of this notice in the **Federal Register**. Industrial users and (if the merchandise under investigation is sold at the retail level) representative consumer organizations have the right to appear as parties in Commission antidumping duty and countervailing duty investigations. The Secretary will prepare a public service list containing the names and addresses of all persons, or their representatives, who are parties to these investigations upon the expiration of the period for filing entries of appearance.

Limited disclosure of business proprietary information (BPI) under an administrative protective order (APO) and BPI service list.—Pursuant to § 207.7(a) of the Commission's rules, the Secretary will make BPI gathered in these investigations available to authorized applicants representing interested parties (as defined in 19 U.S.C. 1677(9)) who are parties to the investigations under the APO issued in the investigations, provided that the application is made not later than seven days after the publication of this notice in the **Federal Register**. A separate service list will be maintained by the Secretary for those parties authorized to receive BPI under the APO.

Conference.—The Office of Investigations will hold a staff conference in connection with the preliminary phase of these investigations beginning at 9:30 a.m. on May 18, 2023. Requests to appear at the conference should be emailed to *preliminaryconferences@usitc.gov* (DO NOT FILE ON EDIS) on or before May 16, 2023. Please provide an email address for each conference participant in the email. Information on conference procedures, format, and virtual witness attendance, if relevant, will be available on the Commission's Public Calendar. A nonparty who has testimony that may aid the Commission's deliberations may request permission to participate by submitting a short statement.

Please note the Secretary's Office will accept only electronic filings during this time. Filings must be made through the Commission's Electronic Document Information System (EDIS, *https://edis.usitc.gov*). No in-person paper-based filings or paper copies of any electronic filings will be accepted until further notice.

Written submissions.—As provided in §§ 201.8 and 207.15 of the Commission's rules, any person may submit to the Commission on or before May 23, 2023, a written brief containing information and arguments pertinent to the subject matter of the investigations. Parties shall file written testimony and supplementary material in connection with their presentation at the conference no later than noon on May 17, 2023. All written submissions must conform with the provisions of § 201.8 of the Commission's rules; any submissions that contain BPI must also conform with the requirements of §§ 201.6, 207.3, and 207.7 of the Commission's rules. The Commission's *Handbook on Filing Procedures,* available on the Commission's website at *https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf,* elaborates upon the Commission's procedures with respect to filings.

In accordance with §§ 201.16(c) and 207.3 of the rules, each document filed by a party to the investigations must be served on all other parties to the investigations (as identified by either the public or BPI service list), and a certificate of service must be timely filed. The Secretary will not accept a document for filing without a certificate of service.

Certification.—Pursuant to § 207.3 of the Commission's rules, any person submitting information to the Commission in connection with these investigations must certify that the information is accurate and complete to the best of the submitter's knowledge. In making the certification, the submitter will acknowledge that any information that it submits to the Commission during these investigations may be disclosed to and used: (i) by the Commission, its employees and Offices, and contract personnel (a) for developing or maintaining the records of these or related investigations or reviews, or (b) in internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission including under 5 U.S.C. Appendix 3; or (ii) by U.S. government employees and contract personnel, solely for cybersecurity purposes. All contract personnel will sign appropriate nondisclosure agreements.

Authority: These investigations are being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to § 207.12 of the Commission's rules.

By order of the Commission.

Issued: April 28, 2023.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2023–09369 Filed 5–2–23; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 731–TA–1607–1611 (Preliminary)]

Boltless Steel Shelving Units Prepackaged for Sale From India, Malaysia, Taiwan, Thailand, and Vietnam; Revised Schedule for the Subject Investigations

AGENCY: International Trade Commission.

ACTION: Notice.

DATES: April 28, 2023.

FOR FURTHER INFORMATION CONTACT: Jordan Harriman (202–205–2610), Office of Investigations, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000. General information concerning the Commission may also be obtained by accessing its internet server (*https://www.usitc.gov*). The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.*

SUPPLEMENTARY INFORMATION: On April 26, 2023, the Commission established a schedule for the conduct of the preliminary phase of the subject investigations, which included an in-person staff conference. The Commission will now hold its staff conference via video conference beginning 9:30 a.m. on May 16, 2023. Requests to appear at the conference should be emailed to *preliminaryconferences@usitc.gov* (DO NOT FILE ON EDIS) on or before Friday, May 12, 2023. Please provide an email address for each conference participant in the email. Information on conference procedures will be provided separately and guidance on joining the video conference will be available on the Commission's Daily Calendar.

For further information concerning this proceeding, see the Commission's notice cited above and the Commission's Rules of Practice and Procedure, part 201, subparts A through E (19 CFR part 201), and part 207, subparts A and C (19 CFR part 207).

Authority: These investigations are being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to § 207.21 of the Commission's rules.

By order of the Commission.

Issued: April 28, 2023.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2023–09394 Filed 5–2–23; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Federal Bureau of Investigation

Notice of Charter Reestablishment

In accordance with the provisions of the Federal Advisory Committee Act, Title 5, United States Code, section 10, and Title 41, Code of Federal Regulations, section 102–3.65, with the concurrence of the Attorney General, I have determined that the reestablishment of the Criminal Justice Information Services (CJIS) Advisory Policy Board (APB) is in the public interest. In connection with the performance of duties imposed upon the FBI by law, I hereby give notice of the reestablishment of the APB Charter.

The APB provides me with general policy recommendations with respect to the philosophy, concept, and operational principles of the various criminal justice information systems managed by the FBI's CJIS Division.

The APB includes representatives from state and local criminal justice agencies; tribal law enforcement representatives; members of the judicial, prosecutorial, and correctional sectors of the criminal justice community, as well as one individual representing a national security agency; a representative of the National Crime Prevention and Privacy Compact Council; a representative of federal agencies participating in the CJIS Division Systems; and representatives of criminal justice professional associations (*i.e.,* the American Probation and Parole Association; American Society of Crime Laboratory Directors; International Association of Chiefs of Police; National District Attorneys Association; National Sheriffs Association; Major Cities Chiefs Association; Major County Sheriffs' of America; and a representative from a national professional association representing the courts or court administrators nominated by the Conference of Chief Justices). The Attorney General has granted me the authority to appoint all members to the APB.

The APB functions solely as an advisory body in compliance with the provisions of the Federal Advisory Committee Act. The Charter has been filed in accordance with the provisions of the Act.

Dated: April 20, 2023.

Christopher A. Wray,

Director.

[FR Doc. 2023–09330 Filed 5–2–23; 8:45 am]

BILLING CODE 4410–02–P

DEPARTMENT OF JUSTICE

Notice of Lodging of Proposed Consent Decree Under the Clean Air Act

On April 27, 2023, the Department of Justice lodged a proposed First Material Modification to the Consent Decree entered by the United States District Court for the Western District of Texas on September 28, 2016, in the lawsuit entitled *United States, et. al* v. *Tesoro Refining & Marketing Company, LLC et al.,* Civ. A. No: SA–16–cv–00722. The Consent Decree resolved the United States and several states' claims under the Clean Air Act, 42 U.S.C. 7413, alleged in the Complaint at six petroleum refineries in six states. This First Material Modification only addresses the Martinez, California Refinery which is owned and operated by Defendant Tesoro Refining & Marketing Company, LLC. The proposed modification requires Tesoro to pay a penalty of $27.5 million dollars for violations of the Consent Decree and Clean Air Act, implement various injunctive relief to assure compliance with specified emissions standards whether it engages in petroleum refining or renewable fuel production at the facility, and retire emissions credits to mitigate the harm from its violations.

The publication of this notice opens a period for public comment on the Consent Decree. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and should refer to *United States* v. *Tesoro Refining & Marketing Company, LLC,* D.J. Ref. No 90–5–2–1–09512/1. All comments must be submitted no later than thirty (30) days after the publication date of this notice. Comments may be submitted either by email or by mail:

To submit comments:	*Send them to:*
By email	*pubcomment-ees.enrd@usdoj.gov.*
By mail	Assistant Attorney General, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044–7611.

During the public comment period, the Consent Decree may be examined

and downloaded at this Justice Department website: *https://www.justice.gov/enrd/consent-decrees.* We will provide a paper copy of the Consent Decree upon written request and payment of reproduction costs. Please mail your request and payment to: Consent Decree Library, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044–7611.

Please enclose a check or money order for $71.75 (25 cents per page reproduction cost) payable to the United States Treasury.

Susan M. Akers,

Deputy Section Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 2023–09329 Filed 5–2–23; 8:45 am]

BILLING CODE 4410–15–P

NATIONAL SCIENCE FOUNDATION

Astronomy and Astrophysics Advisory Committee; Notice of Meeting

In accordance with the Federal Advisory Committee Act (Pub. L. 92–463, as amended), the National Science Foundation (NSF) announces the following meeting:

Name and Committee Code: Astronomy and Astrophysics Advisory Committee (#13883) (Virtual).

Date and Time: June 1, 2023; 9:30 a.m.–3:30 p.m.

Place: National Science Foundation, 2415 Eisenhower Avenue, Alexandria, VA 22314 (Zoom Videoconference).

Attendance information for the meeting will be forthcoming on the advisory committee's website: *https://www.nsf.gov/mps/ast/aaac.jsp.*

Type of Meeting: Open.

Contact Person: Dr. Carrie Black, Program Director, Division of Astronomical Sciences, Suite W 9188, National Science Foundation, 2415 Eisenhower Avenue, Alexandria, VA 22314; Telephone: 703–292–2426.

Purpose of Meeting: To provide advice and recommendations to the National Science Foundation (NSF), the National Aeronautics and Space Administration (NASA) and the U.S. Department of Energy (DOE) on issues within the field of astronomy and astrophysics that are of mutual interest and concern to the agencies. To prepare the annual report.

Agenda: To provide updates on Agency activities.

Dated: April 28, 2023.

Crystal Robinson,

Committee Management Officer.

[FR Doc. 2023–09388 Filed 5–2–23; 8:45 am]

BILLING CODE 7555–01–P

NUCLEAR REGULATORY COMMISSION

[Docket Nos. 50–498 and 50–499; NRC–2023–0095]

STP Nuclear Operating Company; South Texas Project, Units 1 and 2

AGENCY: Nuclear Regulatory Commission.

ACTION: Exemption; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) has issued an exemption in response to an April 13, 2023, request, as supplemented (replaced in its entirety) by letter dated April 17, 2023, from STP Nuclear Operating Company that requested a one-time exemption that would allow for the reporting of Radiation Exposure Information and Reporting System data from South Texas Project, Units 1 and 2 (STP) to be extended from the required date of April 30, 2023, until August 31, 2023.

DATES: The exemption was issued on April 27, 2023.

ADDRESSES: Please refer to Docket ID NRC–2023–0095 when contacting the NRC about the availability of information regarding this document. You may obtain publicly available information related to this document using any of the following methods:

- *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2023–0095. Address questions about Docket IDs in *Regulations.gov* to Stacy Schumann; telephone: 301–415–0624; email: *Stacy.Schumann@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *PDR.Resource@nrc.gov.* The request for the exemption was submitted by letter dated April 13, 2023, as supplemented (replaced in its entirety) by letter dated April 17, 2023, and are available in ADAMS under Accession Nos. ML23103A432 and ML23107A251, respectively.
- *NRC's PDR:* You may examine and purchase copies of public documents, by appointment, at the NRC's PDR, Room P1 B35, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852. To make an appointment to visit the PDR, please send an email to *PDR.Resource@nrc.gov* or call 1–800–397–4209 or 301–415–4737, between 8 a.m. and 4 p.m. eastern time (ET), Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Dennis Galvin, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, telephone: 301–415–6256; email: *Dennis.Galvin@nrc.gov.*

SUPPLEMENTARY INFORMATION: The text of the exemption is attached.

Dated: April 28, 2023.

For the Nuclear Regulatory Commission.

Thomas J. Wengert,

Senior Project Manager, Plant Licensing Branch IV, Division of Operating Reactor Licensing, Office of Nuclear Reactor Regulation.

Attachment—Exemption

NUCLEAR REGULATORY COMMISSION

Docket Nos. 50–498 and 50–499

South Texas Project Nuclear Operating Company South Texas Project, Units 1 and 2

Exemption

I. Background

STP Nuclear Operating Company (STPNOC, the licensee) is the holder of Renewed Facility Operating License Nos. NPF–76 and NPF–80, which authorize operation of South Texas Project, Units 1 and 2 (STP), respectively. The licenses provide, among other things, that the facility is subject to all rules, regulations, and orders of the U.S. Nuclear Regulatory Commission (NRC, the Commission) now or hereafter in effect. The facility consists of two pressurized-water reactors located in Matagorda County, Texas.

II. Request/Action

By application dated April 13, 2023 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML23103A432), as supplemented (replaced in its entirety) on April 17, 2023 (ML23107A251), STPNOC requested an exemption from the reporting requirement in Title 10 of the *Code of Federal Regulations* (10 CFR) 20.2206(c). Specifically, the licensee's requested one-time exemption would allow for the reporting of Radiation Exposure Information and Reporting System (REIRS) data from STP to be extended from the required

date of April 30, 2023, until August 31, 2023. The licensee requested the exemption because its vendor that is processing the 2022 STPNOC dosimetry has not yet provided the data necessary for submittal of an annual report of the results of individual monitoring in accordance with 10 CFR 20.2206(c) and the licensee does not have confidence that the vendor will provide the data by April 30, 2023.

The regulation in 10 CFR 20.2206, ''Reports of individual monitoring,'' requires the annual submittal to the NRC of a report of the results of radiation dose monitoring conducted by licensees under the provisions of 10 CFR 20.1502, ''Conditions requiring individual monitoring of external and internal occupational dose,'' covering the preceding year; the report is to be submitted on or before April 30 of each year. The regulations in 10 CFR 20.1502 provide the conditions that require individual monitoring of external and internal occupational radiation doses. The regulations in 10 CFR 20.2106, ''Records of individual monitoring results,'' require, in part, that each licensee maintain records of radiation doses received by all individuals for whom radiation dose monitoring was required by 10 CFR 20.1502, and records of doses received during planned special exposures, accidents, and emergency conditions.

III. Discussion

Pursuant to 10 CFR 20.2301 ''Applications for exemptions,'' the Commission may, upon application by a licensee or upon its own initiative, grant exemptions from the requirements of 10 CFR part 20, ''Standards for Protection Against Radiation,'' if it determines that the exemptions are authorized by law and would not result in undue hazard to life or property.

A. The Exemption Is Authorized by Law

There are no provisions in the Atomic Energy Act of 1954, as amended (or in any other Federal statute) that impose a requirement for submitting reports of the results of required radiation dose monitoring by April 30 of each year to the NRC; rather, this requirement appears in 10 CFR part 20, which also allows the NRC to issue exemptions from those requirements. Therefore, the NRC staff concludes that there is no statutory or regulatory prohibition on the issuance of the requested exemption and the NRC is authorized to grant the exemption by law, upon finding that the exemption is otherwise acceptable.

B. The Exemption Presents no Undue Hazard to Life or Property

In determining that granting the exemption would not result in undue hazard to life,[1] the NRC staff conducted a risk-informed assessment of the impact of the exemption on the purpose of the NRC's standards for protection against radiation, as stated in 10 CFR 20.1001(b). Specifically, the regulation in 10 CFR 20.1001(b) states, in part:

> It is the purpose of the regulations in this part to control the receipt, possession, use, transfer, and disposal of licensed material by any licensee in such a manner that the total dose to an individual (including doses resulting from licensed and unlicensed radioactive material and from radiation sources other than background radiation) does not exceed the standards for protection against radiation prescribed in the regulations in this part.

This risk-informed assessment considered the impact of the exemption on reports of exposure information to individuals and the NRC.

Reports to Individuals

The regulation in 10 CFR 19.13, ''Notifications and reports to individuals,'' provides requirements for notifications and reports of radiation dose data to individuals. For example, 10 CFR 19.13(b) requires licensees to make records maintained under the provisions of 10 CFR 20.2106 available to workers and to provide an annual report to each individual monitored under the provisions of 10 CFR 20.1502 if the individual's occupational dose exceeds a total effective dose equivalent (TEDE) of 100 millirem (mrem) (1 millisievert (mSv)), or 100 mrem (1 mSv) to any individual organ or tissue, or upon request of the individual.

As stated in 10 CFR 20.1001, the ultimate purpose of the requirements in 10 CFR part 20 are to ensure that doses to individuals do not exceed the NRC's radiation protection standards. The monitoring, recording, and reporting of radiation dose data for occupationally exposed individuals as required by 10 CFR part 20 is essential in ensuring that radiation protection standards are not exceeded for any individual worker, because it allows licensees to track doses and, if necessary, take action before applicable limits are exceeded. The recording of this information is also necessary to ensure that workers who transition from one employer to another are adequately protected in that the total annual dose to workers from all employers is kept within applicable limits.

In its exemption request, the licensee described three methods of obtaining personnel radiation dose data. First, doses from radiation exposures can be estimated using information collected from electronic dosimeters that are issued to workers. Second, the dose data can be determined by conducting exposure investigations. Lastly, data from individually issued thermoluminescent dosimeters (TLDs) can be obtained from the licensee's contracted dosimetry service provider. The first and second methods are currently available to the licensee; however, the licensee prefers to submit TLD-based data in part to remain consistent with previous years' reports. This is consistent with long-standing industry practice that passive dosimetry, like TLDs, are used as dosimetry of legal record. However, the licensee states that the TLD-based data has not yet been provided to the licensee by its contracted dosimetry service provider and the licensee does not have confidence that it will obtain the data in time to meet the April 30 reporting deadline.

The licensee states that it is awaiting TLD-based data for over 800 personnel. Conducting exposure investigations and reconciling electronic dosimeter data to establish a final record of doses for this magnitude of individuals is a resource intensive activity that would impose an undue burden on the licensee to achieve before April 30. Nor does there appear to be any safety benefit in assembling those data before the contractor provides the dosimetry results. In this regard, the licensee reviewed the electronic dosimeter data and determined that no individual's annual dose reached regulatory limits, and no irregularities are expected between the electronic dosimeter data and the final record data that is to be submitted.

The NRC staff expects that the reports required per 10 CFR 19.13(b)(1) will be provided by the licensee to the applicable individuals, after the licensee establishes its final record of doses, which is expected on or before August 31, 2023. However, because the licensee maintains electronic dosimeter data and can perform exposure investigations, it is able to satisfy the purpose of 10 CFR part 20, to ensure that the annual doses to individuals do not exceed the NRC's radiation protection standards. Additionally, the licensee is able to meet its obligations per 10 CFR 19.13, to provide exposure information to individuals upon request.

[1] The NRC staff determined that the exemption as requested and evaluated by the NRC does not impact property.

Reports to the NRC

The regulation in 10 CFR 20.2206(a) provides a list of categories of NRC licensees that are required to provide reports of individual radiation dose monitoring to the NRC. The regulation in 10 CFR 20.2206(b) states that licensees who fit a category listed in 10 CFR 20.2206(a), such as STPNOC, shall submit to the NRC reports of the results of individual radiation dose monitoring carried out by the licensee during the prior year for individuals for whom monitoring was required by 10 CFR 20.1502. Additionally, the regulation in 10 CFR 20.2206(c) requires that these reports, covering the preceding year, be submitted on or before April 30 each year. The NRC collects radiation dose data to support decision-making in its oversight of radiation protection performance of its licensees. The preface to NUREG–0713, Volume 42, ''Occupational Radiation Exposure at Commercial Nuclear Power Reactors and Other Facilities 2020,'' dated September 2022 (ML22276A269), states that the NRC uses these data, in combination with other information, to provide facts regarding routine occupational exposures to radiation and radioactive material that occur in connection with certain NRC-licensed activities, for use in making decisions that impact public health and safety. The Preface to NUREG–0713 provides examples of how the NRC uses these data, including:

1. The evaluation of trends, both favorable and unfavorable, from the viewpoint of the effectiveness of overall NRC/licensee radiation protection and as low as is reasonably achievable (ALARA) efforts by licensees.

2. The evaluation of the radiological risk associated with certain categories of NRC-licensed activities and the comparative analysis of radiation protection performance by country, reactor type, civilian/military, facility, and industry.

3. Use of the data in the NRC Reactor Oversight Process for inspection planning and in the Significance Determination Process.

4. Use of the data in making evidence-based decisions regarding the radiation exposure to transient individuals.

5. Use of the data to establish priorities for the use of NRC health physics resources: research, standards development, regulatory program development, and inspections conducted at NRC-licensed facilities.

6. Use of the data in answering Congressional and administrative inquiries as well as responding to questions raised by the public.

7. Use of the data to provide radiation exposure histories to individuals who were exposed to radiation at NRC-licensed facilities.

8. Use of the data in conducting epidemiologic studies.

As may be seen in the above description, the NRC's use of radiation dose data for occupationally exposed individuals serves various long-term initiatives that necessarily depend on data spanning multiple years in broad categories of licensees. Therefore, while the continued collection of this data is essential to the NRC's mission as it pertains to radiation protection, a licensee's delay by several months in reporting the data for its facility would have minimal impact on the NRC's ability to ensure adequate protection of public health and safety, and would not impact individual worker safety since the data pertaining to each worker would be readily available at the facility despite the requested delay in reporting to the NRC. Therefore, the NRC staff concludes that granting the exemption would not result in undue hazard to life or property.

C. Environmental Considerations

The NRC staff determined that the exemption discussed herein meets the eligibility criteria for the categorical exclusion set forth in 10 CFR 51.22(c)(25), and there are no extraordinary circumstances present that would preclude reliance on this exclusion. The NRC staff determined, per 10 CFR 51.22(c)(25)(vi)(B), that the requirements from which the exemption is sought involve reporting requirements.

The NRC staff also determined that approval of this one-time exemption involves no significant hazards consideration because it does not authorize any physical changes to the facility or any of its safety systems and does not involve modifications that could alter the manner in which facility structures, systems, and components are operated and maintained.

There is no significant change in the types or significant increase in the amounts of any effluents that may be released offsite because this exemption does not affect the types, characteristics, or quantities of effluents discharged to the environment. There is no significant increase in individual or cumulative public or occupational radiation exposure because this exemption does not affect limits on the release of any radioactive material, or the limits provided in 10 CFR part 20 for radiation exposure to workers or members of the public. There is no significant construction impact because this exemption does not involve any physical changes to the facility. There is no significant increase in the potential for or consequences from radiological accidents because the exemption does not alter any of the assumptions or limits in the licensee's safety analysis. In addition, the NRC staff determined that there would be no significant impacts to biota, water resources, historic properties, cultural resources, or socioeconomic conditions in the region. Therefore, pursuant to 10 CFR 51.22(b), no environmental impact statement or environmental assessment need be prepared in connection with the approval of the requested exemption.

IV. Conclusions

Accordingly, the Commission has determined that, pursuant to 10 CFR 20.2301, the exemption is authorized by law, and will not present an undue hazard to life and property. Therefore, the Commission hereby grants STPNOC a one-time exemption from 10 CFR 20.2206 to delay the reporting of its REIRS data as required on April 30, 2023, until August 31, 2023.

Dated at Rockville, Maryland, this 27th day of April 2023.

For the Nuclear Regulatory Commission.

Gregory F. Suber,

Deputy Director, Division of Operating Reactor Licensing, Office of Nuclear Reactor Regulation.

[FR Doc. 2023–09373 Filed 5–2–23; 8:45 am]

BILLING CODE 7590–01–P

OFFICE OF PERSONNEL MANAGEMENT

Submission for Review: 3206–0138, Reinstatement of Disability Annuity Previously Terminated Because of Restoration to Earning Capacity, RI 30–9

AGENCY: Office of Personnel Management.

ACTION: 60-Day notice and request for comments.

SUMMARY: Retirement Services, Office of Personnel Management (OPM) offers the general public and other federal agencies the opportunity to comment on an existing information collection request (ICR), without change, Reinstatement of Disability Annuity Previously Terminated Because of Restoration to Earning Capacity, RI 30–9.

DATES: Comments are encouraged and will be accepted until July 3, 2023.

ADDRESSES: You may submit comments, identified by docket number and/or

Regulatory Information Number (RIN) and title, by the following method:

—*Federal Rulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

All submissions received must include the agency name and docket number or RIN for this document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: A copy of this ICR, with applicable supporting documentation, may be obtained by contacting the Retirement Services Publications Team, Office of Personnel Management, 1900 E Street NW, Room 3316–L, Washington, DC 20415, Attention: Cyrus S. Benson, or sent via electronic mail to *Cyrus.Benson@opm.gov* or faxed to (202) 606–0910 or via telephone at (202) 936–0401.

SUPPLEMENTARY INFORMATION: As required by the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. chapter 35) as amended by the Clinger-Cohen Act (Pub. L. 104–106), OPM is soliciting comments for this collection (OMB No. 3206–0138). The Office of Management and Budget is particularly interested in comments that:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of functions of the agency, including whether the information will have practical utility;

2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

3. Enhance the quality, utility, and clarity of the information to be collected; and

4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses.

RI 30–9, Reinstatement of Disability Annuity Previously Terminated Because of Restoration to Earning Capacity, informs former annuitants of their right to request reconsideration. It also specifies the conditions to be met and the documentation that must be submitted with a request for reinstatement.

Analysis

Agency: Retirement Operations, Retirement Services, Office of Personnel Management.

Title: Reinstatement of Disability Annuity Previously Terminated Because of Restoration to Earning Capacity (RI 30–9).

OMB Number: 3206–0138.

Frequency: On occasion.

Affected Public: Individuals or Households.

Number of Respondents: 200.

Estimated Time per Respondent: 60 minutes.

Total Burden Hours: 200 hours.

Office of Personnel Management.

Stephen Hickman,

Federal Register Liaison.

[FR Doc. 2023–09346 Filed 5–2–23; 8:45 am]

BILLING CODE 6325–38–P

OFFICE OF PERSONNEL MANAGEMENT

Submission for Review: 3206–0226, It's Time To Sign Up for Direct Deposit or Direct Express, RI 38–128

AGENCY: Office of Personnel Management.

ACTION: 60-Day notice and request for comments.

SUMMARY: Retirement Services, Office of Personnel Management (OPM) offers the general public and other federal agencies the opportunity to comment on an expiring information collection request (ICR), without change, It's Time to Sign Up for Direct Deposit or Direct Express, RI 38–128.

DATES: Comments are encouraged and will be accepted until July 3, 2023.

ADDRESSES: You may submit comments, identified by docket number and/or Regulatory Information Number (RIN) and title, by the following method:

—*Federal Rulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

All submissions received must include the agency name and docket number or RIN for this document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: A copy of this ICR with applicable supporting documentation, may be obtained by contacting the Retirement Services Publications Team, Office of Personnel Management, 1900 E Street NW, Room 3316–L, Washington, DC 20415, Attention: Cyrus S. Benson, or sent via electronic mail to *Cyrus.Benson@opm.gov* or faxed to (202) 606–0910 or via telephone at (202) 936–0401.

SUPPLEMENTARY INFORMATION: As required by the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. chapter 35) as amended by the Clinger-Cohen Act (Pub. L. 104–106), OPM is soliciting comments for this collection (OMB No. 3206–0226). The Office of Management and Budget is particularly interested in comments that:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of functions of the agency, including whether the information will have practical utility;

2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

3. Enhance the quality, utility, and clarity of the information to be collected; and

4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses.

RI 38–128, It's Time to Sign Up for Direct Deposit or Direct Express, provides the opportunity for the annuitant to elect Direct Deposit or Direct Express. This election is required only once: when a person is first put on our rolls.

Analysis

Agency: Retirement Operations, Retirement Services, Office of Personnel Management.

Title: It's Time to Sign Up for Direct Deposit or Direct Express (RI 38–128).

OMB Number: 3206–0226.

Frequency: On occasion.

Affected Public: Individuals or Households.

Number of Respondents: 20,000.

Estimated Time per Respondent: 30 minutes.

Total Burden Hours: 10,000 hours.

Office of Personnel Management.

Stephen Hickman,

Federal Register Liaison.

[FR Doc. 2023–09347 Filed 5–2–23; 8:45 am]

BILLING CODE 6325–38–P

OFFICE OF PERSONNEL MANAGEMENT

Submission for Review: 3206–0121, Application for Deferred Retirement (for Persons Separated On or After October 1, 1956), OPM 1496A

AGENCY: Office of Personnel Management.

ACTION: 30-Day notice and request for comments.

SUMMARY: Retirement Services, Office of Personnel Management (OPM) offers the general public and other federal agencies the opportunity to comment on a revised information collection request (ICR) with minor edits, Application for Deferred Retirement (for persons separated on or after October 1, 1956), OPM 1496A. The revisions include (1) Revised instructions for hearing impaired users to utilize the Federal Relay Service by dialing 711 or their local communications provider to reach a Communications Assistant (2) Included instructions to attach Internal Revenue Service (IRS) Form W–4P (version 2022 or later). (3) Updated Retirement Information Office hours of operation.

DATES: Comments are encouraged and will be accepted until June 2, 2023.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *http://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''*Currently under Review—Open for Public Comments*'' or by using the search function or fax to (202) 395–6974.

FOR FURTHER INFORMATION CONTACT: A copy of this information collection, with applicable supporting documentation, may be obtained by contacting the Retirement Services Publications Team, Office of Personnel Management, 1900 E Street NW, Room 3316–L, Washington, DC 20415, Attention: Cyrus S. Benson, or sent via electronic mail to *Cyrus.Benson@opm.gov* or faxed to (202) 606–0910 or via telephone at (202) 936–0401.

SUPPLEMENTARY INFORMATION: As required by the Paperwork Reduction Act of 1995 OPM is soliciting comments for this collection. The information collection (OMB No. 3206–0121) was previously published in the **Federal Register** on February 6, 2023 at 88 FR 7766, allowing for a 60-day public comment period. No comments were received.

The Office of Management and Budget is particularly interested in comments that:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of functions of the agency, including whether the information will have practical utility;

2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

3. Enhance the quality, utility, and clarity of the information to be collected; and

4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses.

OPM Form 1496A is used by eligible former Federal employees to apply for a deferred Civil Service annuity.

Analysis

Agency: Retirement Operations, Retirement Services, Office of Personnel Management.

Title: Application for Deferred Retirement (for Persons Separated on or After October 1, 1956).

OMB Number: 3206–0121.

Frequency: On occasion.

Affected Public: Individuals or Households.

Number of Respondents: 2,800.

Estimated Time per Respondent: 1 hour.

Total Burden Hours: 2,800 hours.

Office of Personnel Management.

Stephen Hickman,

Federal Register Liaison.

[FR Doc. 2023–09338 Filed 5–2–23; 8:45 am]

BILLING CODE 6325–38–P

OFFICE OF PERSONNEL MANAGEMENT

Submission for Review: 3206–0143, Request to Disability Annuitant for Information on Physical Condition and Employment, RI 30–1

AGENCY: Office of Personnel Management.

ACTION: 60-Day notice and request for comments.

SUMMARY: Retirement Services, Office of Personnel Management (OPM) offers the general public and other federal agencies the opportunity to comment on an existing information collection request (ICR), without change, Request to Disability Annuitant for Information on Physical Condition and Employment, RI 30–1.

DATES: Comments are encouraged and will be accepted until July 3, 2023.

ADDRESSES: You may submit comments, identified by docket number and/or Regulatory Information Number (RIN) and title, by the following method:

—*Federal Rulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

All submissions received must include the agency name and docket number or RIN for this document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: A copy of this ICR with applicable supporting documentation, may be obtained by contacting the Retirement Services Publications Team, Office of Personnel Management, 1900 E Street NW, Room 3316–L, Washington, DC 20415, Attention: Cyrus S. Benson, or sent via electronic mail to *Cyrus.Benson@opm.gov* or faxed to (202) 606–0910 or via telephone at (202) 936–0401.

SUPPLEMENTARY INFORMATION: As required by the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. chapter 35) as amended by the Clinger-Cohen Act (Pub. L. 104–106), OPM is soliciting comments for this collection (OMB No. 3206–0143). The Office of Management and Budget is particularly interested in comments that:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of functions of the agency, including whether the information will have practical utility;

2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

3. Enhance the quality, utility, and clarity of the information to be collected; and

4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses.

RI 30–1, Request to Disability Annuitant for Information on Physical Condition and Employment, is used by persons who are not yet age 60 and who are receiving a disability annuity and are subject to inquiry regarding their medical condition as OPM deems reasonably necessary.

Analysis

Agency: Retirement Operations, Retirement Services, Office of Personnel Management.

Title: Request to Disability Annuitant for Information on Physical Condition and Employment (RI 30–1).

OMB Number: 3206–0143.

Frequency: On occasion.

Affected Public: Individuals or Households.

Number of Respondents: 8,000.

Estimated Time per Respondent: 60 minutes.

Total Burden Hours: 8,000 hours.

Office of Personnel Management.

Stephen Hickman,

Federal Register Liaison.

[FR Doc. 2023–09341 Filed 5–2–23; 8:45 am]

BILLING CODE 6325–38–P

OFFICE OF PERSONNEL MANAGEMENT

Submission for Review: OMB Control No. 3206–NEW

AGENCY: Office of Personnel Management.

ACTION: 60-Day notice and request for comments.

SUMMARY: The Office of Personnel Management (OPM) offers the general public and other Federal agencies the opportunity to comment on a new information collection request (ICR) 3206–NEW, *USA Hire Assessment Satisfaction Survey, Form USAH–1.*

DATES: Comments are encouraged and will be accepted until July 3, 2023. This process is conducted in accordance with 5 CFR 1320.1.

ADDRESSES: Interested persons are invited to submit written comments on the proposed information collection by one of the following means:

Federal Rulemaking Portal: http://www.regulations.gov. All submissions received must include the agency name and docket number for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: A copy of this information collection request, with applicable supporting documentation, may be obtained by contacting Jeffrey Cain at *jeffrey.cain@opm.gov* or 202–936–2863. Please put ''3206_New'' in the subject line of the email.

SUPPLEMENTARY INFORMATION: As required by the Paperwork Reduction Act of 1995, (Pub. L. 104–13, 44 U.S.C. chapter 35) as amended by the Clinger-Cohen Act (Pub. L. 104–106), OPM is soliciting comments for this collection. ICR 3206–NEW *Assessment Satisfaction Survey, Form USAH–1* is the Federal Government's centralized source for USA Hire online assessment process feedback and reflects the minimal critical elements collected across the Federal Government to begin an application for information collection under the authority of sections 1104,1302, 3301, 3304, 3320, 3361, 3393, and 3394 of Title 5, United States Code. This is a new information collection request for OPM's USA Hire Program. USA Hire seeks to use the ''USA Hire Assessment Satisfaction Survey'' to collect feedback on the USA Hire online assessment process.

This effort will help enable USA Hire to continually implement improvements to the assessment process for applicants and agency stakeholders. As this is a new collection, we invite comments that:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

3. Enhance the quality, utility, and clarity of the information to be collected; and

4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses.

Analysis

Agency: HR Solutions/Federal Staffing Center, Office of Personnel Management.

Title: USA Hire Assessment Satisfaction Survey.

OMB Number: 3206–NEW.

Frequency: Annually.

Affected Public: Individuals.

Number of Respondents: 200,000.

Estimated Time per Respondent: 1 Minute.

Total Burden Hours: 3,400.

U.S. Office of Personnel Management.

Stephen Hickman,

Federal Register Liaison.

[FR Doc. 2023–09337 Filed 5–2–23; 8:45 am]

BILLING CODE 6325–43–P

OFFICE OF PERSONNEL MANAGEMENT

Submission for Review: Initial Certification of Full-Time School Attendance, RI 25–41, 3206–0099

AGENCY: Office of Personnel Management.

ACTION: 60-Day notice and request for comments.

SUMMARY: Retirement Services, Office of Personnel Management (OPM) offers the general public and other federal agencies the opportunity to comment on an expiring information collection, without change, RI 25–41, Initial Certification of Full-Time School Attendance.

DATES: Comments are encouraged and will be accepted until July 3, 2023.

ADDRESSES: You may submit comments, identified by docket number and title, via the Federal eRulemaking Portal: *http://www.regulations.gov.* Follow the instructions for submitting comments. All submissions received must include the agency name, docket number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: A copy of this ICR with applicable supporting documentation, may be obtained by contacting the Retirement Services Publications Team, Office of Personnel Management, 1900 E Street NW, Room 3316–AC, Washington, DC 20415, Attention: Cyrus S. Benson, or sent via email to *Cyrus.Benson@opm.gov* or faxed to (202) 606–0910 or reached via telephone at (202) 936–0401.

SUPPLEMENTARY INFORMATION: As required by the Paperwork Reduction

Act of 1995 (Pub. L. 104–13, 44 U.S.C. chapter 35) as amended by the Clinger-Cohen Act (Pub. L. 104–106), OPM is soliciting comments for this collection (OMB No. 3206–0099). The Office of Management and Budget is particularly interested in comments that:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of functions of the agency, including whether the information will have practical utility;

2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

3. Enhance the quality, utility, and clarity of the information to be collected; and

4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses.

RI 25–41, Initial Certification of Full-Time School Attendance is used to determine whether a child is unmarried and a full-time student in a recognized school. OPM must determine this in order to pay survivor annuity benefits to children who are age 18 or older under 5 U.S.C Sections 8341(A)(4) and 8441 (4)(C).

Analysis

Agency: Retirement Operations, Retirement Services, Office of Personnel Management.

Title: Initial Certification of Full-Time School Attendance.

OMB: 3206–0099.

Frequency: On occasion.

Affected Public: Individuals or Households.

Number of Respondents: 1,200.

Estimated Time per Respondent: 90 minutes.

Total Burden Hours: 1,800.

Office of Personnel Management.

Stephen Hickman,

Federal Register Liaison.

[FR Doc. 2023–09342 Filed 5–2–23; 8:45 am]

BILLING CODE 6325–38–P

OFFICE OF PERSONNEL MANAGEMENT

Submission for Review: 3206–0237, Information and Instructions on Your Reconsideration Rights, RI 38–47

AGENCY: Office of Personnel Management.

ACTION: 60-Day notice and request for comments.

SUMMARY: Retirement Services, Office of Personnel Management (OPM) offers the general public and other Federal agencies the opportunity to comment on an expiring information collection request (ICR), without change, Information and Instruction on Your Reconsideration Rights, RI 38–47.

DATES: Comments are encouraged and will be accepted until July 3, 2023.

ADDRESSES: You may submit comments, identified by docket number and/or Regulatory Information Number (RIN) and title, by the following method:

Federal Rulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

All submissions received must include the agency name and docket number or RIN for this document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: A copy of this ICR with applicable supporting documentation, may be obtained by contacting the Retirement Services Publications Team, Office of Personnel Management, 1900 E Street NW, Room 3316–L, Washington, DC 20415, Attention: Cyrus S. Benson, or sent by email to *Cyrus.Benson@opm.gov* or faxed to (202) 606–0910 or reached via telephone at (202) 936–0401.

SUPPLEMENTARY INFORMATION: As required by the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. chapter 35) as amended by the Clinger-Cohen Act (Pub. L. 104–106), OPM is soliciting comments for this collection (OMB No. 3206–0237). The Office of Management and Budget is particularly interested in comments that:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of functions of OPM, including whether the information will have practical utility;

2. Evaluate the accuracy of OPM's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

3. Enhance the quality, utility, and clarity of the information to be collected; and

4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses.

RI 38–47 outlines the procedures required to request reconsideration of an initial OPM decision about Civil Service or Federal Employees retirement, Federal or Retired Federal Employees Health Benefits requests to enroll or change enrollment or Federal Employees' Group Life Insurance coverage. This form lists the procedures and time periods required for requesting reconsideration.

Analysis

Agency: Retirement Operations, Retirement Services, Office of Personnel Management.

Title: Information and Instruction on Your Reconsideration Rights.

OMB: 3206–0237.

Frequency: On occasion.

Affected Public: Individuals or Households.

Number of Respondents: 3,100.

Estimated Time per Respondent: 45 minutes.

Total Burden Hours: 2,325 hours.

U.S. Office of Personnel Management.

Stephen Hickman,

Federal Register Liaison.

[FR Doc. 2023–09344 Filed 5–2–23; 8:45 am]

BILLING CODE 6325–38–P

OFFICE OF PERSONNEL MANAGEMENT

Submission for Review: 3206–0162, Report of Medical Examination of Person Electing Survivor Benefits, OPM 1530

AGENCY: Office of Personnel Management.

ACTION: 60-Day notice and request for comments.

SUMMARY: Retirement Services, Office of Personnel Management (OPM) offers the general public and other federal agencies the opportunity to comment on an expiring information collection request (ICR), without change, Report of Medical Examination of Person Electing Survivor Benefits, OPM 1530.

DATES: Comments are encouraged and will be accepted until July 3, 2023.

ADDRESSES: You may submit comments, identified by docket number and/or Regulatory Information Number (RIN) and title, by the following method:

—*Federal Rulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

All submissions received must include the agency name and docket number or RIN for this document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: A copy of this ICR with applicable supporting documentation, may be obtained by contacting the Retirement Services Publications Team, Office of Personnel Management, 1900 E Street NW, Room 3316–L, Washington, DC 20415, Attention: Cyrus S. Benson, or sent via electronic mail to *Cyrus.Benson@opm.gov* or faxed to (202) 606–0910 or reached via telephone at (202) 936–0401.

SUPPLEMENTARY INFORMATION: As required by the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. chapter 35) as amended by the Clinger-Cohen Act (Pub. L. 104–106), OPM is soliciting comments for this collection (OMB No. 3206–0162). The Office of Management and Budget is particularly interested in comments that:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of functions of the agency, including whether the information will have practical utility;

2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

3. Enhance the quality, utility, and clarity of the information to be collected; and

4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses.

OPM Form 1530 is used to collect information regarding an annuitant's health so that OPM can determine whether the insurable interest survivor benefit election can be allowed.

Analysis

Agency: Retirement Operations, Retirement Services, Office of Personnel Management.

Title: Report of Medical Examination of Person Electing Survivor Benefits.

OMB Number: 3206–0162.

Frequency: On occasion.

Affected Public: Individuals or Households.

Number of Respondents: 500.

Estimated Time per Respondent: 90 minutes.

Total Burden Hours: 750.

U.S. Office of Personnel Management.

Stephen Hickman,

Federal Register Liaison.

[FR Doc. 2023–09339 Filed 5–2–23; 8:45 am]

BILLING CODE 6325–38–P

OFFICE OF PERSONNEL MANAGEMENT

Submission for Review: 3206–0128, Application for Refund of Retirement Deductions (CSRS)—SF 2802 and Current/Former Spouse's Notification of Application for Refund of Retirement Deductions Under CSRS—SF 2802A

AGENCY: Office of Personnel Management.

ACTION: 60-Day notice and request for comments.

SUMMARY: Retirement Services, Office of Personnel Management (OPM) offers the general public and other federal agencies the opportunity to comment on an expiring information collection request (ICR), without change, Application for Refund of Retirement Deductions Under the Civil Service Retirement System, SF 2802 and Current/Former Spouse's Notification of Application for Refund of Retirement Deductions Under the Civil Service Retirement System, SF 2802A.

DATES: Comments are encouraged and will be accepted until July 3, 2023.

ADDRESSES: You may submit comments, identified by docket number and/or Regulatory Information Number (RIN) and title, by the following method:

—*Federal Rulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

All submissions received must include the agency name and docket number or RIN for this document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: A copy of this ICR with applicable supporting documentation, may be obtained by contacting the Retirement Services Publications Team, Office of Personnel Management, 1900 E Street NW, Room 3316–L, Washington, DC 20415, Attention: Cyrus S. Benson, or sent via electronic mail to *Cyrus.Benson@opm.gov* or faxed to (202) 606–0910 or via telephone at (202) 936–0401.

SUPPLEMENTARY INFORMATION: As required by the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. chapter 35) as amended by the Clinger-Cohen Act (Pub. L. 104–106), OPM is soliciting comments for this collection (OMB No. 3206–0128). The Office of Management and Budget is particularly interested in comments that:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of functions of the agency, including whether the information will have practical utility;

2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

3. Enhance the quality, utility, and clarity of the information to be collected; and

4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses.

Standard Form 2802 is used to support the payment of monies from the Retirement Fund. It identifies the applicant for refund of retirement deductions. Standard Form 2802A is used to comply with the legal requirement that any spouse or former spouse of the applicant has been notified that the former employee is applying for a refund.

Analysis

Agency: Retirement Operations, Retirement Services, Office of Personnel Management.

Title: Application for Refund of Retirement Deductions (CSRS) and Current/Former Spouse's Notification of Application for Refund of Retirement Deductions under the Civil Service Retirement System.

OMB Number: 3206–0128.

Frequency: On occasion.

Affected Public: Individuals or Households.

Number of Respondents: SF 2802 = 3,741; SF 2802A = 3,389.

Estimated Time per Respondent: SF 2802 = 60 minutes; SF 2802A = 15 minutes.

Total Burden Hours: 4,588.

Office of Personnel Management.

Stephen Hickman,

Federal Register Liaison.

[FR Doc. 2023–09348 Filed 5–2–23; 8:45 am]

BILLING CODE 6325–38–P

OFFICE OF PERSONNEL MANAGEMENT

Submission for Review: 3206–0228, CSRS/FERS Documentation in Support of Disability Retirement Application, Standard Form 3112

AGENCY: Office of Personnel Management.

ACTION: 60-Day notice and request for comments.

SUMMARY: Retirement Services, Office of Personnel Management (OPM) offers the general public and other federal agencies the opportunity to comment on an existing information collection request (ICR), without change, CSRS/FERS Documentation in Support of Disability Retirement Application, Standard Form 3112.

DATES: Comments are encouraged and will be accepted until July 3, 2023.

ADDRESSES: You may submit comments, identified by docket number and/or Regulatory Information Number (RIN) and title, by the following method:

—*Federal Rulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

All submissions received must include the agency name and docket number or RIN for this document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: A copy of this ICR with applicable supporting documentation, may be obtained by contacting the Retirement Services Publications Team, Office of Personnel Management, 1900 E Street NW, Room 3316–L, Washington, DC 20415, Attention: Cyrus S. Benson, or sent via electronic mail to *Cyrus.Benson@opm.gov* or faxed to (202) 606–0910 or via telephone at (202) 936–0401.

SUPPLEMENTARY INFORMATION: As required by the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. chapter 35) as amended by the Clinger-Cohen Act (Pub. L. 104–106), OPM is soliciting comments for this collection (OMB No. 3206–0228). The Office of Management and Budget is particularly interested in comments that:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of functions of the agency, including whether the information will have practical utility;

2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

3. Enhance the quality, utility, and clarity of the information to be collected; and

4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses.

Standard Form 3112, CSRS/FERS Documentation in Support of Disability Retirement Application, collects information from applicants for disability retirement so that OPM can determine whether to approve a disability retirement under 5 U.S.C. 8337 and 8455. The applicant will only complete Standard Forms 3112A and 3112C. Standard Forms 3112B, 3112D, and 3112E will be completed by the immediate supervisor and the employing agency of the applicant.

Analysis

Agency: Retirement Operations, Retirement Services, Office of Personnel Management.

Title: CSRS/FERS Documentation in Support of Disability Retirement.

OMB Number: 3206–0228.

Frequency: On occasion.

Affected Public: Individuals or Households.

Number of Respondents: 13,450 [1,350 (SF 3112A) and 12,100 (SF 3112C)].

Estimated Time per Respondent: 30 minutes (SF 3112A) and 60 minutes (SF 3112C).

Total Burden Hours: 12,775 hours [675 hours (SF 3112A) and 12,100 hours (SF 3112C)].

Office of Personnel Management.

Stephen Hickman,

Federal Register Liaison.

[FR Doc. 2023–09340 Filed 5–2–23; 8:45 am]

BILLING CODE 6325–38–P

OFFICE OF SCIENCE AND TECHNOLOGY POLICY

Request for Information; Automated Worker Surveillance and Management

AGENCY: Office of Science and Technology Policy (OSTP).

ACTION: Notice of request for information (RFI).

SUMMARY: Employers are increasingly using automated systems to monitor, manage, and evaluate their workers. These systems may allow employers to manage supply chains, improve health and safety, or make other informed business decisions. At the same time, applications of surveillance and monitoring systems can also pose risks to workers, including to their health and safety, equal employment opportunities, privacy, ability to meet critical needs, access to workplace accommodations, and exercise of workplace and labor rights, including their rights to form or join a labor union. The White House Office of Science and Technology Policy (OSTP) seeks comments from the public to better understand automated surveillance and management of workers, including its prevalence, purposes, deployment, and impacts, as well as opportunities for Federal agencies to work with employers, workers, and other stakeholders to ensure that these systems do not undermine workers' rights, opportunities, access, health, or safety.

DATES: Interested persons and organizations are invited to submit comments on or before 5 p.m. ET, June 15, 2023.

ADDRESSES: Comments must be submitted via the Federal eRulemaking Portal at *regulations.gov.* However, if you require an accommodation or cannot otherwise submit your comments via *regulations.gov,* please contact the program contact person listed under **FOR FURTHER INFORMATION CONTACT**. OSTP will not accept comments by fax, or comments submitted after the comment period closes. To ensure that OSTP does not receive duplicate copies, please submit your comments only once. Additionally, please include the Docket ID at the top of your comments.

Federal eRulemaking Portal: Go to *www.regulations.gov* to submit your comments electronically. Information on how to use *Regulations.gov,* including instructions for accessing agency documents, submitting comments, and viewing the docket, is available on the site under ''FAQ'' (*https://www.regulations.gov/faq*).

Privacy Note: OSTP's policy is to make all comments received from members of the public available for public viewing in their entirety on the Federal eRulemaking Portal at *www.regulations.gov.* Therefore, commenters should be careful to include in their comments only information that they wish to make publicly available. OSTP requests that no proprietary information, copyrighted information, or personally identifiable information be submitted in response to this RFI.

Instructions: Response to this RFI is voluntary. Respondents may answer as many or as few questions as they wish. Responses containing references, studies, research, and other empirical data that are not widely published should include copies of or electronic links to the referenced materials. Any information obtained from this RFI is intended to be used by the government on a non-attribution basis for planning and strategy development. OSTP will not respond to individual submissions. A response to this RFI will not be viewed as a binding commitment to develop or pursue the project or ideas discussed. This RFI is not accepting applications for financial assistance or financial incentives. All comments, including attachments and other supporting materials, will become part of the public record and subject to public disclosure. Proprietary information or sensitive personal information, such as account numbers or Social Security numbers, or names of other individuals, should not be included in the body of your response. Respondents interested in submitting anonymous comments should use the option on *www.regulations.gov/.*

FOR FURTHER INFORMATION CONTACT: Alan Mislove, Assistant Director for Data and Democracy, *workersurveillance@ostp.eop.gov,* 202–456–4444.

SUPPLEMENTARY INFORMATION:

Background: Employers are increasingly using automated systems to monitor, manage, and evaluate their workers—both on and off the job. According to a 2022 investigation by the *New York Times,* eight of the ten largest private U.S. employers track the productivity metrics of individual workers.[1] Use of automated surveillance and management systems has increased with the spread of remote work during the pandemic, and now often extends to workers' homes.[2] Private-sector research suggests that the percentage of large employers using automated tools to track their workforce may have doubled since the beginning of the pandemic to some 60%.[3]

Automated worker surveillance and management systems may track workers' location, pace or quality of work, communications (*e.g.,* text, chats, emails, social media), interactions with other workers or customers, and computer activity. Such surveillance can be accomplished through a variety of techniques, ranging from software on workers' computers to dedicated electronic devices that workers wear or carry on their person. The market for these technologies and systems has greatly expanded in recent years, and a number of vendors are now developing products to help employers electronically monitor and manage their workers in a variety of contexts.

Examples of applications of automated surveillance and management of workers that have been reported in the press include:

- Warehouse workers who are tracked by whether they are actively moving products
- Grocery store cashiers who are monitored on the speed of their transactions with customers
- Office workers whose keystrokes, chats, emails, and other communications are collected and monitored
- Lawyers whose computer cameras track whether their eyes are actively focused on the screen
- Call center workers whose calls are monitored by a computer that judges the emotional state of customers
- Copywriters whose computers automatically take screenshots of their activity to track which applications they are using
- Home healthcare workers whose locations are monitored by an app that verifies patient visits
- Nurses whose time on task and location are tracked through radio frequency identification (RFID) tags in identification badges
- Delivery or rideshare drivers whose vehicles track their location, speed, and driving behavior
- Long-haul truckers whose eye movements are monitored and locations tracked
- Fast food workers whose pace of work in preparing meals is tracked and reported
- Teachers whose lessons delivered remotely online are recorded and analyzed electronically

These systems may allow employers to more closely monitor worker performance; protect public health and safety; make decisions about promotion, discipline, or termination; or manage work assignments, schedules, and supply chains. At the same time, applications of automated surveillance and management systems can also pose risks to workers and even violate labor and employment laws.[4] Emerging research suggests that certain applications of these systems may undermine the quality of work; workers' rights to a safe and healthy workplace; compensation for time worked; labor market competition; and workers' ability to organize and work collectively with their coworkers to improve working conditions, including through labor unions. Certain applications of these systems—when paired with decisions about working conditions, promotion, discipline, or termination—may also treat otherwise similar workers differently on the basis of their race, ethnicity, gender, religion, age, national origin, health or disability, or other protected status. Some systems may also violate antitrust and privacy laws, for instance, if employers use technologies to artificially reduce wages.

Automated worker surveillance and management can also cause and exacerbate disabilities and interfere with legal protections for those with disabilities. Automated worker surveillance and management systems can potentially put workers at risk for physical injury and mental health distress that can cause or exacerbate anxiety, depression, cognitive disability, and trauma responses; interfere with legally-protected workplace accommodations that enable individuals with disabilities to participate in the workforce; and reveal workers' otherwise-undisclosed disabilities to employers.

In 2022, the White House Office of Science and Technology Policy released the *Blueprint for an AI Bill of Rights* (''Blueprint''), which stated that individuals ''should be free from unchecked surveillance.'' [5] The Blueprint noted that continuous surveillance can pose harms to workers, using the example of electronic monitoring intended to stymie workers'

[1] *https://www.yahoo.com/video/bosses-giving-return-office-fight-191121126.html.*

[2] *https://www.shrm.org/hr-today/news/all-things-work/pages/monitoring-remote-workers.aspx.*

[3] *https://www.gartner.com/en/articles/the-right-way-to-monitor-your-employee-productivity.*

[4] See for instance, *https://laborcenter.berkeley.edu/wp-content/uploads/2021/11/Data-and-Algorithms-at-Work.pdf, https://cdt.org/insights/report-warning-bossware-may-be-hazardous-to-your-health/,* and *https://equitablegrowth.org/research-paper/workplace-surveillance-is-becoming-the-new-normal-for-u-s-workers/.*

[5] *https://www.whitehouse.gov/ostp/ai-bill-of-rights/data-privacy-2/.*

efforts to organize a labor union. Consistent with the Blueprint, the Office of Science and Technology Policy seeks to further study the use of automated surveillance and management systems in the workplace, including their prevalence, impacts, and deployment, as well as opportunities for Federal agencies to work together with employers and workers to ensure that these systems do not undermine workers' rights or their safety.

This focus on automated surveillance and management in the workplace is also consistent with the Administration's commitment to ensuring that all workers have access to high-quality, well-paying jobs, including jobs with opportunities to organize and bargain collectively with their employers through labor unions, as articulated in the Executive Order 14025 (*Worker Organizing and Empowerment*) [6] and through a competitive market for their labor, as articulated in Executive Order 14036 (*Promoting Competition in the American Economy*).[7] This initiative advances the Biden-Harris Administration's historic commitment to racial equity and support for underserved communities, by investigating whether automated surveillance and management systems ''contribute to unjustified different treatment or impacts,'' as articulated in Executive Order 14091 (*Further Advancing Racial Equity and Support for Underserved Communities Through the Federal Government*) as well as the Administration's call for robust protections for Americans' privacy.

Request for Comment: This request for information seeks input from the public on the prevalence, uses and purposes, and deployment of automated worker surveillance and management systems, including impacts of these systems on workers' legal rights and lives. It includes workers' physical and mental health; privacy, dignity, and autonomy; and ability to exercise workplace rights, including rights to collective action, pay, reasonable accommodation, health, and safety, and freedom from retaliation, discrimination, and harassment. It also seeks input on how employers may share data collected through these surveillance applications and how worker surveillance may contribute to unfair competition between firms.

This RFI focuses on automated surveillance and management by employers that may track workers' locations, pace of work, performance or output, compliance with policy or regulations, or social media activity; their emails, texts, chats, phone calls, and other communications; or other similar measures. Such surveillance may take place during or outside of work hours, and on or off the worksite. This request for information also covers workers in traditional employment relationships (*i.e.,* W–2 employment) as well as other employment relationships, such as independent contractors and gig economy workers.

OSTP is particularly interested in hearing from:

- Workers who have experienced automated surveillance and management (including workers of color, low-paid workers, immigrant workers, and workers with disabilities);
- Worker organizations (including worker advocacy groups, worker centers, labor unions, and workplace legal services providers);
- Civil rights and privacy organizations;
- Employers (including for-profit, non-profit, and government employers) that are using automated surveillance and management systems or considering using such systems;
- Platforms, crowdsourcing websites, transportation network companies, ride-hailing services, and other entities that match workers with opportunities to generate income;
- Trade and business associations representing employers;
- Developers and vendors developing or selling automated surveillance or management systems;
- Researchers (including researchers using both qualitative and quantitative methods to understand the use, prevalence, benefits and risks, and impacts of automated surveillance and management systems on individuals and society); and
- State, Tribal, local, and territorial governments.

To assist commenters in developing responses, OSTP has crafted the questions below that commenters may answer. Respondents may provide information for one or more of the topics below, as desired. *However, OSTP welcomes members of the public to submit any personal experiences, data, information, and research relating to the use and impact of automated worker surveillance and management systems. Please do not to include personally identifying information in the body of your response.*

1. If you are a *worker or organization representing workers (such as a worker center, union, or legal services provider),* please tell us about your experiences with automated worker surveillance and management systems or the experiences of the workers you interact with, including:

a. The type of work you do (*e.g.,* describe the relevant job, employer, and industry);

b. Whether you are a member of a labor union;

c. The type of automated surveillance or management you have experienced, including the location of the monitoring technology (such as an app you had to use or download; a device you had to use, carry, or wear; or a camera that monitors you);

d. Whether the automated surveillance or management was used during a labor organizing drive;

e. Whether and when your employer informed you about their use of automated worker surveillance and management systems;

f. Whether you (or, if relevant, your representative, like a labor union) have any input or control over how, where, and over what automated surveillance occurs;

g. Whether you know how the data generated by surveillance is used for management or other purposes (including purposes related to employment or labor market competition);

h. Whether you (or, if relevant, your representative, like a labor union) have any visibility into the data collected on you or how it is used, including whether data on you collected by surveillance can be shared with other companies, trade groups, or third parties;

i. How the use of automated surveillance and management systems has changed how you do your job or how your employer treated you at your job;

j. Whether your employer has used information from an automated surveillance and management system in support of any discipline against you—and if so, what the action was, how and when you were informed, and what information was provided to you or your representative (such as a labor union);

k. How automated surveillance and management has affected you—whether positively or negatively—including any economic, safety, physical, mental, and emotional impacts;

l. How automated surveillance and management systems have affected your workplace rights, including rights around collective action, labor

[6] *https://www.whitehouse.gov/briefing-room/presidential-actions/2021/04/26/executive-order-on-worker-organizing-and-empowerment/.*

[7] *https://www.whitehouse.gov/briefing-room/presidential-actions/2021/07/09/executive-order-on-promoting-competition-in-the-american-economy/.*

organizing, collective bargaining, pay, reasonable accommodations, health and safety, discrimination, and harassment—or your expectation of retaliation when exercising these rights;

m. How these systems have impacted your non-working hours, personal time, or the privacy of other members of your household;

n. If you are disabled or have a health condition, how automated surveillance and management systems have impacted or may impact your use of reasonable accommodations; such as assistive technology or accessibility features of software or breaks, or affected your ability to keep information about your condition private from your employer, supervisor, or coworkers;

o. If you are disabled or have a health condition, how automated surveillance and management systems have affected performance reviews or other management activities, or concerns about how these systems may affect performance reviews or how your management treats you; and

p. Whether you work for an employer that receives Federal funds (for instance, as a Federal contractor).

2. If you are an employer or organization representing employers, please tell us about your experiences implementing or using automated worker surveillance and management systems, including:

a. The type of business you are in, or represent, including your industry and roughly how many workers you employ;

b. Whether any of your employees are represented by a labor union;

c. The types of automated worker surveillance and management systems your business has implemented or is considering implementing;

d. The purposes for which your business decided to implement automated worker surveillance and management systems, such as safety and health, productivity, competition, liability or insurance, compliance, or resource and worker management;

e. How your business decided to use specific automated worker surveillance and management systems, including decisions not to use particular products or types of systems, to limit their scope, and relevant training;

f. In what ways your business uses the information collected through automated surveillance and management systems, such as for management, human resources, and business operations, including whether the information is sold or shared with other businesses or otherwise influenced by other businesses' activities;

g. Any steps your business has taken to solicit or incorporate worker input into how automated worker surveillance and management systems are adopted, implemented, and used; whether workers may opt out of such systems (and any consequences for doing so); and how generated data is used or shared with other parties;

h. Any involvement of third parties (such as vendors) in collecting or maintaining information on workers and any control retained by the employer;

i. Any steps you have taken to ensure that the use or sharing of automated worker surveillance and management systems does not infringe on workers' rights;

j. How you decide the categories of workers for whom you deploy automated worker surveillance and management systems (*e.g.,* managerial versus non-managerial workers);

k. Any policies or protocols adopted to govern the use of automated worker surveillance and management systems or the data they produce; and Whether your organization receives Federal funds.

3. If you are a technology developer or vendor, please tell us about your experience developing or distributing automated worker surveillance and management systems, including:

a. The purposes for which employers adopt your products and how they deploy these products;

b. How the impact, performance, and efficacy of your products is audited and validated by you, employers, and workers;

c. How you and the users of your products manage data collection, storage, and maintenance, including access to data by third parties;

d. Whether you provide guidance to employers on your products and their appropriate use, including guidance on notifying workers about the use of technology, and offering opportunities for workers to consent to or opt out of data collection;

e. Whether you engage with employers to help them implement your products in ways that protect workers' rights, health, and safety—or otherwise take steps to help protect workers who will engage with your products; and

f. Any steps you have taken to ensure that the use of automated worker surveillance and management systems does not infringe on workers' rights.

4. Data and research-related questions we are interested in include:

a. What data and evidence exist on the prevalence of automated worker surveillance and management systems across different industries, occupations, and regions, including changes over time?

b. What data and evidence exist on the impact of automated worker surveillance and management systems on workers, including workers' pay, benefits, and employment, physical and mental health, and ability to exercise workplace rights?

c. What data and evidence exist on the impact of automated worker surveillance and management systems on labor rights, including workers' abilities to form and join unions and bargain collectively with their employers?

d. What data and evidence exist on how the impact of automated worker surveillance and management systems differs across groups of workers, including based on characteristics such as race, national origin, sex, age, disability, religion, or health status?

e. What data or evidence exists on whether automated worker surveillance and management systems are being used for discriminatory purposes or resulting in discrimination?

f. What data and evidence exist on whether automated workers surveillance and management systems impact employers' ability to recruit and retain workers?

g. What data or evidence exists on how the provision of reasonable accommodations is accounted for in the design and operation of automated worker surveillance and management systems?

h. What data and evidence exist on why employers decide to adopt automated worker surveillance and management systems?

i. Are there any existing or new systems that aggregate worker surveillance data across multiple employers?

j. What are new or emergent automated worker surveillance and management systems—or new and emergent uses of existing technologies—that Federal agencies should be tracking?

k. Where might further research, including by the Federal government, be helpful in understanding the prevalence and impact of automated worker surveillance and management systems?

5. Last, we are especially interested in the following questions about policies, practices, or standards that could protect workers:

a. What guidelines, standards, or best practices might inform the design of automated worker surveillance and management systems to protect workers' rights?

b. Are there policy approaches to regulating automated worker

surveillance and management systems from State, Tribal, territorial, or local governments or other countries that Federal agencies could learn from?

c. What policies or actions should Federal agencies consider to protect workers' rights and wellbeing as automated worker surveillance and management systems are developed and deployed, including through regulations, enforcement, contracting, and grantmaking?

Dated: April 28, 2023.

Stacy Murphy,

Deputy Chief Operations Officer/Security Officer.

[FR Doc. 2023–09353 Filed 5–2–23; 8:45 am]

BILLING CODE 3270–F1–P

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 34902]

Deregistration Under Section 8(f) of the Investment Company Act of 1940

AGENCY: Securities and Exchange Commission (''Commission'' or ''SEC'')

ACTION: Notice of applications for deregistration under section 8(f) of the Investment Company Act of 1940.

The following is a notice of applications for deregistration under section 8(f) of the Investment Company Act of 1940 for the month of April 2023. A copy of each application may be obtained via the Commission's website by searching for the applicable file number listed below, or for an applicant using the Company name search field, on the SEC's EDGAR system. The SEC's EDGAR system may be searched at *https://www.sec.gov/edgar/searchedgar/legacy/companysearch.html.* You may also call the SEC's Public Reference Room at (202) 551–8090. An order granting each application will be issued unless the SEC orders a hearing. Interested persons may request a hearing on any application by emailing the SEC's Secretary at *Secretarys-Office@sec.gov* and serving the relevant applicant with a copy of the request by email, if an email address is listed for the relevant applicant below, or personally or by mail, if a physical address is listed for the relevant applicant below. Hearing requests should be received by the SEC by 5:30 p.m. on May 23, 2023, and should be accompanied by proof of service on applicants, in the form of an affidavit or, for lawyers, a certificate of service. Pursuant to Rule 0–5 under the Act, hearing requests should state the nature of the writer's interest, any facts bearing upon the desirability of a hearing on the matter, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by writing to the Commission's Secretary at *Secretarys-Office@sec.gov.*

ADDRESSES: The Commission: *Secretarys-Office@sec.gov.*

FOR FURTHER INFORMATION CONTACT: Shawn Davis, Assistant Director, at (202) 551–6413 or Chief Counsel's Office at (202) 551–6821; SEC, Division of Investment Management, Chief Counsel's Office, 100 F Street NE, Washington, DC 20549–8010.

CornerCap Group of Funds/VA/ [File No. 811–04581]

Summary: Applicant seeks an order declaring that it has ceased to be an investment company. The applicant has transferred its assets to CornerCap Small-Cap Value Fund, a series of Managed Portfolio Series, and on November 18, 2022 made a final distribution to its shareholders based on net asset value. Expenses of $37,989.57 incurred in connection with the reorganization were paid by the applicant's investment adviser.

Filing Dates: The application was filed on February 7, 2023, and amended on April 13, 2023.

Applicant's Address: 1355 Peachtree Street, North East Suite 1700, Atlanta, Georgia 30309.

FS Series Trust [File No. 811–23216]

Summary: Applicant seeks an order declaring that it has ceased to be an investment company. The applicant has transferred its assets to The Advisors' Inner Circle Fund III, and on April 11, 2022 made a final distribution to its shareholders based on net asset value. Expenses of $527,498 incurred in connection with the reorganization were paid by the applicant's investment adviser and the acquiring fund.

Filing Date: The application was filed on April 10, 2023.

Applicant's Address: 201 Rouse Boulevard, Philadelphia, Pennsylvania 19112.

IndexIQ Trust [File No. 811–22185]

Summary: Applicant seeks an order declaring that it has ceased to be an investment company. On August 7, 2018, applicant made a liquidating distribution to its shareholders based on net asset value. Expenses of $2,500.00 incurred in connection with the liquidation were paid by the applicant's investment adviser.

Filing Date: The application was filed on April 5, 2023.

Applicant's Address: 51 Madison Avenue, New York, New York 10010.

ML of New York Variable Annuity Separate Account C [File No. 811–21119]

Summary: Applicant, a unit investment trust, seeks an order declaring that it has ceased to be an investment company. No expenses were incurred in connection with the liquidation.

Filing Date: The application was filed on March 21, 2023.

Applicant's Address: 4333 Edgewood Road Northeast, Cedar Rapids, Indiana 52499.

SunAmerica Income Funds [File No. 811–04708]

Summary: Applicant seeks an order declaring that it has ceased to be an investment company. The applicant has transferred its assets to Touchstone Strategic Trust and Touchstone Funds Group Trust, and on July 16, 2021 made a final distribution to its shareholders based on net asset value. Expenses of $7,150,960 incurred in connection with the reorganization were paid by the applicant's investment adviser.

Filing Date: The application was filed on November 23, 2022.

Applicant's Address: Harborside 5, 185 Hudson Street, Suite 3300, Jersey City, New Jersey 07311.

SunAmerica Senior Floating Rate Fund Inc [File No. 811–08727]

Summary: Applicant seeks an order declaring that it has ceased to be an investment company. The applicant has transferred its assets to the Touchstone Credit Opportunities Fund, a series of Touchstone Funds Group Trust, and on July 16, 2021 made a final distribution to its shareholders based on net asset value. Expenses of $7,150,960 incurred in connection with the reorganization were paid by the applicant's investment adviser.

Filing Date: The application was filed on November 23, 2022.

Applicant's Address: Harborside 5, 185 Hudson Street, Suite 3300, Jersey City, New Jersey 07311.

Torray Fund [File No. 811–06096]

Summary: Applicant seeks an order declaring that it has ceased to be an investment company. The applicant has transferred its assets to Torray Fund, a series of The RBB Fund Trust, and on December 9, 2022 made a final distribution to its shareholders based on net asset value. Expenses of $170,354.55 incurred in connection with the reorganization were paid by the applicant's investment adviser.

Filing Dates: The application was filed on March 6, 2023, and amended on April 17, 2023.

Applicant's Address: 7501 Wisconsin Avenue, Suite 750W, Bethesda, Maryland 20814.

VALIC Company II [File No. 811–08789]

Summary: Applicant seeks an order declaring that it has ceased to be an investment company. The applicant has transferred its assets to VALIC Company I, and on April 19, 2021 and May 24, 2021 made a final distribution to its shareholders based on net asset value. Expenses of $5,298,100 incurred in connection with the reorganization were paid by the applicant's investment adviser and the acquiring fund's investment adviser, and/or their affiliates.

Filing Date: The application was filed on August 16, 2022.

Applicant's Address: 2919 Allen Parkway, Houston, Texas 77019.

Zazove Convertible Securities Fund, Inc. [File No. 811–09189]

Summary: Applicant, a closed-end investment company, seeks an order declaring that it has ceased to be an investment company. Applicant currently has 76 beneficial owners, is not presently making an offering of securities and does not propose to make any offering of securities. Applicant will continue to operate as a private investment fund in reliance on section 3(c)(1) of the Act.

Filing Dates: The application was filed on November 30, 2022, and amended on March 30, 2023.

Applicant's Address: 520 Lake Cook Road, Suite 178, Deerfield, Illinois 60015.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

Dated: April 28, 2023.

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2023–09402 Filed 5–2–23; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–97394; File No. SR–NYSEAMER–2023–17]

Self-Regulatory Organizations; NYSE American LLC; Notice of Designation of a Longer Period for Commission Action on Proposed New Rule 980NYP and Conforming Amendments to Rule 935NY

April 27, 2023.

On February 28, 2023, NYSE American LLC (''Exchange'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] a proposed rule change to adopt Rule 980NYP (Electronic Complex Order Trading) to reflect the implementation of the Exchange's PILLAR trading technology on its options market and to make conforming amendments to Rule 935NY (Order Exposure Requirements). The proposed rule change was published for comment in the **Federal Register** on March 17, 2023.[3]

Section 19(b)(2) of the Act [4] provides that, within 45 days of the publication of notice of the filing of a proposed rule change, or within such longer period up to 90 days as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding, or as to which the self-regulatory organization consents, the Commission shall either approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether the proposed rule change should be disapproved. The 45th day after publication of the notice for this proposed rule change is May 1, 2023.

The Commission is extending this 45-day time period. The Commission finds that it is appropriate to designate a longer period within which to take action on the proposed rule change so that it has sufficient time to consider the proposed rule change. Accordingly, the Commission, pursuant to Section 19(b)(2) of the Act,[5] designates June 15, 2023, as the date by which the Commission shall either approve or disapprove, or institute proceedings to determine whether to disapprove, the proposed rule change (File No. SR–NYSEAMER–2023–17).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[6]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2023–09333 Filed 5–2–23; 8:45 am]

BILLING CODE 8011–01–P

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 97125 (March 13, 2023), 88 FR 16467.

[4] 15 U.S.C. 78s(b)(2).

[5] *Id.*

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–97392; File No. SR–CboeBZX–2023–026]

Self-Regulatory Organizations; Cboe BZX Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Its Fee Schedule

April 27, 2023.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on April 17, 2023, Cboe BZX Exchange, Inc. (''Exchange'' or ''BZX'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Cboe BZX Exchange, Inc. (the ''Exchange'' or ''BZX'' or ''BZX Equities'') proposes to amend its Fee Schedule. The text of the proposed rule change is provided in Exhibit 5.

The text of the proposed rule change is also available on the Exchange's website (*http://markets.cboe.com/us/equities/regulation/rule_filings/bzx/*), at the Exchange's Office of the Secretary, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the

[6] 17 CFR 200.30–3(a)(31).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend its Fee Schedule applicable to its equities trading platform (''BZX Equities'') as follows: (1) modify Step-Up Tier 1; and (2) modify the Non-Displayed Step-Up Tier. The Exchange proposes to implement the proposed changes to its fee schedule on April 3, 2023.[3]

The Exchange first notes that it operates in a highly competitive market in which market participants can readily direct order flow to competing venues if they deem fee levels at a particular venue to be excessive or incentives to be insufficient. More specifically, the Exchange is only one of 16 registered equities exchanges, as well as a number of alternative trading systems and other off-exchange venues that do not have similar self-regulatory responsibilities under the Exchange Act, to which market participants may direct their order flow. Based on publicly available information,[4] no single registered equities exchange has more than 17% of the market share. Thus, in such a low-concentrated and highly competitive market, no single equities exchange possesses significant pricing power in the execution of order flow. The Exchange in particular operates a ''Maker-Taker'' model whereby it pays credits to Members that add liquidity and assesses fees to those that remove liquidity. The Exchange's fee schedule sets forth the standard rebates and rates applied per share for orders that provide and remove liquidity, respectively. Currently, for orders in securities priced at or above $1.00, the Exchange provides a standard rebate of $0.00160 per share for orders that add liquidity and assesses a fee of $0.0030 per share for orders that remove liquidity.[5] For orders in securities priced below $1.00, the Exchange does not provide a rebate or assess a fee for orders that add liquidity and assesses a fee of 0.30% of total dollar value for orders that remove liquidity.[6] Additionally, in response to the competitive environment, the Exchange also offers tiered pricing which provides Members opportunities to qualify for higher rebates or reduced fees where certain volume criteria and thresholds are met. Tiered pricing provides an incremental incentive for Members to strive for higher tier levels, which provides increasingly higher benefits or discounts for satisfying increasingly more stringent criteria.

Step-Up Tiers

Pursuant to footnote 2 of the Fee Schedule, the Exchange currently offers Step Up Tiers (tiers 1 through 4) that provide Members an opportunity to receive an enhanced rebate from the standard rebate for liquidity adding orders that yield fee codes B,[7] V,[8] and Y[9] where they increase their relative liquidity each month over a predetermined baseline. The Exchange now proposes to modify the criteria of Step-Up Tier 1. The current criteria for Step-Up Tier 1 is as follows:

• Tier 1 offers an enhanced rebate of $0.0031 per share for qualifying orders (*i.e.,* orders yielding fee codes B, V, or Y) where 1) Member has a Step-Up ADAV[10] from January 2023 ≥10,000,000 or Member has a Step-Up Add TCV[11] from January 2023 ≥0.10%; and 2) Member has an ADV[12] ≥0.60% of the TCV.

The Exchange proposes to modify the criteria for Step-Up Tier 1 to the following:

• Proposed Tier 1 would offer an enhanced rebate of $0.0031 per share for qualifying orders (*i.e.,* orders yielding fee codes B, V, or Y) where (1) Member has a Step-Up Add TCV from January 2023 ≥0.09%; and (2) Member has an ADV ≥0.60% of the TCV; and (3) Member adds an ADV ≥5,000,000 for Non-Displayed orders[13] that yield fee codes HB,[14] HI,[15] HV,[16] or HY.[17]

Also pursuant to footnote 2 of the Fee Schedule, the Exchange currently offers a Non-Displayed Step-Up Tier, which provides Members an opportunity to receive an enhanced rebate from the standard rebate[18] for liquidity adding non-displayed orders that yield fee codes HB, HV, and HY and meet certain required volume-based criteria. The criteria for the Non-Displayed Step-Up Tier is as follows:

• The Non-Displayed Step-Up Tier offers an enhanced rebate of $0.0025 per share for qualifying orders (*i.e.,* orders yielding fee codes HB, HV, or HY) where (1) Member has a Step-Up ADAV from January 2023 ≥10,000,000 or Member has a Step-Up Add TCV from January 2023 ≥0.10%; and (2) Member has an ADV ≥0.60% of the TCV.

The Exchange proposes to modify the criteria of the Non-Displayed Step-Up Tier to the following:

• The Non-Displayed Step-Up Tier offers an enhanced rebate of $0.0025 per share for qualifying orders (*i.e.,* orders yielding fee codes HB, HV, or HY) where (1) Member has a Step-Up Add TCV from January 2023 ≥0.09%; and (2) Member has an ADV ≥0.60% of the TCV; and (3) Member adds an ADV ≥5,000,000 for Non-Displayed Orders that yield fee codes HB, HI, HV, or HY.

The Exchange notes that the Step-Up Tiers in general are designed to provide Members with additional opportunities to receive enhanced rebates by increasing their order flow to the Exchange, which further contributes to a deeper, more liquid market and provides even more execution opportunities for active market participants. The proposed modifications to the criteria of Step-Up Tier 1 and the Non-Displayed Step-Up Tier are designed to increase the Members' provision of liquidity to the Exchange, which increases execution opportunities and provides for overall enhanced price discovery and price improvement opportunities on the Exchange. Increased overall order flow benefits all Members by contributing

[3] The Exchange initially filed the proposed fee changes on April 3, 2023 (SR–CboeBZX–2023–022). On April 17, 2023, the Exchange withdrew that filing and submitted SR–CboeBZX–2023–025. On April 17, 2023, the Exchange withdrew SR–CboeBZX–2023–025 and submitted this proposal.

[4] *See* Cboe Global Markets, U.S. Equities Market Volume Summary, Month-to-Date (March 24, 2023), available at *https://www.cboe.com//equities/market_statistics/*.

[5] *See* BZX Equities Fee Schedule, Standard Rates.

[6] *Id.*

[7] Orders yielding Fee Code ''B'' are displayed orders adding liquidity to BZX (Tape B).

[8] Orders yielding Fee Code ''V'' are displayed orders adding liquidity to BZX (Tape A).

[9] Orders yielding Fee Code ''Y'' are displayed orders adding liquidity to BZX (Tape C).

[10] ''Step-Up ADAV'' means ADAV in the relevant baseline month subtracted from current ADAV. ADAV means average daily added volume calculated as the number of shares added per day. ADAV is calculated on a monthly basis.

[11] ''Step-Up Add TCV'' means ADAV as a percentage of TCV in the relevant baseline month subtracted from current ADAV as a percentage of TCV. TCV means total consolidated volume calculated as the volume reported by all exchanges and trade reporting facilities to a consolidated transaction reporting plan for the month for which the fees apply.

[12] ''ADV'' means average daily volume calculated as the number of shares added or removed, combined, per day. ADV is calculated on a monthly basis.

[13] *See* Exchange Rule 11.9(c)(11).

[14] Orders yielding Fee Code ''HB'' are non-displayed orders adding liquidity to BZX (Tape B).

[15] Orders yielding Fee Code ''HI'' are non-displayed orders that receive price improvement while adding liquidity to BZX .

[16] Orders yielding Fee Code ''HV'' are non-displayed orders adding liquidity to BZX (Tape A).

[17] Orders yielding Fee Code ''HY'' are non-displayed orders adding liquidity to BZX (Tape C).

[18] Currently, the Exchange provides a standard rebate of $0.00100 per share for liquidity adding non-displayed orders that yield fee codes HB, HV, or HY.

towards a robust and well-balanced market ecosystem.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Act and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of section 6(b) of the Act.[19] Specifically, the Exchange believes the proposed rule change is consistent with the section 6(b)(5) [20] requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. Additionally, the Exchange believes the proposed rule change is consistent with the section 6(b)(5) [21] requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers as well as section 6(b)(4) [22] as it is designed to provide for the equitable allocation of reasonable dues, fees and other charges among its Members and other persons using its facilities.

As described above, the Exchange operates in a highly competitive market in which market participants can readily direct order flow to competing venues if they deem fee levels at a particular venue to be excessive or incentives to be insufficient. The Exchange believes that its proposed modifications to Step-Up Tier 1 and the Non-Displayed Step-Up Tier reflects a competitive pricing structure designed to incentivize market participants to direct their order flow to the Exchange, which the Exchange believes would enhance market quality to the benefit of all Members. The Exchange believes the proposed modifications to Step-Up Tier 1 and the Non-Displayed Step-Up Tier are reasonable as they serve to incentivize Members to increase their liquidity-adding, displayed volume (Step-Up Tier 1) and liquidity-adding, non-displayed volume (Non-Displayed Step-Up Tier), which benefit all market participants by incentivizing continuous liquidity and thus, deeper, more liquid markets as well as increased execution opportunities. Particularly, the proposed incentives to provide displayed liquidity are designed to incentivize continuous displayed liquidity, which signals other market participants to take the additional execution opportunities provided by such liquidity, while the proposed incentives to provide non-displayed liquidity will further contribute to a deeper, more liquid market and provide even more execution opportunities for active market participants at improved prices. This overall increase in activity deepens the Exchange's liquidity pool, offers additional cost savings, supports the quality of price discovery, promotes market transparency, and improves market quality for all investors.

In particular, the Exchange believes the proposed modifications to Step-Up Tier 1 and the Non-Displayed Step-Up Tier represent an equitable allocation of rebates and are not unfairly discriminatory because all Members are eligible for those tiers and would have the opportunity to meet a tier's criteria and would receive the proposed rebate if such criteria is met. Further, the proposed rebates are commensurate with the proposed criteria. That is, the rebates reasonably reflect the difficulty in achieving the applicable criteria as proposed. Without having a view of activity on other markets and off-exchange venues, the Exchange has no way of knowing whether this proposed rule change would definitely result in any Members qualifying for the proposed tier. While the Exchange has no way of predicting with certainty how the proposed tiers will impact Member activity, the Exchange anticipates that at least one Member will be able to satisfy the criteria proposed under Step-Up Tier 1 and the Non-Displayed Step-Up Tier. The Exchange also notes that proposed tier/rebate will not adversely impact any Member's ability to qualify for other reduced fee or enhanced rebate tiers. Should a Member not meet the proposed criteria under the modified tier, the Member will merely not receive that corresponding enhanced rebate.

Additionally, the Exchange notes that relative volume-based incentives and discounts have been widely adopted by exchanges,[23] including the Exchange,[24] and are reasonable, equitable and non-discriminatory because they are open to all Members on an equal basis and provide additional benefits or discounts that are reasonably related to (i) the value to an exchange's market quality and (ii) associated higher levels of market activity, such as higher levels of liquidity provision and/or growth patterns. Competing equity exchanges offer similar tiered pricing structures, including schedules of rebates and fees that apply based upon members achieving certain volume and/or growth thresholds, as well as assess similar fees or rebates for similar types of orders, to that of the Exchange.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. Rather, as discussed above, the Exchange believes that the proposed changes would encourage the submission of additional order flow to a public exchange, thereby promoting market depth, execution incentives and enhanced execution opportunities, as well as price discovery and transparency for all Members. As a result, the Exchange believes that the proposed changes further the Commission's goal in adopting Regulation NMS of fostering competition among orders, which promotes ''more efficient pricing of individual stocks for all types of orders, large and small.'' [25]

The Exchange believes the proposed rule changes do not impose any burden on intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act. Particularly, the proposed tier changes apply to all Members equally in that all Members continue to be eligible for Step-Up Tier 1 and the Non-Displayed Step-Up Tier, have a reasonable opportunity to meet the tiers' criteria and will receive the corresponding additional rebates if such criteria are met. Additionally, the proposed tier changes are designed to attract additional order flow to the Exchange. The Exchange believes that the proposed tier criteria would incentivize market participants to direct liquidity adding displayed and non-displayed order flow to the Exchange, bringing with it additional execution opportunities for market participants and improved price transparency. Greater overall order flow, trading opportunities, and pricing transparency benefits all market participants on the Exchange by enhancing market quality and continuing to encourage Members to send orders, thereby contributing

[19] 15 U.S.C. 78f(b).

[20] 15 U.S.C. 78f(b)(5).

[21] *Id.*

[22] 15 U.S.C. 78f(b)(4)

[23] *See e.g.,* EDGX Equities Fee Schedule, Footnote 1, Add/Remove Volume Tiers.

[24] *See e.g.,* BZX Equities Fee Schedule, Footnote 1, Add/Remove Volume Tiers.

[25] Securities Exchange Act Release No. 51808, 70 FR 37495, 37498–99 (June 29, 2005) (S7–10–04) (Final Rule).

towards a robust and well-balanced market ecosystem.

Next, the Exchange believes the proposed rule change does not impose any burden on intermarket competition that is not necessary or appropriate in furtherance of the purposes of the Act. As previously discussed, the Exchange operates in a highly competitive market. Members have numerous alternative venues that they may participate on and direct their order flow, including 15 other equities exchanges and off exchange venues and alternative trading systems. Additionally, the Exchange represents a small percentage of the overall market. Based on publicly available information, no single equities exchange has more than 17% [26] of the market share. Therefore, no exchange possesses significant pricing power in the execution of order flow. Indeed, participants can readily choose to send their orders to other exchange and off-exchange venues if they deem fee levels at those other venues to be more favorable. Moreover, the Commission has repeatedly expressed its preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. Specifically, in Regulation NMS, the Commission highlighted the importance of market forces in determining prices and SRO revenues and, also, recognized that current regulation of the market system ''has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.'' [27] The fact that this market is competitive has also long been recognized by the courts. In NetCoalition v. Securities and Exchange Commission, the D.C. Circuit stated as follows: ''[n]o one disputes that competition for order flow is 'fierce.' . . . As the SEC explained, '[i]n the U.S. national market system, buyers and sellers of securities, and the broker-dealers that act as their order-routing agents, have a wide range of choices of where to route orders for execution'; [and] 'no exchange can afford to take its market share percentages for granted' because 'no exchange possesses a monopoly, regulatory or otherwise, in the execution of order flow from broker dealers'. . . .''.[28] Accordingly, the Exchange does not believe its proposed fee change imposes any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to section 19(b)(3)(A) of the Act [29] and paragraph (f) of Rule 19b–4 [30] thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission will institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–CboeBZX–2023–026 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–CboeBZX–2023–026. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*https://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to File Number SR–CboeBZX–2023–026, and should be submitted on or before May 24, 2023.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[31]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2023–09334 Filed 5–2–23; 8:45 am]

BILLING CODE 8011–01–P

[26] *Supra* note 3.

[27] *See* Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005).

[28] NetCoalition v. SEC, 615 F.3d 525, 539 (D.C. Cir. 2010) (quoting Securities Exchange Act Release No. 59039 (December 2, 2008), 73 FR 74770, 74782–83 (December 9, 2008) (SR–NYSEArca–2006–21)).

[29] 15 U.S.C. 78s(b)(3)(A).

[30] 17 CFR 240.19b–4(f).

[31] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–97393; File No. SR–CboeEDGX–2023–030

Self-Regulatory Organizations; Cboe EDGX Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Its Fee Schedule

April 27, 2023.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on April 17, 2023, Cboe EDGX Exchange, Inc. (''Exchange'' or ''EDGX'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Cboe EDGX Exchange, Inc. (the ''Exchange'' or ''EDGX'') proposes to amend its Fee Schedule. The text of the proposed rule change is provided in Exhibit 5.

The text of the proposed rule change is also available on the Exchange's website (*http://markets.cboe.com/us/options/regulation/rule_filings/edgx/*), at the Exchange's Office of the Secretary, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend its Fee Schedule applicable to its equities trading platform (''EDGX Equities'') as follows: (1) by modifying and introducing certain Growth Tiers; (2) by modifying the criteria of Non-Displayed Step-Up Volume Tier 1; (3) by modifying and introducing certain Remove Volume Tiers; (4) by modifying the criteria of Retail Growth Tier 3; and (5) by modifying the rates associated with certain fee codes. The Exchange proposes to implement these changes effective April 3, 2023.[3]

The Exchange first notes that it operates in a highly competitive market in which market participants can readily direct order flow to competing venues if they deem fee levels at a particular venue to be excessive or incentives to be insufficient. More specifically, the Exchange is only one of 16 registered equities exchanges, as well as a number of alternative trading systems and other off-exchange venues that do not have similar self-regulatory responsibilities under the Securities Exchange Act of 1934 (the ''Act''), to which market participants may direct their order flow. Based on publicly available information,[4] no single registered equities exchange has more than 17% of the market share. Thus, in such a low-concentrated and highly competitive market, no single equities exchange possesses significant pricing power in the execution of order flow. The Exchange in particular operates a ''Maker-Taker'' model whereby it pays rebates to members that add liquidity and assesses fees to those that remove liquidity. The Exchange's Fee Schedule sets forth the standard rebates and rates applied per share for orders that provide and remove liquidity, respectively. Currently, for orders in securities priced at or above $1.00, the Exchange provides a standard rebate of $0.00160 per share for orders that add liquidity and assesses a fee of $0.0030 per share for orders that remove liquidity.[5] For orders in securities priced below $1.00, the Exchange provides a standard rebate of $0.00009 per share for orders that add liquidity and assesses a fee of 0.30% of the total dollar value for orders that remove liquidity.[6] Additionally, in response to the competitive environment, the Exchange also offers tiered pricing which provides Members opportunities to qualify for higher rebates or reduced fees where certain volume criteria and thresholds are met. Tiered pricing provides an incremental incentive for Members to strive for higher tier levels, which provides increasingly higher benefits or discounts for satisfying increasingly more stringent criteria.

Growth Tiers

Under footnote 1 of the Fee Schedule, the Exchange currently offers various Add/Remove Volume Tiers. In particular, the Exchange offers two Growth Tiers that each provide an enhanced rebate for Members' qualifying orders yielding fee codes B,[7] V,[8] Y,[9] 3,[10] and 4,[11] where a Member reaches certain add volume-based criteria, including ''growing'' its volume over a certain baseline month. First, the Exchange is proposing to introduce new Growth Tier 1 to provide Members an additional manner in which they could receive an enhanced rebate if certain criteria is met. The proposed criteria for proposed Growth Tier 1 is as follows:

- Growth Tier 1 provides a rebate of $0.0020 per share for securities priced above $1.00 to qualifying orders (*i.e.,* orders yielding fee B, V, Y, 3, or 4) where Member adds a Step-Up ADAV[12] from January 2023 ≥0.10% of the TCV[13] or Member adds a Step-Up ADAV from January 2023 ≥10,000,000.

Proposed Growth Tier 1 will provide a lower rebate than other existing Growth Tiers, but this lower rebate is commensurate with the difficulty of meeting the less stringent criteria associated with proposed Growth Tier 1.

Second, the Exchange proposes to renumber current Growth Tiers 1 and 2 and modify the criteria of proposed Growth Tier 3 (current Growth Tier 2). Currently, Growth Tier 2 (proposed Growth Tier 3) reads as follows:

- Growth Tier 2 provides a rebate of $0.0034 per share to qualifying orders (*i.e.,* orders yielding fee codes B, V, Y, 3, or 4) where (1) Member adds a Step-Up ADAV from October 2022 ≥0.15% of the TCV or Member adds a Step-Up ADAV from October 2022 ≥15,000,000; and (2) Member has a total remove ADV[14] ≥0.45% of TCV or Member has a total remove ADV ≥45,000,000; and (3) Member adds a Retail Step-Up ADV[15]

[3] The Exchange initially filed the proposed fee changes on April 3, 2023 (SR–CboeEDGX–2023–024). On April 17, 2023, the Exchange withdrew that filing and submitted SR–CboeEDGX–2023–029. On April 17, 2023, the Exchange withdrew SR–CboeEDGX–2023–029 and submitted this proposal.

[4] *See* Cboe Global Markets, U.S. Equities Market Volume Summary, Month-to-Date (March 24, 2023), available at *https://www.cboe.com/us/equities/_statistics/.*

[5] *See* EDGX Equities Fee Schedule, Standard Rates.

[6] *Id.*

[7] Fee code B is appended to orders adding liquidity to EDGX in Tape B securities.

[8] Fee code V is appended to orders adding liquidity to EDGX in Tape A securities.

[9] Fee code Y is appended to orders adding liquidity to EDGX in Tape C securities.

[10] Fee code 3 is appended to orders adding liquidity to EDGX in the pre and post market in Tapes A or C securities.

[11] Fee code 4 is appended to orders adding liquidity to EDGX in the pre and post market in Tape B securities.

[12] ''Step-Up ADAV'' means ADAV in the relevant baseline month subtracted from current ADAV. ADAV means average daily added volume calculated as the number of shares added per day. ADAV is calculated on a monthly basis.

[13] ''TCV'' means total consolidated volume calculated as the volume reported by all exchanges and trade reporting facilities to a consolidated transaction reporting plan for the month for which the fees apply.

[14] ''ADV'' means average daily volume calculated as the number of shares added to, removed from, or routed by, the Exchange, or any combination or subset thereof, per day. ADV is calculated on a monthly basis.

[15] ''Step-Up ADV'' means ADV in the relevant baseline month subtracted from current day ADV.

(*i.e.,* yielding fee codes ZA [16] or ZO [17]) from August 2022 ≥0.10% of TCV.

Now, the Exchange proposes to remove the third prong of criteria. The proposed criteria for current Growth Tier 2 (proposed Growth Tier 3) is as follows:

• Proposed Growth Tier 3 provides a rebate of $0.0034 per share to qualifying orders (*i.e.,* orders yielding fee codes B, V, Y, 3, or 4) where (1) Member adds a Step-Up ADAV from October 2022 ≥0.15% of the TCV or Member adds a Step-Up ADAV from October 2022 ≥15,000,000; and (2) Member has a total remove ADV ≥0.45% of TCV or Member has a total remove ADV ≥45,000,000.

The proposed modification to proposed Growth Tier 3 removes a criteria designed to encourage Members to grow their volume in retail orders on the Exchange. By removing a criteria while keeping the enhanced rebate the same, the proposed criteria slightly decreases the difficulty required for Members to meet the applicable tier threshold. By introducing proposed Growth Tier 1 and decreasing the difficulty required under proposed Growth Tier 3, Members are still incentivized to grow their volume on the Exchange, thereby contributing to a deeper and more liquid market, which benefits all market participants and provides greater execution opportunities on the Exchange.

Non-Displayed Add Volume Tiers

In addition to the Growth Tiers offered under footnote 1, the Exchange also offers Non-Displayed Add Volume Tiers that each provide an enhanced rebate for Members' qualifying orders yielding fee codes DM,[18] HA,[19] MM,[20] and RP,[21] where a Member reaches certain volume-based criteria offered in each tier. The Exchange now proposes to amend the criteria of current Non-Displayed Step-Up Volume Tier 1. Currently, the criteria for Non-Displayed Step-Up Volume Tier 1 is as follows:

• Non-Displayed Step-Up Volume Tier 1 provides a rebate of $0.0026 per share to qualifying orders (*i.e.,* orders yielding fee code DM, HA, MM, or RP) where (1) Members adds a Step-Up ADAV from October 2022 ≥0.15% of the TCV or Member adds a Step-Up ADAV from October 2022 ≥15,000,000; and (2) Member has a total remove ADV ≥0.45% of TCV or Member has a total remove ADV ≥45,000,000; and (3) Member adds a Retail Step-Up ADV (*i.e.,* yielding fee codes ZA or ZO) from August 2022 ≥0.10% of TCV.

Now, the Exchange proposes to remove the third prong of criteria. The proposed criteria for Non-Displayed Step-Up Volume Tier 1 is as follows:

• Non-Displayed Step-Up Volume Tier 1 provides a rebate of $0.0026 per share to qualifying orders (*i.e.,* orders yielding fee code DM, HA, MM, or RP) where (1) Members adds a Step-Up ADAV from October 2022 ≥0.15% of the TCV or Member adds a Step-Up ADAV from October 2022 ≥15,000,000; and (2) Member has a total remove ADV ≥0.45% of TCV or Member has a total remove ADV ≥45,000,000.

The proposed modification to Non-Displayed Step-Up Volume Tier 1 is intended to remove criteria designed to incentivize Members to add non-displayed retail volume on the Exchange. By removing a criteria while keeping the enhanced rebate the same, the proposed criteria slightly decreases the difficulty required for Members to meet the applicable tier threshold while continuing to encourage Members to add non-displayed liquidity to the Exchange, thereby contributing to a deeper and more liquid market, which benefits all market participants and provides greater execution opportunities on the Exchange.

Remove Volume Tiers

In addition to the Growth Tiers and Non-Displayed Add Volume Tiers offered under footnote 1, the Exchange also offers two Remove Volume Tiers that each assess a reduced fee for Members' qualifying orders yielding fee codes BB,[22] N,[23] and W [24] where a Member reaches certain add or remove volume-based criteria. The Exchange first proposes to amend the criteria in Remove Volume Tiers 1 and 2. Currently, the criteria for these tiers is as follows:

• Remove Volume Tier 1 provides a reduced fee of $0.00275 per share for securities priced above $1.00 or 0.28% of the total dollar value in securities priced below $1.00 to qualifying orders (*i.e.,* orders yielding fee codes BB, N, or W) where (1) Member adds a Step-Up ADAV from June 2021 ≥0.10% of the TCV or Member adds a Step-Up ADAV from June 2021 ≥8,000,000; and (2) Member has a total remove ADV ≥0.60% of the TCV or Member has a total remove ADV ≥45,000,000.

• Remove Volume Tier 2 assesses a reduced fee of $0.00275 per share for securities priced above $1.00 or 0.28% of the total dollar value in securities priced below $1.00 to qualifying orders (*i.e.,* orders yielding fee codes BB, N, or W) where (1) Member has an ADAV ≥0.25% TCV with displayed orders that yield fee codes B, V, or Y; or (2) Member adds Retail Order ADV (*i.e.,* yielding fee codes ZA or ZO) ≥0.45% of the TCV.

Now, the Exchange proposes to replace the existing criteria with a single prong of criteria for each tier and slightly increase the reduced fee assessed by Remove Volume Tier 1. The proposed criteria is as follows:

• Remove Volume Tier 1 assesses a reduced fee of $0.00285 per share for securities priced above $1.00 or 0.28% of the total dollar value in securities priced below $1.00 to qualifying orders (*i.e.,* orders yielding fee codes BB, N, or W) where Member has an ADAV ≥0.25% TCV with displayed orders that yield fee codes B, V, or Y.

• Remove Volume Tier 2 assesses a reduced fee of $0.00275 per share for securities priced above $1.00 or 0.28% of the total dollar value in securities priced below $1.00 to qualifying orders (*i.e.,* orders yielding fee codes BB, N, or W) where Member adds Retail Order ADV (*i.e.,* yielding fee codes ZA or ZO) ≥0.45% of the TCV.

The proposed change to Remove Volume Tier 1 will provide a slightly lower reduced fee in exchange for less difficult criteria that continues to encourage Members to strive to meet the criteria by removing liquidity on the Exchange. Similarly, the proposed change to Remove Volume Tier 2 will assess the current reduced fee while lessening the difficulty of meeting the criteria in Remove Volume Tier 2.

Second, the Exchange proposes to introduce Remove Volume Tier 3. The proposed criteria in proposed Remove Volume Tier 3 is as follows:

• Proposed Remove Volume Tier 3 assesses a reduced fee of $0.00275 per share in securities priced above $1.00 or 0.28% of the total dollar value in securities priced below $1.00 for qualifying orders (*i.e.,* orders yielding fee codes BB, N, or W) where (1) Member adds a Step-Up ADAV from June 2021 ≥0.10% of the TCV or Member adds a Step-Up ADAV from June 2021 ≥8,000,000; and (2) Member has a total remove ADV ≥0.60% of the TCV or Members has a total remove ADV ≥45,000,000; and (3) Member adds

[16] Fee code ZA is appended to Retail Orders that add liquidity.

[17] Fee code ZO is appended to Retail orders that adds liquidity during the pre- and post-market.

[18] Fee code DM is appended to orders that add liquidity using MidPoint Discretionary Order within discretionary range.

[19] Fee code HA is appended to non-displayed orders that add liquidity.

[20] Fee code MM is appended to non-displayed orders that add liquidity using Mid-Point Peg.

[21] Fee code RP is appended to non-displayed orders that add liquidity using Supplemental Peg.

[22] Fee code BB is appended to orders that remove liquidity from EDGX in Tape B securities.

[23] Fee code N is appended to orders that remove liquidity from EDGX in Tape C securities.

[24] Fee code W is appended to orders that remove liquidity from EDGX in Tape A securities.

Retail Order ADV (*i.e.,* yielding fee codes ZA or ZO) ≥0.10% of the TCV.

The addition of proposed Remove Volume Tier 3 is designed to provide Members an alternative opportunity to earn a reduced fee where Members achieve certain add or remove volume-based criteria. The Exchange believes assessing an identical fee as Remove Volume Tier 2 albeit using slightly more difficult criteria will encourage Members to strive to meet the criteria by removing liquidity on the Exchange. The proposed changes to the Remove Volume Tiers are designed to incentivize Members to provide additional volume to the Exchange. An increase in remove liquidity on the Exchange signals an overall increase in activity from other market participants, contributes to a deeper, more liquid market, and provides additional execution opportunities for active market participants, which benefits the entire market system.

Retail Growth Tiers

Pursuant to footnote 2 of the Fee Schedule, the Exchange offers Retail Volume Tiers which provide Retail Member Organizations (''RMOs'') [25] an opportunity to receive an enhanced rebate from the standard rebate for Retail Orders [26] that add liquidity (*i.e.,* yielding fee code ZA or ZO). Currently, the Retail Volume Tiers offer three Retail Growth Tiers, where a Member is eligible for an enhanced rebate for qualifying orders (*i.e.,* yielding fee code ZA or ZO) meeting certain add volume-based criteria, including ''growing'' its volume over a certain baseline month. The Exchange now proposes to amend the criteria of Retail Growth Tier 3. Currently, the criteria for Retail Growth Tier 3 is as follows:

• Retail Growth Tier 3 provides a rebate of $0.0037 per share to qualifying orders (*i.e.,* orders yielding fee code ZA or ZO) where (1) Member adds a Step-Up ADAV from October 2022 ≥0.15% of the TCV or Member adds a Step-Up ADAV from October 2022 ≥15,000,000; (2) Member has a total remove ADV ≥0.45% of TCV or Member has a total remove ADV ≥45,000,000; and (3) Members adds a Retail Step-Up ADV (*i.e.,* yielding fee code ZA or ZO) from August 2022 ≥0.10% of TCV.

Now, the Exchange proposes to delete the third prong of criteria. The proposed criteria for Retail Growth Tier 3 is as follows:

• Retail Growth Tier 3 provides a rebate of $0.0037 per share to qualifying orders (*i.e.,* orders yielding fee code ZA or ZO) where (1) Member adds a Step-Up ADAV from October 2022 ≥0.15% of the TCV or Member adds a Step-Up ADAV from October 2022 ≥15,000,000; and (2) Member has a total remove ADV ≥0.45% of TCV or Member has a total remove ADV ≥45,000,000.

The proposed modification to Retail Growth Tier 3 removes a criteria designed to encourage RMOs to grow their volume in retail orders on the Exchange. By removing a criteria while keeping the enhanced rebate the same, the proposed criteria slightly decreases the difficulty required for Members to meet the applicable tier threshold while continuing to encourage RMOs to grow their volume in retail orders.

Furthermore, the Growth Tiers, Non-Displayed Add Volume Tiers, Remove Volume Tiers, and Retail Volume Tiers are intended to provide Members an opportunity to receive an enhanced rebate or reduced fee by increasing their order flow to the Exchange, which further contributes to a deeper, more liquid market and provides even more execution opportunities for active market participants. Incentivizing an increase in liquidity adding or removing volume, through enhanced rebate or reduced fee opportunities, encourages liquidity adding Members on the Exchange to contribute to a deeper, more liquid market, and liquidity executing Members on the Exchange to increase transactions and take execution opportunities provided by such increased liquidity, together providing for overall enhanced price discovery and price improvement opportunities on the Exchange. As such, increased overall order flow benefits all Members by contributing towards a robust and well-balanced market ecosystem.

Fee Code Changes

The Exchange currently offers fee code DX, which is appended to Midpoint Discretionary Orders (''MDOs'') [27] using the Quote Depletion Protection (''QDP'') [28] order instruction that remove liquidity from the Exchange. QDP is designed to provide enhanced protections to MDOs by tracking significant executions that constitute the best bid or offer on the EDGX Book [29] and enabling Users [30] to avoid potentially unfavorable executions by preventing MDOs entered with the optional QDP instruction from exercising discretion to trade at more aggressive prices when QDP has been triggered.[31] Currently, orders appended with fee code DX are be assessed a fee of $0.00060 per share in securities at or above $1.00 and 0.30% of dollar value for securities priced below $1.00. The Exchange proposes to increase the fee to $0.0010 per share in securities at or above $1.00. There is no proposed change in the fee assessed to securities priced below $1.00.

The Exchange also offers various fee codes for orders routed away from the Exchange. The Exchange is proposing to modify the routing fees associated with fee codes RZ,[32] I,[33] BY,[34] AA,[35] AY,[36] RR,[37] and RY [38] to match the base add or remove rate for the associated market center to which the order is routed. The rebates for fee codes RZ, I, AA, and RR will be revised to $0.0016 per share in securities priced above $1.00.[39] The rebates for fee codes BY and AY will be revised to $0.0002 per share in securities priced above $1.00.[40] The fee for fee code RY will be revised to $0.0020 per share in securities priced above $1.00.[41] There are no changes to the fees or rebates associated with securities priced below $1.00.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Act and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of

[25] *See* EDGX Rule 11.21(a)(1). A ''Retail Member Organization'' or ''RMO'' is a Member (or a division thereof) that has been approved by the Exchange under this Rule to submit Retail Orders.

[26] *See* EDGX Rule 11.21(a)(2). A ''Retail Order'' is an agency or riskless principal order that meets the criteria of FINRA Rule 5320.03 that originates from a natural person and is submitted to the Exchange by a Retail Member Organization, provided that no change is made to the terms of the order with respect to price or side of market and the order does not originate from a trading algorithm or any other computerized methodology.

[27] *See* Exchange Rule 11.8(g).

[28] *See* Exchange Rule 11.8(g)(10).

[29] *See* Exchange Rule 1.5(d).

[30] *See* Exchange Rule 1.5(ee).

[31] *See* Securities Exchange Act Release No. 89007 (June 4, 2020), 85 FR 35454 (June 10, 2020) (SR–CboeEDGX–2020–010) (''Notice of Filing of Amendment No. 1 and Order Granting Accelerated Approval of a Proposed Rule Change, as Modified by Amendment No. 1, to Amend the Rule Relating to MidPoint Discretionary Orders to Allow Optional Offset or Quote Depletion Protection Instructions'').

[32] Fee code RZ is appended to orders routed to BZX that add liquidity.

[33] Fee code I is appended to orders routed to EDGA using the ROUC routing strategy.

[34] Fee code BY is appended to orders routed to BYX using Destination Specific (''DIRC'') or ROUC routing strategy.

[35] Fee code AA is appended to orders routed to EDGA using the ALLB routing strategy.

[36] Fee code AY is appended to orders routed to BYX using the ALLB routing strategy.

[37] Fee code RR is appended to orders routed to EDGA using the DIRC routing strategy.

[38] Fee code RY is appended to orders routed to BYX that add liquidity.

[39] *See* BZX Equities Fee Schedule, Standard Rates; EDGA Equities Fee Schedule, Standard Rates.

[40] *See* BYX Equities Fee Schedule, Standard Rates.

[41] *Id.*

section 6(b) of the Act.[42] Specifically, the Exchange believes the proposed rule change is consistent with the section 6(b)(5)[43] requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. Additionally, the Exchange believes the proposed rule change is consistent with the section 6(b)(5)[44] requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers as well as section 6(b)(4)[45] as it is designed to provide for the equitable allocation of reasonable dues, fees and other charges among its Members and other persons using its facilities.

As described above, the Exchange operates in a highly competitive market in which market participants can readily direct order flow to competing venues if they deem fee levels at a particular venue to be excessive or incentives to be insufficient. The Exchange believes that its proposal to: (1) introduce a new Growth Tier and modify current Growth Tiers 1 and 2; (2) modify Non-Displayed Step-Up Volume Tier 1; (3) introduce a new Remove Volume Tier and modify current Remove Volume Tiers 1 and 2; and (4) modify Retail Growth Tier 3 reflects a competitive pricing structure designed to incentivize market participants to direct their order flow to the Exchange, which the Exchange believes would enhance market quality to the benefit of all Members. Additionally, the Exchange notes that relative volume-based incentives and discounts have been widely adopted by exchanges,[46] including the Exchange,[47] and are reasonable, equitable and non-discriminatory because they are open to all Members on an equal basis and provide additional benefits or discounts that are reasonably related to (i) the value to an exchange's market quality and (ii) associated higher levels of market activity, such as higher levels of liquidity provision and/or growth patterns. Competing equity exchanges offer similar tiered pricing structures, including schedules of rebates and fees that apply based upon members achieving certain volume and/or growth thresholds, as well as assess similar fees or rebates for similar types of orders, to that of the Exchange.

In particular, the Exchange believes its proposal to: (1) introduce a new Growth Tier and modify current Growth Tiers 1 and 2; (2) modify Non-Displayed Step-Up Volume Tier 1; (3) introduce a new Remove Volume Tier and modify current Remove Volume Tiers 1 and 2; and (4) modify Retail Growth Tier 3 is reasonable because the revised tiers will be available to all Members and provide all Members with an additional opportunity to receive an enhanced rebate or a reduced fee. The Exchange further believes the proposed modifications to its Growth Tiers, Non-Displayed Step-Up Volume Tier 1, Remove Volume Tiers, and Retail Growth Tier 3 will provide a reasonable means to encourage liquidity adding displayed orders, liquidity adding non-displayed orders, and retail orders, respectively, in Members' order flow to the Exchange and to incentivize Members to continue to provide liquidity adding volume to the Exchange by offering them an additional opportunity to receive an enhanced rebate or reduced fee on qualifying orders. An overall increase in activity would deepen the Exchange's liquidity pool, offers additional cost savings, support the quality of price discovery, promote market transparency and improve market quality, for all investors.

The Exchange believes that the proposed changes to its Growth Tiers, Non-Displayed Step-Up Volume Tier 1, Remove Volume Tiers, and Retail Growth Tier 3 are reasonable as they do not represent a significant departure from the criteria currently offered in the Fee Schedule. Further, the Exchange believes its proposed changes to the routing fee codes and to fee code DX are reasonable as these changes do not represent a significant departure from the Exchange's general pricing structure. The Exchange notes that the proposed changes to fee code DX are a modest increase over existing prices and yet the proposed fee is lower than other similar fees to remove volume on the Exchange.[48] Indeed, the proposed changes to fee codes RZ, I, BY, AA, AY, RR, and RY are intended to match the base add or remove rates on the Exchange's affiliates.[49] The Exchange also believes that the proposal represents an equitable allocation of fees and rebates and is not unfairly discriminatory because all Members will be eligible for the proposed new tiers and have the opportunity to meet the tiers' criteria and receive the corresponding enhanced rebate if such criteria is met. Without having a view of activity on other markets and off-exchange venues, the Exchange has no way of knowing whether this proposed rule change would definitely result in any Members qualifying the new proposed tiers. While the Exchange has no way of predicting with certainty how the proposed changes will impact Member activity, based on the prior months volume, the Exchange anticipates that at least one Member will be able to satisfy proposed Growth Tier 1, at least two Members will be able to satisfy proposed Growth Tier 3, at least two Members will be able to satisfy proposed Non-Displayed Step-Up Volume Tier 1, at least two Members will be able to satisfy proposed Remove Volume Tier 1, at least two Members will be able to satisfy proposed Remove Volume Tier 2, at least one Member will be able to satisfy proposed Remove Volume Tier 3, and at least two Members will be able to satisfy proposed Retail Growth Tier 3. The Exchange also notes that proposed changes will not adversely impact any Member's ability to qualify for enhanced rebates offered under other tiers. Should a Member not meet the proposed new criteria, the Member will merely not receive that corresponding enhanced rebate.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. Rather, as discussed above, the Exchange believes that the proposed changes would encourage the submission of additional order flow to a public exchange, thereby promoting market depth, execution incentives and enhanced execution opportunities, as well as price discovery and transparency for all Members. As a result, the Exchange believes that the proposed changes further the Commission's goal in adopting Regulation NMS of fostering competition among orders, which promotes ''more efficient pricing of individual stocks for all types of orders, large and small.''

[42] 15 U.S.C. 78f(b).

[43] 15 U.S.C. 78f(b)(5).

[44] *Id.*

[45] 15 U.S.C. 78f(b)(4)

[46] *See e.g.,* BZX Equities Fee Schedule, Footnote 1, Add/Remove Volume Tiers.

[47] *See e.g.,* EDGX Equities Fee Schedule, Footnote 1, Add/Remove Volume Tiers.

[48] *See,* Cboe EDGX Equities Fee Schedule, Fee Codes and Associated Fees.

[49] *Supra* notes 38–39.

The Exchange believes the proposed rule changes do not impose any burden on intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act. Particularly, the proposed changes to the Exchange's Growth Tiers, Non-Displayed Step-Up Volume Tier 1, Remove Volume Tiers, and Retail Growth Tier 3 will apply to all Members equally in that all Members are eligible for each of the Tiers, have a reasonable opportunity to meet the Tiers' criteria and will receive the enhanced rebate on their qualifying orders if such criteria is met. The Exchange does not believe the proposed changes burdens competition, but rather, enhances competition as it is intended to increase the competitiveness of EDGX by amending an existing pricing incentive and adopting pricing incentives in order to attract order flow and incentivize participants to increase their participation on the Exchange, providing for additional execution opportunities for market participants and improved price transparency. Greater overall order flow, trading opportunities, and pricing transparency benefits all market participants on the Exchange by enhancing market quality and continuing to encourage Members to send orders, thereby contributing towards a robust and well-balanced market ecosystem.

The Exchange does not believe the proposal to revise the applicable fee or rebate associated with the Exchange's routing fee codes or fee code DX does not impose a burden on intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed fee associated with fee code DX would apply to all Members equally in that all Members would be subject to the same flat fee for the execution of an MDO with a QDP instruction that removes liquidity from the Exchange. Both MDO and the associated QDP instruction are available to all Members on an equal and non-discriminatory basis. As a result, any Member can decide to use (or not use) the QDP instruction based on the benefits provided by that instruction in potentially avoiding unfavorable executions, and the associated charge that the Exchange proposes to amend. In addition, the fees and rebates associated with routing orders away from the Exchange similarly apply to all Members on an equal and non-discriminatory basis and Members can choose to use (or not use) the Exchange's routing functionality as part of their decision to submit order flow to the Exchange.

Next, the Exchange believes the proposed rule changes does not impose any burden on intermarket competition that is not necessary or appropriate in furtherance of the purposes of the Act. As previously discussed, the Exchange operates in a highly competitive market. Members have numerous alternative venues that they may participate on and direct their order flow, including other equities exchanges, off-exchange venues, and alternative trading systems. Additionally, the Exchange represents a small percentage of the overall market. Based on publicly available information, no single equities exchange has more than 17% of the market share.[50] Therefore, no exchange possesses significant pricing power in the execution of order flow. Indeed, participants can readily choose to send their orders to other exchange and off-exchange venues if they deem fee levels at those other venues to be more favorable. Moreover, the Commission has repeatedly expressed its preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. Specifically, in Regulation NMS, the Commission highlighted the importance of market forces in determining prices and SRO revenues and, also, recognized that current regulation of the market system ''has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.'' [51] The fact that this market is competitive has also long been recognized by the courts. In *NetCoalition* v. *Securities and Exchange Commission*, the D.C. Circuit stated as follows: ''[n]o one disputes that competition for order flow is 'fierce.' . . . As the SEC explained, '[i]n the U.S. national market system, buyers and sellers of securities, and the broker-dealers that act as their order-routing agents, have a wide range of choices of where to route orders for execution'; [and] 'no exchange can afford to take its market share percentages for granted' because 'no exchange possesses a monopoly, regulatory or otherwise, in the execution of order flow from broker dealers'. . . .''.[52] Accordingly, the Exchange does not believe its proposed fee change imposes any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to section 19(b)(3)(A) of the Act [53] and paragraph (f) of Rule 19b–4 [54] thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission will institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–CboeEDGX–2023–030 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–CboeEDGX–2023–030. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*https://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent

[50] *Supra* note 3.

[51] *See* Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005).

[52] *NetCoalition* v. *SEC*, 615 F.3d 525, 539 (D.C. Cir. 2010) (quoting Securities Exchange Act Release No. 59039 (December 2, 2008), 73 FR 74770, 74782–83 (December 9, 2008) (SR–NYSEArca–2006–21)).

[53] 15 U.S.C. 78s(b)(3)(A).

[54] 17 CFR 240.19b–4(f).

amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to File Number SR–CboeEDGX–2023–030, and should be submitted on or before May 24, 2023.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[55]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2023–09335 Filed 5–2–23; 8:45 am]

BILLING CODE 8011–01–P

DEPARTMENT OF STATE

[Public Notice: 12064]

Notice of Determinations; Culturally Significant Object Being Imported for Exhibition—Determinations: ''The Artist's Mother: Whistler and Philadelphia'' Exhibition

SUMMARY: Notice is hereby given of the following determinations: I hereby determine that a certain object being imported from abroad pursuant to an agreement with its foreign owner or custodian for temporary display in the exhibition ''The Artist's Mother: Whistler and Philadelphia'' at the Philadelphia Museum of Art, Philadelphia, Pennsylvania, and at possible additional exhibitions or venues yet to be determined, is of cultural significance, and, further, that its temporary exhibition or display within the United States as aforementioned is in the national interest. I have ordered that Public Notice of these determinations be published in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Elliot Chiu, Attorney-Adviser, Office of the Legal Adviser, U.S. Department of State (telephone: 202–632–6471; email: *section2459@state.gov*). The mailing address is U.S. Department of State, L/PD, 2200 C Street NW (SA–5), Suite 5H03, Washington, DC 20522–0505.

SUPPLEMENTARY INFORMATION: The foregoing determinations were made pursuant to the authority vested in me by the Act of October 19, 1965 (79 Stat. 985; 22 U.S.C. 2459), E.O. 12047 of March 27, 1978, the Foreign Affairs Reform and Restructuring Act of 1998 (112 Stat. 2681, *et seq.;* 22 U.S.C. 6501 note, *et seq.*), Delegation of Authority No. 234 of October 1, 1999, Delegation of Authority No. 236–3 of August 28, 2000, and Delegation of Authority No. 523 of December 22, 2021.

Scott Weinhold,

Principal Deputy Assistant Secretary for Educational and Cultural Affairs, Bureau of Educational and Cultural Affairs, Department of State.

[FR Doc. 2023–09413 Filed 5–2–23; 8:45 am]

BILLING CODE 4710–05–P

SURFACE TRANSPORTATION BOARD

[Docket No. FD 36693]

BNSF Railway Company—Trackage Rights Exemption—Montana Rail Link, Inc.

BNSF Railway Company (BNSF) has filed a verified notice of exemption under 49 CFR 1180.2(d)(7), for acquisition of local and overhead trackage rights over approximately 65.7 miles of non-contiguous rail line owned by Montana Rail Link, Inc. (MRL), as follows: (1) from milepost 0.00 at Sappington, Mont., to milepost 9.84 at Harrison, Mont.; (2) from milepost 0.00 at East Helena, Mont., to milepost 4.86 at Montana City, Mont.; and (3) from milepost 0.00 at Logan, Mont., to milepost 51.00 at Spire Rock, Mont. (the Branch Lines).

BNSF and MRL have entered into a written trackage rights agreement [1] that grants BNSF exclusive local and overhead trackage rights over the Branch Lines. This agreement is related to a recent Board decision in which MRL obtained authority to discontinue service over approximately 656.47 miles of rail line and to discontinue trackage rights service over approximately 66.47 miles of rail line in Montana, Idaho, and Washington, thereby allowing BNSF to resume operations along this corridor.[2] According to the verified notice, MRL has agreed to grant BNSF trackage rights over the Branch Lines in order to facilitate that restored BNSF service. While MRL will continue to own the Branch Lines, BNSF states that it has agreed with MRL that BNSF will fulfill any and all common carrier obligations and responsibilities relating to the Branch Lines in connection with BNSF's trackage rights operations.

The transaction may be consummated on or after May 17, 2023, the effective date of the exemption.

As a condition to this exemption, any employees affected by the acquisition of the trackage rights will be protected by the conditions imposed in *Norfolk & Western Railway—Trackage Rights—Burlington Northern, Inc.,* 354 I.C.C. 605 (1978), as modified in *Mendocino Coast Railway—Lease & Operate—California Western Railroad,* 360 I.C.C. 653 (1980).

If the notice contains false or misleading information, the exemption is void ab initio. Petitions to revoke the exemption under 49 U.S.C. 10502(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the effectiveness of the exemption. Petitions for stay must be filed no later than May 10, 2023 (at least seven days before the exemption becomes effective).

All pleadings, referring to Docket No. FD 36693, must be filed with the Surface Transportation Board via e-filing on the Board's website or in writing addressed to 395 E Street SW, Washington, DC 20423–0001. In addition, a copy of each pleading must be served on BNSF's representative, Peter W. Denton, Steptoe & Johnson LLP, 1330 Connecticut Ave. NW, Washington, DC 20036.

According to BNSF, this action is categorically excluded from environmental review under 49 CFR 1105.6(c) and from historic preservation reporting requirements under 49 CFR 1105.8(b).

Board decisions and notices are available at *www.stb.gov.*

Decided: April 27, 2023.

[55] 17 CFR 200.30–3(a)(12).

[1] A redacted version of the trackage rights agreement between BNSF and MRL was filed with the verified notice. An unredacted version of the agreement was submitted to the Board under seal concurrently with a motion for protective order, which is addressed in a separate decision.

[2] *Mont. Rail Link, Inc.—Discontinuance of Service Exemption—in Yellowstone, Stillwater, Sweet Grass, Park, Gallatin, Broadwater, Jefferson, Lewis & Clark, Powell, Deer Lodge, Granite, Missoula, Lake, Mineral, & Sanders Cntys., Mont.; Bonner & Kootenai Cntyss, Idaho; & Spokane Cnty., Wash.,* AB 575 (Sub-No. 2X) (STB served Mar. 8, 2023).

By the Board, Mai T. Dinh, Director, Office of Proceedings.

Brendetta Jones,

Clearance Clerk.

[FR Doc. 2023–09360 Filed 5–2–23; 8:45 am]

BILLING CODE 4915–01–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

[Docket No. FHWA–2023–0011]

Agency Information Collection Activities: Request for Comments for a New Information Collection

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice and request for comments.

SUMMARY: The FHWA invites public comments about our intention to request the Office of Management and Budget's (OMB) approval for a new information collection, which is summarized below under **SUPPLEMENTARY INFORMATION**. We are required to publish this notice in the **Federal Register** by the Paperwork Reduction Act of 1995.

DATES: Please submit comments by July 3, 2023.

ADDRESSES: You may submit comments identified by DOT Docket ID Number 2023–0011 by any of the following methods:

Website: For access to the docket to read background documents or comments received go to the Federal eRulemaking Portal: Go to *http://www.regulations.gov.*

Follow the online instructions for submitting comments.

Fax: 1–202–493–2251.

Mail: Docket Management Facility, U.S. Department of Transportation, West Building, Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590–00012.

Hand Delivery or Courier: U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590, between 9 a.m. and 5 p.m. ET, Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Dan Parker, Senior Program Analyst at *danial.parker@dot.gov,* Federal Highway Administration, Department of Transportation, 1200 New Jersey Ave. SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Title: Federal Share Flexibility Pilot Program.

Background: This is a request for Office of Management and Budget (OMB) emergency clearance for a new information collection request (ICR) to enable the Department of Transportation (DOT) Federal Highway Administration (FHWA) to implement the Federal Share Flexibility Pilot Program (FSFPP). The FSFPP was authorized in the Bipartisan Infrastructure Law (BIL), enacted as the Infrastructure Investment and Jobs Act (Act) (Pub. L. 117–58) on November 15, 2021. This historic Act is a once-in-a-generation opportunity to support transformational investments in our Nation's transportation infrastructure that will create good jobs, modernize our infrastructure, improve safety, tackle the climate crisis, and invest in communities that have too often been left behind. The Act includes the FSFPP to improve the safety, efficiency, and reliability of the movement of people and freight by replacing, rehabilitating, preserving, and protecting bridges in the National Bridge Inventory (NBI).

The FSFPP is critical to enabling State Department of Transportation (State DOT) agencies participating in the pilot added flexibility in the management and reimbursement of FHWA funded programs. The statutory requirements of the FSFPP are found under section 11107 of the BIL and codified at 23 U.S.C. 120(l). This new provision under Title 23 requires the establishment of a FSFPP not later than 180 days after the date of enactment of the BIL. Under the pilot, up to 10 State DOTs may be selected to participate. Selected State DOTs in the pilot are allowed to determine the Federal share on an individual project that is more than 0 percent and up to 100 percent as long as the average annual Federal share of all participating projects does not exceed the average of the maximum Federal share of those projects if those projects were not carried out under the pilot program.

Respondents: States, units of local government, and an Indian Tribe as defined in section 4 of the Indian Self-Determination and Education Assistance Act (25 U.S.C. 5304).

Expected Number of Respondents: 50.

Frequency: One-time application, to be followed by project agreement execution, reimbursement of funds, reporting, and project closeout.

Estimated Average Burden Hours per Response: 16.

Estimated Total Annual Burden Hours: 800.

Public Comments Invited: You are asked to comment on any aspect of this information collection, including: (1) Whether the proposed collection is necessary for the FHWA's performance; (2) the accuracy of the estimated burdens; (3) ways for the FHWA to enhance the quality, usefulness, and clarity of the collected information; and (4) ways that the burden could be minimized, including the use of electronic technology, without reducing the quality of thecollected information. The agency will summarize and/or include your comments in the request for OMB's clearance of this information collection.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. chapter 35, as amended; 23 U.S.C. 134 and 135; and 23 CFR chapter 1, subchapter E, part 450.

Dated: April 27, 2023.

Michael Howell,

FHWA Information Collection Officer.

[FR Doc. 2023–09313 Filed 5–2–23; 8:45 am]

BILLING CODE 4910–22–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[FMCSA Docket No. FMCSA–2023–0030]

Qualification of Drivers; Exemption Applications; Epilepsy and Seizure Disorders

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), Department of Transportation (DOT).

ACTION: Notice of final disposition.

SUMMARY: FMCSA announces its decision to exempt 11 individuals from the requirement in the Federal Motor Carrier Safety Regulations (FMCSRs) that interstate commercial motor vehicle (CMV) drivers have ''no established medical history or clinical diagnosis of epilepsy or any other condition which is likely to cause loss of consciousness or any loss of ability to control a CMV.'' The exemptions enable these individuals who have had one or more seizures and are taking anti-seizure medication to operate CMVs in interstate commerce.

DATES: The exemptions were applicable on April 26, 2023. The exemptions expire on April 26, 2025.

FOR FURTHER INFORMATION CONTACT: Ms. Christine A. Hydock, Chief, Medical Programs Division, FMCSA, DOT, 1200 New Jersey Avenue SE, Room W64–224, Washington, DC 20590–0001, (202) 366–4001, *fmcsamedical@dot.gov.* Office hours are from 8:30 a.m. to 5 p.m. ET Monday through Friday, except Federal holidays. If you have questions regarding viewing or submitting material to the docket, contact Dockets Operations, (202) 366–9826.

SUPPLEMENTARY INFORMATION:

I. Public Participation

A. Viewing Comments

To view comments go to *www.regulations.gov.* Insert the docket number, (FMCSA–2023–0030) in the keyword box and click ''Search.'' Next, sort the results by ''Posted (Newer-Older),'' choose the first notice listed, and click ''Browse Comments.'' If you do not have access to the internet, you may view the docket online by visiting Dockets Operations in Room W12–140 on the ground floor of the DOT West Building, 1200 New Jersey Avenue SE, Washington, DC 20590–0001, between 9 a.m. and 5 p.m. ET Monday through Friday, except Federal holidays. To be sure someone is there to help you, please call (202) 366–9317 or (202) 366–9826 before visiting Dockets Operations.

B. Privacy Act

In accordance with 49 U.S.C. 31315(b)(6), DOT solicits comments from the public on the exemption requests. DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov.* As described in the system of records notice DOT/ALL 14 (Federal Docket Management System), which can be reviewed at *https://www.transportation.gov/individuals/privacy/privacy-act-system-records-notices,* the comments are searchable by the name of the submitter.

II. Background

On March 22, 2023, FMCSA published a notice announcing receipt of applications from 11 individuals requesting an exemption from the epilepsy and seizure disorders prohibition in 49 CFR 391.41(b)(8) and requested comments from the public (88 FR 17287). The public comment period ended on April 21, 2023, and no comments were received.

FMCSA has evaluated the eligibility of these applicants and determined that granting exemptions to these individuals would likely achieve a level of safety that is equivalent to, or greater than, the level that would be achieved by complying with § 391.41(b)(8).

The physical qualification standard for drivers regarding epilepsy found in § 391.41(b)(8) states that a person is physically qualified to drive a CMV if that person has no established medical history or clinical diagnosis of epilepsy or any other condition which is likely to cause the loss of consciousness or any loss of ability to control a CMV.

In addition to the regulations, FMCSA has published advisory criteria [1] to assist medical examiners (MEs) in determining whether drivers with certain medical conditions are qualified to operate a CMV in interstate commerce.

III. Discussion of Comments

FMCSA received no comments in this proceeding.

IV. Basis for Exemption Determination

Under 49 U.S.C. 31136(e) and 31315(b), FMCSA may grant an exemption from the FMCSRs for no longer than a 5-year period if it finds such exemption would likely achieve a level of safety that is equivalent to, or greater than, the level that would be achieved absent such exemption. The statutes allow the Agency to renew exemptions at the end of the 5-year period. However, FMCSA grants medical exemptions from the FMCSRs for a 2-year period to align with the maximum duration of a driver's medical certification.

The Agency's decision regarding these exemption applications is based on the 2007 recommendations of the Agency's Medical Expert Panel. The Agency conducted an individualized assessment of each applicant's medical information, including the root cause of the respective seizure(s) and medical information about the applicant's seizure history, the length of time that has elapsed since the individual's last seizure, the stability of each individual's treatment regimen and the duration of time on or off of anti-seizure medication. In addition, the Agency reviewed the treating clinician's medical opinion related to the ability of the driver to safely operate a CMV with a history of seizure and each applicant's driving record found in the commercial driver's license Information System for commercial driver's license (CDL) holders, and interstate and intrastate inspections recorded in the Motor Carrier Management Information System. For non-CDL holders, the Agency reviewed the driving records from the State Driver's Licensing Agency. A summary of each applicant's seizure history was discussed in the March 22, 2023, **Federal Register** notice (88 FR 17287) and will not be repeated in this notice.

These 11 applicants have been seizure-free over a range of 31 years while taking anti-seizure medication and maintained a stable medication treatment regimen for the last 2 years. In each case, the applicant's treating physician verified his or her seizure history and supports the ability to drive commercially.

The Agency acknowledges the potential consequences of a driver experiencing a seizure while operating a CMV. However, the Agency believes the drivers granted this exemption have demonstrated that they are unlikely to have a seizure and their medical condition does not pose a risk to public safety.

Consequently, FMCSA finds further that in each case exempting these applicants from the epilepsy and seizure disorder prohibition in § 391.41(b)(8) would likely achieve a level of safety equal to that existing without the exemption, consistent with the applicable standard in 49 U.S.C. 31315(b)(1).

V. Conditions and Requirements

The terms and conditions of the exemption are provided to the applicants in the exemption document and include the following: (1) each driver must remain seizure-free and maintain a stable treatment during the 2-year exemption period; (2) each driver must submit annual reports from their treating physicians attesting to the stability of treatment and that the driver has remained seizure-free; (3) each driver must undergo an annual medical examination by a certified ME, as defined by § 390.5T; and (4) each driver must provide a copy of the annual medical certification to the employer for retention in the driver's qualification file, or keep a copy of his/her driver's qualification file if he/she is self-employed. The driver must also have a copy of the exemption when driving, for presentation to a duly authorized Federal, State, or local enforcement official.

VI. Preemption

During the period the exemption is in effect, no State shall enforce any law or regulation that conflicts with this exemption with respect to a person operating under the exemption.

VII. Conclusion

Based upon its evaluation of the 11 exemption applications, FMCSA exempts the following drivers from the epilepsy and seizure disorder prohibition in § 391.41(b)(8), subject to the requirements cited above:

Keith Dohrmann (MN)
Wallace Ferguson (CO)
Derek Jazdzewski (WI)

[1] These criteria may be found in APPENDIX A TO PART 391—MEDICAL ADVISORY CRITERIA, section H. Epilepsy: § 391.41(b)(8), paragraphs 3, 4, and 5, which is available on the internet at *https://www.gpo.gov/fdsys/pkg/CFR-2015-title49-vol5/pdf/CFR-2015-title49-vol5-part391-appA.pdf.*

Charles E. Johnson (KS)
Michael Littleton (CO)
Robert Newhand (NY)
Kristopher Pettitt (CA)
Taylor Ramey (TX)
Herbert Spike (CT)
Scott Stone (WY)
Andrew Toler (VA)

In accordance with 49 U.S.C. 31315(b), each exemption will be valid for 2 years from the effective date unless revoked earlier by FMCSA. The exemption will be revoked if the following occurs: (1) the person fails to comply with the terms and conditions of the exemption; (2) the exemption has resulted in a lower level of safety than was maintained prior to being granted; or (3) continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31136, 49 U.S.C. chapter 313, or the FMCSRs.

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2023–09327 Filed 5–2–23; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[Docket No. FRA–2022–0004]

Equivalent Protective Arrangements for Railroad Employees; Withdrawal of Notice of Final Guidance

AGENCY: Federal Railroad Administration (FRA), Department of Transportation (DOT).

ACTION: Notice; withdrawal.

SUMMARY: On November 28, 2022, the Federal Railroad Administration (FRA) published a notice in the **Federal Register** announcing the availability of final guidance issued by FRA in connection with statutorily required protective arrangements for employees impacted by certain projects financed by the Federal government. This document withdraws that notice, FR Doc. 2022–25882. The final guidance issued by FRA remains in effect.

DATES: As of May 3, 2023, FR Doc. 2202–25882, published on November 28, 2022, is withdrawn.

FOR FURTHER INFORMATION CONTACT: For further information, please contact Kevin MacWhorter, Attorney-Adviser, Development Law Office, at telephone: (202) 641–8727, email: *Kevin.MacWhorter@dot.gov.*

SUPPLEMENTARY INFORMATION: FR Doc. 2202–25882, published on November 28, 2022, (87 FR 73064), is withdrawn by this notice.

Issued in Washington, DC.

Allison Ishihara Fultz,

Chief Counsel.

[FR Doc. 2023–09384 Filed 5–2–23; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA–2023–0019]

Agency Information Collection Activities; Notice and Request for Comment; State Data Transfer for Vehicle Crash Information

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT).

ACTION: Notice and request for comments on a request for modification of a currently approved information collection.

SUMMARY: The National Highway Traffic Safety Administration (NHTSA) invites public comments about our intention to request approval from the Office of Management and Budget (OMB) for a modification of a currently approved information collection. Before a Federal agency can collect certain information from the public, it must receive approval from OMB. Under procedures established by the Paperwork Reduction Act of 1995, before seeking OMB approval, Federal agencies must solicit public comment on proposed collections of information, including extensions and reinstatement of previously approved collections. This document describes a collection of information for which NHTSA intends to seek OMB approval on State Data Transfer for Vehicle Crash Information collection.

DATES: Comments must be submitted on or before July 3, 2023.

ADDRESSES: You may submit comments identified by the Docket No. NHTSA–2021–0039 through any of the following methods:

- *Electronic Submissions:* Go to the Federal eRulemaking Portal at *http://www.regulations.gov.* Follow the online instructions for submitting comments.
- *Fax:* (202) 493–2251.
- *Mail or Hand Delivery:* Docket Management, U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays. To be sure someone is there to help you, please call (202) 366–9322 before coming.

Instructions: All submissions must include the agency name and docket number for this notice. Note that all comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided. Please see the Privacy Act heading below.

Privacy Act: Anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477–78) or you may visit *https://www.transportation.gov/privacy.*

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* or the street address listed above. Follow the online instructions for accessing the dockets via internet.

FOR FURTHER INFORMATION CONTACT: For additional information or access to background documents, contact Liza Lemaster-Sandbank, Office of State Data Reporting System Division, (NSA–0130), (202) 366–4257, National Highway Traffic Safety Administration, W53–306, U.S. Department of Transportation, 1200 New Jersey Avenue SE, Washington, DC 20590.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.,*), before an agency submits a proposed collection of information to OMB for approval, it must first publish a document in the **Federal Register** providing a 60-day comment period and otherwise consult with members of the public and affected agencies concerning each proposed collection of information. The OMB has promulgated regulations describing what must be included in such a document. Under OMB's regulation (at 5 CFR 1320.8(d)), an agency must ask for public comment on the following: (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) how to enhance the quality, utility, and clarity of the information to be collected; and (d) how to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated,

electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.* permitting electronic submission of responses. In compliance with these requirements, NHTSA asks for public comments on the following proposed collection of information for which the agency is seeking approval from OMB.

Title: State Data Transfer (SDT) for Vehicle Crash Information.

OMB Control Number: 2127–0753.

Form Number(s): None.

Type of Request: Modification a currently approved information collection.

Type of Review Requested: Regular.

Requested Expiration Date of Approval: 3 years from date of approval.

Summary of the Collection of Information: The State Data Transfer (SDT) program is a voluntary collection of motor vehicle crash data. State agencies collect this information about motor vehicle crashes on Police Accident Reports (PARs) [1] for their own needs. In general, a PAR includes information about the vehicles and individuals involved in a crash, injuries or fatalities resulting from a crash, roadway information, environmental information, information to reconstruct the crash scenes, etc. The SDT is a process through which participating States transfer their PAR data to NHTSA. SDT has two components that NHTSA's National Center for Statistics and Analysis (NCSA) calls protocols:

1. The *State Data System (SDS)* protocol obtains PAR crash data from States that submit data on an annual basis to NCSA. The data is submitted via electronic media, such as encrypted CD–ROM/DVD, or through secured mail or a secure file transfer protocol (SFTP). Files submitted through the SDS protocol are referred to as ''annual crash files.''

2. The *Electronic Data Transfer (EDT)* protocol obtains PAR crash data, crash reports, and crash images from participating State crash systems through an electronic data transfer. Generally, this transfer occurs on a nightly basis following State data quality control checks and acceptance from each State's centralized database. The information is transmitted using Extensible Markup Language (XML) or JavaScript Object Notation (JSON) files through a web service using Hypertext Transfer Protocol Secure (HTTPS) protocol between a State's crash data system and NHTSA. NHTSA started using this EDT protocol in 2015. The data NHTSA receives is in the States' format, which is not standardized. NHTSA does not currently provide regular funding to the States to participate in EDT.

On November 15, 2021, President Biden signed the Infrastructure Investment and Jobs Act (IIJA or the Bipartisan Infrastructure Law), Public Law 117–58. Section 24108 (d) authorizes the Secretary of Transportation to establish the State Electronic Data Collection (SEDC) program to provide grants to States to establish, upgrade, and standardize their centralized statewide crash data repositories to enable electronic data collection, intrastate data sharing, and electronic data transfer to NHTSA. The objective is to increase the accuracy, timeliness, and accessibility of the data, including data related to fatalities involving vulnerable road users. Through SEDC, NHTSA will award grants to States to modernize or establish a centralized statewide crash data repository to enable full electronic data transfer to NHTSA, increase their alignment to the Model Minimum Uniform Crash Criteria (MMUCC) Sixth Edition data, and transmit the data in a standardized format to NHTSA. This information collection request is to modify NHTSA's existing information collection for SDT to account for changes resulting from the new grant program. The new grant program will not only increase the number of States using the EDT protocol, but it will also request data standardization and increased alignment with the MMUCC. States awarded the SEDC grant will be referred to as SEDC States; States that continue to electronically transmit their crash data to NHTSA through the EDT protocol without SEDC grant funds will be referred to as non-SEDC States.

The SDT process allows States to submit all their PAR data to NHTSA. NCSA uses this data to develop a census of the participating State's crashes. The dataset helps NCSA identify existing and emerging highway safety trends and assess the effectiveness of motor vehicle safety standards and new and emerging technologies on vehicle and highway safety programs. NHTSA also uses the dataset to support NHTSA's Corporate Average Fuel Economy (CAFE) program. Specifically, NHTSA uses the data to analyze the effects vehicle mass has on fatalities in cost benefit analyses for CAFE rulemakings.

Description of the Need for the Information and Proposed Use of the Information: NHTSA utilizes the SDT data to identify existing and emerging highway safety trends, assess the effectiveness of motor vehicle safety standards, and study the impact of new and emerging technologies on vehicles and highway safety programs. For example, NHTSA combines data from the SDT with information about the type of advanced driver assistance systems (ADAS) on crash-involved vehicles to estimate the effectiveness of ADAS technologies such as lane keeping support, automatic emergency braking, and blind spot detection.

NHTSA also uses the SDT data to automatically pre-populate the motor vehicle crash data it collects for several other NHTSA data collection programs. The following are brief descriptions of these data collection programs:

- FARS (OMB Control No. 2127–0006) is a nationwide census of fatalities caused by motor vehicle traffic crashes. In addition to PAR data, FARS includes detailed information regarding the location of the crash, the vehicles, and the people involved. FARS cases can also include toxicology report data, medical records, medical examiner reports, etc.[2]
- CRSS (OMB Control No. 2127–0714) is a nationally representative sample of police-reported crashes involving all types of motor vehicles, pedestrians, and cyclists, ranging from property-damage-only crashes to those that result in fatalities. CRSS data elements are a subset of the data elements on each State's PAR.[3]
- Investigation-based Crash Data Studies (OMB Control Number 2127–0706) includes CISS, SCI and Special Studies. CISS is a nationally representative sample of minor, serious, and fatal crashes involving at least one passenger vehicle—cars, light trucks, sport utility vehicles, and vans—towed from the scene. CISS collects data at both the crash level through scene analysis and the vehicle level through vehicle damage assessment together with injury coding. Data collected through CISS expands upon the information that is collected in a PAR.[4]

The SCI Program provides NHTSA with the most in-depth crash data collected by the agency. The data collected ranges from basic information contained in routine police and insurance crash reports, to comprehensive data from special reports

[1] Police Accident Reports (PARs) are also known as Police Crash Reports (PCRs) in some jurisdictions.

[2] Additional details about FARS and how the agency collects this information are available in the supporting statements for the ICR with OMB Control No. 2127–0006.

[3] Additional details about CRSS and how the agency collects this information are available in the supporting statements for the ICR with OMB Control No. 2127–0714.

[4] Additional details about CISS and how the agency collects this information are available in the supporting statements for the ICR with OMB Control No. 2127–0706.

produced by professional crash investigation teams. Hundreds of data elements relevant to the vehicle, occupants, injury mechanisms, roadway, and safety systems are collected for each of the over 100 crashes designated for study annually.

• The Non-Traffic Surveillance (NTS) is a data collection effort for collecting information about non-traffic crashes and non-crash incidents. The NTS data provide counts and details regarding fatalities and injuries that occur in non-traffic crashes and in non-crash incidents. The NTS non-traffic crash data are obtained through NHTSA's data collection efforts for the Crash Report Sampling System (CRSS), the Crash Investigation Sampling System (CISS), and the Fatality Analysis Reporting System (FARS). NTS also includes data outside of NHTSA's own data collections. NTS' non-crash injury data is based upon emergency department records from a special study conducted by the Consumer Product Safety Commission's National Electronic Injury Surveillance System (NEISS) All Injury Program. NTS non-crash fatality data is derived from death certificate information from the Centers for Disease Control's National Vital Statistics System.

• CIREN combines crash data collection with professional multidisciplinary analysis of medical and engineering evidence to determine injury causation in every crash investigation conducted. The mission of the CIREN is to improve the prevention, treatment, and rehabilitation of motor vehicle crash injuries to reduce deaths, disabilities, and human and economic costs.

Before EDT, the transfer of motor vehicle crash data from a State's crash data system to NHTSA's FARS, CRSS and CISS required individuals to manually enter all State vehicle crash data into each of the crash data systems operated by NHTSA. The SDT program's EDT protocol enabled NHTSA to automate the transfer of State motor vehicle crash data into NHTSA's data collection systems and automate some of the data coding processes in FARS, CRSS and CISS. Through the SEDC program, participating States will build and modernize their centralized statewide crash data repositories and increase their alignment to the MMUCC Sixth Edition; NHTSA will receive more standardized and timely data and increase the usability of the data.

NHTSA's SDT program will reduce the burden of manual data entry and result in more accurate and timely data to help save lives, prevent injuries, and reduce economic costs due to motor vehicle crashes.

In addition, the SDT data are made available to other DOT agencies, such as the Federal Highway Administration and the Federal Motor Carrier Safety Administration, to support their mission to save lives on our national roadways. The SDT data received through SEDC grant will be made available to public as required in BIL.

Affected Public: This voluntary information collection involves State agencies that collect crash data. Specifically, the collection involves State governments, the District of Columbia government, U.S. Territory governments and the Secretary of the Interior, acting on behalf of an Indian Tribe. For purposes of this collection, we refer to the respondents generically as ''States.''

Estimated Number of Respondents: 43.

There are currently 39 States participating in the SDT: 31 States participating using the SDS protocol, and 20 States participating using the EDT protocol. There are 15 States providing data using both protocols.

NHTSA expects that in the next three (3) years, these thirty-nine (39) States will continue to submit their data using either SDS or EDT protocol. NHTSA also expects that, in the next three years, ten (10) out of the twenty (20) existing EDT States will apply and be awarded SEDC grants and start sending more MMUCC-aligned data to NHTSA; three (3) SDS States, that are not EDT States, will apply and be awarded SEDC grants and begin sending MMUCC-aligned data to NHTSA; and two (2) new States, neither SDS nor EDT participating States, will apply and be awarded SEDC grants and begin collecting and transmitting standardized data to NHTSA. Therefore, NHTSA estimates the total number of States participating in the SDT will increase by four (4), to a total of forty-three (43), which is the existing thirty-nine (39) SDT States plus the four (4) new SEDC States in the next three (3) years.

Frequency: The frequency of this information collection varies State-by-State, potentially from daily to annually, as agreed upon by NHTSA and the individual States. State participating in the SDS protocol typically send a file to NHTSA once a year with all the crashes occurring during a calendar year. States send these files when it has completed its quality control process. For the EDT States, the data is usually transferred every night with the crash cases that have completed the quality control process since the last nightly transfer.

Estimated Total Annual Burden Hours: 312,663 hours.

As mentioned above, this information collection request is being updated to incorporate the burden hour and cost estimates for the new SEDC program under the EDT protocol. Due to the different requirements for SDS States, EDT non-SEDC States and EDT SEDC States, the annual burden for these three types of data transmissions are described separately below.

SDS Protocol

SDS information is obtained annually from States and is submitted in a more traditional method via electronic media through secured mail or a Secure File Transfer Protocol (SFTP). NHTSA assumes a participating State already has a centralized statewide crash data repository. Currently, thirty-one (31) States are voluntarily submitting their annual crash database to NHTSA, with five (5) States sending electronic media and twenty-six (26) states uploading the database to an SFTP site. Since NHTSA accepts the States' centralized statewide crash data repository without changes, NHTSA estimates that it will require eight (8) hours for a State Database Administrator to save a copy of the State's annual crash database onto a SFTP site or electronic media. We estimate an additional four (4) hours will be required for an administrative assistant to package and send the electronic media to NHTSA. Therefore, the burden hours for thirty-one (31) SDS States to save a copy of the State's annual crash database onto a SFTP site or electronic media is 248 hours (8 hours × 31 States). An additional burden for the five (5) SDS States to package and send the electronic media to NHTSA is 20 hours (4 hours × 5 States).

To estimate the labor cost associated with submitting the SDS information, NHTSA looked at wage estimates for the type of personnel involved with copying, packaging and sending the data. NHTSA estimates the total labor costs associated with copying the database by looking at the average wage for Database and Network Administrators and Architects. The Bureau of Labor Statistics (BLS) estimates that the average hourly wage for Database and Network Administrators and Architects (Standard Occupational Classification #15–1240, May 2021) is $49.25 [5] The Bureau of Labor Statistics estimates that State and local government workers'

[5] *See* May 2021 National Occupational Employment and Wage Estimates United States, available at *https://www.bls.gov/oes/current/oes_nat.htm* (accessed March 13, 2023).

wages represent 61.9% of total labor compensation costs.[6] Therefore, NHTSA estimates the hourly labor costs for copying the database to be $79.56 ($49.25 ÷ 61.9%) for Database and Network Administrator and Architects. The cost associated with the eight (8) hours of Database and Network Administrator labor is estimated to be $636.48 ($79.56 × 8 hours) per respondent.

For the 5 States sending electronic media, NHTSA estimates the total labor costs for packing and sending the database by looking at the average wage for Secretaries and Administrative Assistants. The BLS estimates that the average hourly wage for Secretaries and Administrative Assistants (Standard Occupational Classification #43–6014, May 2021) is $21.76.[7] By using the same estimate that wages represent 61.9% of the total compensation cost of labor, NHTSA estimates the total labor hour for packing and sending the database on electronic media to be $35.15($21.76 ÷ 61.9%). Therefore, the cost associated with the four (4) hours to send the electronic media is estimated to be $140.60 ($35.15 × 4 hours) per respondent.

Combining these copying, packing, and sending burden estimates for SDS, NHTSA estimates that the total burden hours associated with this collection will be 268 (248 + 20) hours and total labor cost associated with the collection will be $19,731 ($638.48 × 31 States) for copying, and $703 ($140.60 × 5 States) for packing and sending, for a total of $20,434 ($19,731 + $703) for the SDS protocol.

States Using the EDT Protocol

Due to the different requirements including data standardization and alignment to MMUCC for SEDC and non-SEDC State, the cost estimates for these two groups under EDT protocol will be different as described below.

Non-SEDC States Using EDT Protocol

The non-SEDC States using the EDT protocol burden hour estimate is based on the level of effort reported by the States that have fully implemented EDT. NHTSA estimates that in the next three years, there will not be any new States joining the twenty (20) States already participating in the SDT program using the EDT protocol. Any new State will participate in EDT by applying for the SEDC grant and meeting SEDC requirements. In addition, NHTSA estimates that over the next three years, starting in year two (10) existing EDT States will begin participating in the new SEDC grant program and will start sending data aligned to MMUCC. NHTSA estimates that in year one, year two and year three, the number of non-SEDC EDT states will be 20, 15 and 10, respectively. Therefore, NHTSA estimates that there will be, on average, fifteen (15) non-SEDC EDT protocol States in each of the next three years. Since these fifteen (15) non-SEDC States are already using the EDT protocol, the cost and burden estimates for these States only account for annual maintenance effort. The estimates assume a participating State already has a centralized statewide crash data repository. The hourly burden for maintenance on States associated with non-SEDC EDT is estimated at five (5) hours per year, based upon currently participating States' experiences. This time is generally used to troubleshoot any connection issues or refine mapping protocols for any data elements that have changed.

NHTSA estimates the cost for IT personnel burden hours using the Bureau of Labor Statistics' mean wage estimate for Software and Web Developers, Programmers, and Testers (Standard Occupational Classification #15–1250, May 2021) of $54.68.[8] The Bureau of Labor Statistics estimates that for State and local government workers, wages represent 61.9% of total compensation.[9] Therefore, the total hourly cost associated with the IT burden hours is estimated to be $88.34 ($54.68 ÷ 61.9%) per hour.

Per the loaded labor rates for State IT staff outlined above, five (5) hours of work translates to an estimated total annual maintenance burden of $441.70 ($88.34 × 5 hours) per State respondent maintaining participation in the EDT program. NHTSA estimates that there will be, on average, 15 States participating in non-SEDC EDT program in each of the next three years. The total annual responses are 5,475 (15 EDT States × 365 nightly responses). Therefore, the annual maintenance cost for the States is a total of $6,626 ($441.70 × 15 States) per year. The number of total burden hours for the 15 States is 75 hours (5 × 15 States).

SEDC States Using EDT Protocol

NHTSA published a Request for Information (RFI) [10] from May 2, 2022, to July 15, 2022, to assist the agency with the development and implementation of a new discretionary grant program to increase the number of States, U.S. territories, and Indian tribes electronically transferring their motor vehicle crash data to the NHTSA. Sixteen (16) States and Territories responded to the RFI with cost information for updating their centralized statewide crash data repositories and aligning to previous versions of MMUCC. NHTSA used that information to inform NHTSA's burden estimates and estimates the burden as follows.

The cost and burden estimates for the EDT protocol are divided into two efforts: a one-time implementation effort, and an annual maintenance effort. To increase their alignment with the new MMUCC, the States will need to either develop a new electronic Police Accident Report (PAR) and build a centralized statewide crash data repository if they don't already have one or update the existing PAR and centralized statewide crash data repository to increase their alignment to the new MMUCC. In addition, States will need to electronically transfer their data in a standardized format to NHTSA. NHTSA predicts the States will need to take the following specific actions:

- Manually entering PAR data if there are legacy paper PARs to be input into the new and/or updated centralized statewide crash data repository.
- Developing a new PAR to increase alignment with the updated MMUCC.
- Adopting the new State PAR by law enforcement agencies.
- Setting up information technology infrastructure for the electronic centralized statewide crash data repository.
- Identifying and implementing the system changes to align with the updated MMUCC.
- Developing a user guide, data dictionary and training materials for the new and/or updated data collection system.
- Developing and implementing database and data warehouse for the data collection.
- Developing and implementing data transfer protocols for collecting data

[6] *See* table 1. Employer Costs for Employee Compensation by ownership (Sept. 2022), available at *https://www.bls.gov/news.release/ecec.t01.htm* (accessed March 13, 2023).

[7] *See* May 2021 National Occupational Employment and Wage Estimates United States, available at *https://www.bls.gov/oes/current/oes_nat.htm* (accessed March 13, 2023).

[8] May 2021 National Occupational Employment and Wage Estimates United States, Occupational Employment Statistics, Bureau of Labor Statistics, U.S. Department of Labor, *https://www.bls.gov/oes/current/oes_nat.htm#15-0000,* last accessed March 13, 2023.

[9] Employer Costs for Employee Compensation by ownership (Sept. 2022), available at *https://www.bls.gov/news.release/ecec.t01.htm* (accessed March 13, 2023).

[10] Please see detailed information at this website: *https://www.regulations.gov/docket/NHTSA-2022-0030.*

from law enforcement agencies to centralized statewide crash data repository.

- Developing and implementing edit and validation rules for quality assurance for the data collection.
- Developing and implementing data transfer protocols for sharing data among States and sending data to NHTSA.
- Integrating the reporting from other vendors if some law enforcement agencies within a state use other vendor's software.
- Creating data analytics and dashboard for data monitoring and reporting.

NHTSA estimates the labor categories in the rows of table 1 are required for the implementation of tasks above. Based on the information received from the RFI, NHTSA estimates the labor hours for implementation and maintenance for each labor category as in the column ''Implementation Total Hours'' and ''Maintenance Total Hours'' in table 1. Labor category ''Data Entry and Information Processing Workers'' is needed when the States transition from a manual/paper system to an electronic system. Once the transition is complete, this labor category is no longer necessary and therefore is not included in the maintenance burden estimates.

NHTSA uses the Bureau of Labor Statistics' mean hourly wage estimate for each Labor Category in the column labeled '''Labor Rate w/o Fringe and Benefit'' [11] in table 1. The Bureau of Labor Statistics estimates that for State and local government workers, wages represent 61.9% of total compensation.[12] Therefore, the total hourly rate with fringe and benefit associated with the burden hours is calculated as below as shown in column ''Labor Rate with Fringe Benefit'' in table 1.

Labor Rate with Fringe Benefit = Labor Rate w/o Fringe Benefit ÷ Fringe Benefit Rate

The total cost for implementation and maintenance in table 1 are calculated as follows:

Implementation Total Cost = Implementation Total Hours × Labor Rate with Fringe Benefit

Maintenance Total Cost = Maintenance Total Hours × Labor Rate with Fringe Benefit

TABLE 1—BURDEN ESTIMATES FOR SECD EDT STATES USING EDT PROTOCOL

Labor category	Labor series	Implementation total hours (hrs)	Maintenance total hours (hrs)	Implementation labor rate w/o fringe and benefit ($/hr)	Overhead rate (%)	Maintenance labor rate with fringe and benefit ($/hr)	Implementation total labor cost (per state) ($)	Maintenance total labor cost (per state) ($)
Program Manager	11–3021	1,888	832	$78.33	61.90	126.54	238,908	105,281
Computer System Analyst	15–1211	5,080	160	49.14	61.90	79.39	403,301	12,702
Web and Digital Interface Designer	15–1255	1,760	416	49.50	61.90	79.97	140,747	33,268
Software Developer	15–1252	10,240	1,280	58.17	61.90	93.97	962,253	120,282
Web Developers	15–1254	5,920	1,280	39.09	61.90	63.15	373,848	80,832
Software Quality Assurance Analysts and Testers	15–1252	7,040	1,280	46.97	61.90	75.88	534,195	97,126
Database Architects	15–1243	3,520	960	58.58	61.90	94.64	333,133	90,854
Information Security Analysts	15–1212	1,384	80	54.46	61.90	87.98	121,764	7,038
Data Entry and Information Processing Workers	43–9020	4,192	.....	18.70	61.90	30.21	126,640	.....
Total	.....	41,024	6,288	.....	.....	.....	3,234,789	547,384

Thus, total labor cost for SEDC EDT implementation cost per State are estimated to be $3,234,789 with burden hours to be 41,024. The total annual maintenance burden cost per year per State is estimated to be $547,384 with burden hour as 6,288.

NHTSA anticipates that during the first year of the grant, States will be in the development and implementation phase, where data transmission is not expected. Beginning with year two (2), and into year three (3), it is estimated that approximately ten (10) States per year will start transmitting data to NHTSA using the EDT protocol. Therefore, the average of number of State to transmit data to NHTSA for the three (3) years is 7 ((10 + 10) ÷ 3 = 6.77, rounded to the nearest integer). In this case during year three (3), there will be ten (10) states in maintenance phase. These are the ten (10) States which start transmission data to NHTSA during year two (2). The average number of states in maintenance phase is 4 (10 ÷ 3 = 3.33, then round 3.33 up to the nearest integer which is 4).

As NHTSA estimated that there will be average 7 new SEDC EDT States each year, the total implementation cost per year will be $22,643,526 (7 × $3,234,789) with burden hours as 287,168 hours (7 × 41,024 hours); the average annual maintenance cost will be $2,189,536 (4 × $547,384) with burden hours as 25,152 hours (4 × 6,288 hours). The total SEDC EDT labor costs are $24,833,062 ($22,643,526 for implementation and $2,189,536 for annual maintenance). This estimate includes total labor costs to the State respondents, but States may choose to have contractors incur some or all of these labor cost. The total annual responses for SEDC EDT States are 4,015 (11 EDT States × 365 nightly responses).

Summary for SDT Burden Estimates

The total estimated burden for SDT is 312,663 hours (268 hours for SDS + 15 hours for non-SEDC EDT + (287,168 hours + 25,152 hours) for SEDC EDT) and total estimated labor cost is

[11] *See* May 2021 National Occupational Employment and Wage Estimates United States, available at *https://www.bls.gov/oes/current/oes_nat.htm#00-0000.*

[12] *See* table 1. Employer Costs for Employee Compensation by ownership (Sept. 2022), available at *https://www.bls.gov/news.release/ecec.t01.htm* (accessed Feb. 24, 2023).

$24,860,121 ($20,434 for SDS + $6,626 for non-SEDC EDT + ($22,643,526 + $2,1289,536) for SEDC EDT).

A summary of the burden estimates for SDT is provided in table 2.

TABLE 2—SUMMARY FOR ESTIMATED SDT BURDEN

	Number of states	Burden hours	Labor cost ($)
SDS Copying	31	248	19,731
SDS Packing and Sending	5	20	703
Non-SEDC EDT Maintenance	15	75	4,270
SEDC EDT Implementation	7	287,168	22,643,526
SEDC EDT Maintenance	4	25,152	2,189,536
Total	.....	312,663	24,860,121

Estimated Total Annual Burden Cost: $25,000,000.

The SEDC grant, in compliance with BIL, requires a twenty (20) percent match from participating State respondents. NHTSA estimates about half of the program cost for the SEDC grants will be labor costs. NHTSA estimates the total annual burden cost for the SEDC program (beyond the labor costs discussed in question 12) will be about $25,000,000 to respondents. Since the Grant respondents only have to provide at least 20 percent of the total cost, the respondents will have to fund about $5,000,000 annually.

NHTSA does not expect respondents to incur any additional costs for the SDS or non-SEDC States using EDT Protocol (beyond labor costs as discussed in question 12) as a result of this information collection.

Public Comments Invited: You are asked to comment on any aspects of this information collection, including (a) whether the proposed collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; (b) the accuracy of the Department's estimate of the burden of the proposed information collection; (c) whether the States will use contractor(s) to help implement the SEDC grant or manage the implementation in-house with the State's own IT department; (d) ways to enhance the quality, utility and clarity of the information to be collected; and (e) ways to minimize the burden of the collection of information on respondents, including the use of automated collection techniques or other forms of information technology.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. chapter 35, as amended; 49 CFR 1.49; and DOT Order 1351.29.

Chou-Lin Chen,

Associate Administrator, National Center for Statistics and Analysis.

[FR Doc. 2023–09357 Filed 5–2–23; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

Notice of OFAC Sanctions Action

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Notice.

SUMMARY: The U.S. Department of the Treasury's Office of Foreign Assets Control (OFAC) is publishing the names of one or more persons that have been placed on OFAC's Specially Designated Nationals and Blocked Persons List (SDN List) based on OFAC's determination that one or more applicable legal criteria were satisfied. All property and interests in property subject to U.S. jurisdiction of these persons are blocked, and U.S. persons are generally prohibited from engaging in transactions with them.

DATES: See **SUPPLEMENTARY INFORMATION** section for applicable date(s).

FOR FURTHER INFORMATION CONTACT: OFAC: Andrea Gacki, Director, tel.: 202–622–2490; Associate Director for Global Targeting, tel.: 202–622–2420; Assistant Director for Licensing, tel.: 202–622–2480; Assistant Director for Regulatory Affairs, tel.: 202–622–4855; or the Assistant Director for Enforcement, Compliance & Analysis, tel.: 202–622–2490.

SUPPLEMENTARY INFORMATION:

Electronic Availability

The SDN List and additional information concerning OFAC sanctions programs are available on OFAC's website (*https://www.treasury.gov/ofac*).

Notice of OFAC Action(s)

On April 27, 2023, OFAC determined that the property and interests in property subject to U.S. jurisdiction of the following persons are blocked under the relevant sanctions authority listed below.

BILLING CODE 4810–AL–P

Individuals

1. BAZGHANDI, Rouhollah (a.k.a. BAZGHANDI, Ruhollah), Iran; DOB 07 Mar 1981; nationality Iran; Additional Sanctions Information - Subject to Secondary Sanctions; Gender Male; Passport D10008106 (Iran) expires 24 May 2026; IRGC Intelligence Organization Counterintelligence Official (individual) [IRGC] [IFSR] [HOSTAGES-EO14078] (Linked To: ISLAMIC REVOLUTIONARY GUARD CORPS INTELLIGENCE ORGANIZATION).

   Designated pursuant to section 6(a)(i)(B) of Executive Order 14078, "Bolstering Efforts to Bring Hostages and Wrongfully Detained United States Nationals Home" (E.O. 14078), for being owned, controlled, or directed by, or to have acted or purported to act for or on behalf of, directly or indirectly, the ISLAMIC REVOLUTIONARY GUARD CORPS INTELLIGENCE ORGANIZATION, a person whose property and interests in property are blocked pursuant to E.O. 14078.

2. KAZEMI, Mohammad (Arabic: محمد كاظمی), Tehran, Iran; DOB 11 Jul 1961; nationality Iran; Additional Sanctions Information - Subject to Secondary Sanctions; Gender Male; Brigadier General (individual) [IRGC] [IFSR] [IRAN-HR] [HOSTAGES-EO14078] (Linked To: ISLAMIC REVOLUTIONARY GUARD CORPS; Linked To: ISLAMIC REVOLUTIONARY GUARD CORPS INTELLIGENCE ORGANIZATION).

   Designated pursuant to section 6(a)(i)(B) of E.O. 14078 for being owned, controlled, or directed by, or to have acted or purported to act for or on behalf of, directly or indirectly, the ISLAMIC REVOLUTIONARY GUARD CORPS INTELLIGENCE ORGANIZATION, a person whose property and interests in property are blocked pursuant to E.O. 14078.

3. MOHAGHEGHI, Mohammad Hassan, Iran; DOB 23 Jun 1963; nationality Iran; Additional Sanctions Information - Subject to Secondary Sanctions; Gender Male; Passport D10008116 (Iran) expires 24 May 2026; IRGC Intelligence Organization Co-Deputy Chief Brigadier General (individual) [IRGC] [IFSR] [HOSTAGES-EO14078] (Linked To: ISLAMIC REVOLUTIONARY GUARD CORPS INTELLIGENCE ORGANIZATION).

   Designated pursuant to section 6(a)(i)(B) of E.O. 14078 for being owned, controlled, or directed by, or to have acted or purported to act for or on behalf of, directly or indirectly, the ISLAMIC REVOLUTIONARY GUARD CORPS INTELLIGENCE ORGANIZATION, a person whose property and interests in property are blocked pursuant to E.O. 14078.

4. SAYYARI, Mohammad Mehdi (a.k.a. SAYYARI, Mehdi; a.k.a. SIARI, Mehdi), Iran; DOB 12 Jul 1959; nationality Iran; Additional Sanctions Information - Subject to Secondary Sanctions; Gender Male; IRGC Intelligence Organization Co-Deputy Chief (individual) [IRGC] [IFSR] [HOSTAGES-EO14078] (Linked To: ISLAMIC REVOLUTIONARY GUARD CORPS INTELLIGENCE ORGANIZATION).

   Designated pursuant to section 6(a)(i)(B) of E.O. 14078 for being owned, controlled, or directed by, or to have acted or purported to act for or on behalf of, directly or indirectly, the ISLAMIC REVOLUTIONARY GUARD CORPS INTELLIGENCE ORGANIZATION, a person whose property and interests in property are blocked pursuant to E.O. 14078.

Dated: April 27, 2023.

Andrea Gacki,

Director, Office of Foreign Assets Control, U.S. Department of the Treasury.

[FR Doc. 2023–09410 Filed 5–2–23; 8:45 am]

BILLING CODE 4810–AL–C

UNIFIED CARRIER REGISTRATION PLAN

Sunshine Act Meetings

TIME AND DATE: May 4, 2023, 12:00 p.m. to 3:00 p.m., Eastern time.

PLACE: This meeting will be accessible via conference call and via Zoom Meeting and Screenshare. Any interested person may call (i) 1–929–205–6099 (US Toll) or 1–669–900–6833 (US Toll), Meeting ID: 999 3560 1878, to listen and participate in this meeting. The website to participate via Zoom Meeting and Screenshare is *https://kellen.zoom.us/meeting/register/tJ0kdOyurjoiHdwhVQv-o_aW5gTcnk36fbRE.*

STATUS: This meeting will be open to the public.

MATTERS TO BE CONSIDERED: The Unified Carrier Registration Plan Audit Subcommittee (the ''Subcommittee'') will continue its work in developing and implementing the Unified Carrier Registration Plan and Agreement. The subject matter of this meeting will include:

Proposed Agenda

I. Call to Order—UCR Audit Subcommittee Chair

The UCR Audit Subcommittee Chair will welcome attendees, call the meeting to order, call roll for the Audit Subcommittee, confirm whether a quorum is present, and facilitate self-introductions.

II. Verification of Publication of Meeting Notice—UCR Executive Director

The UCR Executive Director will verify the publication of the meeting notice on the UCR website and distribution to the UCR contact list via email followed by the subsequent publication of the notice in the **Federal Register**.

III. Review and Approval of Subcommittee Agenda and Setting of Ground Rules—UCR Audit Subcommittee Chair

For Discussion and Possible Subcommittee Action

The agenda will be reviewed, and the Subcommittee will consider adoption.

Ground Rules

Subcommittee action only to be taken in designated areas on the agenda.

IV. Review and Approval of Subcommittee Minutes From the February 9, 2023 Meeting—UCR Audit Subcommittee Chair

For Discussion and Possible Subcommittee Action

Draft minutes from the February 9, 2023 Subcommittee meeting via teleconference will be reviewed. The Subcommittee will consider action to approve.

V. Discuss Options To Replace the Retreat Audit Program With a Program That Relies on Roadside Inspection Data—UCR Audit Subcommittee Chair, UCR Audit Subcommittee Vice-Chair, DSL Transportation Services, Inc., and Seikosoft

The UCR Audit Subcommittee Chair, UCR Audit Subcommittee Vice-Chair, DSL Transportation Services, Inc., and Seikosoft will lead a discussion on options to replace the Retreat Audit Program currently utilized by the States with a roadside inspection data driven audit for non-IRP plated commercial motor vehicles and the motor carriers operating this type of registered equipment.

VI. Update on Monthly Question and Answer Session for State Auditors—UCR Audit Subcommittee Chair, UCR Audit Subcommittee Vice-Chair, and UCR Executive Director

The UCR Audit Subcommittee Chair, UCR Audit Subcommittee Vice-Chair and UCR Executive Director will provide a summary of the May 3, 2023, UCR State Auditor Question and Answer session and lead a discussion of the value of the 60-minute virtual question and answer sessions.

VII. Review States' Audit Compliance Snapshot for Registration Rates Audit Percentages for Years 2022 and 2023—UCR Audit Subcommittee Chair

The UCR Audit Subcommittee Chair will review audit compliance rates for the states for registration years 2022 and 2023 and related compliance percentages for FARs, retreat audits, and registration compliance percentages.

VIII. General Review and Discussion of Audit Program—UCR Audit Subcommittee Chair and UCR Audit Subcommittee Vice-Chair

The UCR Audit Subcommittee Chair and UCR Audit Subcommittee Vice-Chair will lead discussion on auditing performance standards and direction of the program.

IX. Other Business—UCR Audit Subcommittee Chair

The UCR Audit Subcommittee Chair will call for any other items Subcommittee members would like to discuss.

X. Adjournment—UCR Audit Subcommittee Chair

The UCR Audit Subcommittee Chair will adjourn the meeting.

The agenda will be available no later than 5:00 p.m. Eastern time, April 28, 2023 at: *https://plan.ucr.gov.*

CONTACT PERSON FOR MORE INFORMATION: Elizabeth Leaman, Chair, Unified Carrier Registration Plan Board of Directors, (617) 305–3783, *eleaman@board.ucr.gov.*

Alex B. Leath,

Chief Legal Officer, Unified Carrier Registration Plan.

[FR Doc. 2023–09331 Filed 4–28–23; 11:15 am]

BILLING CODE 4910–YL–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–XXXX]

Agency Information Collection Activity Under OMB Review: Native American Direct Loan (NADL) Processing Requirements

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA) of 1995, this notice announces that the Veterans Benefits Administration (VBA), Department of Veterans Affairs, will submit the collection of information abstracted below to the Office of Management and Budget (OMB) for review and comment. The PRA submission describes the nature of the information collection and its expected cost and burden and it includes the actual data collection instrument.

DATES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. Refer to ''OMB Control No. 2900–XXXX.''

FOR FURTHER INFORMATION CONTACT: Maribel Aponte, Office of Enterprise and Integration, Data Governance Analytics (008), 810 Vermont Ave. NW, Washington, DC 20006, (202) 266–4688 or email *maribel.aponte@va.gov.* Please refer to ''OMB Control No. 2900–XXXX'' in any correspondence.

SUPPLEMENTARY INFORMATION:

Authority: 38 U.S.C. 3761–3765.

Title: Native American Direct Loan (NADL) Processing Requirements.

OMB Control Number: 2900–XXXX.

Type of Review: New collection.

Abstract: The information collected in this package assists Native American Veterans in obtaining the VA home loan benefit to purchase, construct, or improve dwellings on trust lands, or to refinance their existing Native American Direct Loans (NADL) to a lower interest rate.

An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The **Federal Register** Notice with a 60-day comment period soliciting comments on this collection of information was published at 88 FR 12448 on February 27, 2023, pages 12448 and 12449.

Affected Public: Individuals or Households.

Estimated Annual Burden: 1,721.00.

Estimated Average Burden per Respondent: 28.04 minutes.

Frequency of Response: One time.

Estimated Number of Respondents: 737.

By direction of the Secretary.

Dorothy Glasgow,

VA PRA Clearance Officer, (Alt.) Office of Enterprise and Integration, Data Governance Analytics, Department of Veterans Affairs.

[FR Doc. 2023–09352 Filed 5–2–23; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–XXXX]

Agency Information Collection Activity: CFM Stakeholder Feedback Survey

AGENCY: Office of Construction and Facilities Management, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: Office of Construction and Facilities Management, Department of Veterans Affairs (VA), is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act (PRA) of 1995, Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of a currently approved collection, and allow 60 days for public comment in response to the notice.

DATES: Written comments and recommendations on the proposed collection of information should be received on or before July 3, 2023.

ADDRESSES: Submit written comments on the collection of information through Federal Docket Management System (FDMS) at *www.Regulations.gov* or to Sandra Martin, Office of Construction and Facilities Management, 003C6A, Department of Veterans Affairs, 810 Vermont Avenue NW, Washington, DC 20420 or email to *sandra.martin2@va.gov.* Please refer to ''OMB Control No. 2900–XXXX'' in any correspondence. During the comment period, comments may be viewed online through FDMS.

FOR FURTHER INFORMATION CONTACT: Maribel Aponte, Office of Enterprise and Integration, Data Governance Analytics (008), 810 Vermont Ave. NW, Washington, DC 20006, (202) 266–4688 or email *maribel.aponte@va.gov.* Please refer to ''OMB Control No. 2900–XXXX'' in any correspondence.

SUPPLEMENTARY INFORMATION: Under the PRA of 1995, Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. This request for comment is being made pursuant to Section 3506(c)(2)(A) of the PRA.

With respect to the following collection of information, CFM invites comments on: (1) whether the proposed collection of information is necessary for the proper performance of CFM's functions, including whether the information will have practical utility; (2) the accuracy of CFM's estimate of the burden of the proposed collection of information; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or the use of other forms of information technology.

Authority: 44 U.S.C. 3501–21.

Title: CFM Stakeholder Feedback Survey.

OMB Control Number: 2900–XXXX.

Type of Review: New collection.

Abstract: The Office of Construction & Facilities Management (CFM) Stakeholder Feedback Survey collects information for all of CFM's lines of business: major construction, major leases, facility condition assessments, and engineering studies. Respondents are members of project teams, and the information is related to how well the teams are performing. The purpose of the Stakeholder Feedback Survey Program is to improve project team performance across the four lines of business covered by the survey.

Respondents include federal employees in the Department of Veteran Affairs throughout CFM, Veterans Health Administration, and National Cemetery Administration, as well as U.S. Army Corps of Engineers construction management teams. The survey also collects information from members of private contractors associated with the projects described above (*e.g.,* architecture/engineering, construction, developers/lessors). Respondents provide feedback on the performance of the technical sub-teams with whom they have worked on a particular project.

The survey uses a set of ten questions to collect the information on team performance, plus two open-ended questions that address what is going well and concerns. The survey is delivered via email with a link to an online collection instrument. Advance notice and reminder emails are used to encourage participation.

The survey is administered by a federal contracting team (Blue Water Thinking and Booz Allen Hamilton). Raw data is seen and handled only by members of this team. Summary results are provided to CFM via a dashboard designed as part of the contract to design and administer the survey.

Affected Public: Members of private contracting firms associated with the projects described above (*e.g.,* architecture/engineering, construction, developers/lessors) are asked to complete the survey.

Estimated Annual Burden: 77 hours.

Estimated Average Burden per Respondent: 8 minutes.

Frequency of Response: Team members of Major Construction and Major Leasing projects are asked to complete the survey twice a year for the duration of the project. Team members of all other types of projects are asked to complete the survey once a year.

Estimated Number of Respondents: 578.

By direction of the Secretary.

Dorothy Glasgow,

VA PRA Clearance Officer, (Alt.) Office of Enterprise and Integration/Data Governance Analytics, Department of Veterans Affairs.

[FR Doc. 2023–09403 Filed 5–2–23; 8:45 am]

BILLING CODE 8320–01–P

FEDERAL REGISTER

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Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 431, 438, et al.
Medicaid Program; Ensuring Access to Medicaid Services; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 431, 438, 441, and 447

[CMS–2442–P]

RIN 0938–AU68

Medicaid Program; Ensuring Access to Medicaid Services

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Proposed rule.

SUMMARY: This proposed rule takes a comprehensive approach to improving access to care, quality and health outcomes, and better addressing health equity issues in the Medicaid program across fee-for-service (FFS), managed care delivery systems, and in home and community-based services (HCBS) programs. These proposed improvements seek to increase transparency and accountability, standardize data and monitoring, and create opportunities for States to promote active beneficiary engagement in their Medicaid programs, with the goal of improving access to care.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, by July 3, 2023.

ADDRESSES: In commenting, please refer to file code CMS–2442–P.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the ''Submit a comment'' instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–2442–P, P.O. Box 8016, Baltimore, MD 21244–1850.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–2442–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT:

Karen LLanos, (410) 786–9071, for Medical Care Advisory Committee.

Jennifer Bowdoin, (410) 786–8551, for Home and Community-Based Services.

Jeremy Silanskis, (410) 786–1592, for Fee-for-Service Payment.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: *http://www.regulations.gov.* Follow the search instructions on that website to view public comments. CMS will not post on *Regulations.gov* public comments that make threats to individuals or institutions or suggest that the individual will take actions to harm the individual. CMS continues to encourage individuals not to submit duplicative comments. We will post acceptable comments from multiple unique commenters even if the content is identical or nearly identical to other comments.

I. Background

A. Overview

Title XIX of the Social Security Act (the Act) established the Medicaid program as a joint Federal and State program to provide medical assistance to eligible individuals, including many with low incomes. Under the Medicaid program, each State that chooses to participate in the program and receive Federal financial participation (FFP) for program expenditures, establishes eligibility standards, benefits packages, and payment rates, and undertakes program administration in accordance with Federal statutory and regulatory requirements. The provisions of each State's Medicaid program are described in the Medicaid ''State plan'' and, as applicable, related authorities, such as demonstration projects and waivers of State plan requirements. Among other responsibilities, CMS approves State plans, State plan amendments (SPAs), demonstration projects authorized under section 1115 of the Act, and waivers authorized under section 1915 of the Act; and reviews expenditures for compliance with Federal Medicaid law, including the requirements of section 1902(a)(30)(A) of the Act relating to efficiency, economy, quality of care, and access to ensure that all applicable Federal requirements are met.

As of December 2022, the Medicaid program provides essential health care coverage to more than 85 million [1] individuals, and, in 2021, accounted for 17 percent of national health expenditures.[2] The program covers a broad array of health benefits and services critical to underserved populations,[3] including low-income adults, children, parents, pregnant individuals, older adults, and people with disabilities. For example, Medicaid pays for approximately 41 percent of all births in the U.S.[4] and is the largest payer of long-term services and supports (LTSS),[5] the largest, single payer of services to treat substance use disorders,[6] and services to prevent and treat the Human Immunodeficiency Virus.[7]

On January 28, 2021, the President signed Executive Order (E.O.) 14009,[8] ''Strengthening Medicaid and the Affordable Care Act'' which established the policy objective to protect and strengthen Medicaid and the Affordable Care Act and to make high-quality health care accessible and affordable for every American and directed executive departments and agencies to review existing regulations, orders, guidance documents, and policies to determine whether such agency actions are inconsistent with this policy. On April

[1] December 2022 Medicaid and CHIP Enrollment Snapshot. Accessed at *https://www.medicaid.gov/medicaid/national-medicaid-chip-program-information/downloads/December-2022-medicaid-chip-enrollment-trend-snapshot.pdf.*

[2] CMS National Health Expenditure Accounts. National Health Expenditures 2020 Highlight. Accessed at *https://www.cms.gov/files/document/highlights.pdf.*

[3] Executive Order 13985: *https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/20/executive-order-advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government/.*

[4] National Center for Health Statistics. Key Birth Statistics. Accessed at *https://www.cdc.gov/nchs/nvss/births.htm.*

[5] Colello, Kirsten J. *Who Pays for Long-Term Services and Supports?* Congressional Research Service. Updated June 15, 2022. Accessed at *https://crsreports.congress.gov/product/pdf/IF/IF10343.*

[6] Soni, Anita. Health Care Expenditures for Treatment of Mental Disorders: Estimates for Adults Ages 18 and Older, U.S. Civilian Noninstitutionalized Population, 2019. Statistical Brief #539, pg 12. February 2022. Agency for Healthcare Research and Quality, Rockville, MD. Accessed at *https://meps.ahrq.gov/data_files/publications/st539/stat539.pdf.*

[7] Dawson, L. and Kates, J. Insurance Coverage and Viral Suppression Among People with HIV, 2018. September 2020. Kaiser Family Foundation. Accessed at *https://www.kff.org/hivaids/issue-brief/insurance-coverage-and-viral-suppression-among-people-with-hiv-2018/.*

[8] Executive Order 14009: *https://www.federalregister.gov/documents/2021/02/02/2021-02252/strengthening-medicaid-and-the-affordable-care-act.*

5, 2022, E.O. 14070,[9] ''Continuing To Strengthen Americans' Access to Affordable, Quality Health Coverage,'' directed Federal agencies with responsibilities related to Americans' access to health coverage to review agency actions to identify ways to continue to expand the availability of affordable health coverage, to improve the quality of coverage, to strengthen benefits, and to help more Americans enroll in quality health coverage. This proposed rule aims to fulfill E.O.s 14009 and 14070 by helping States to strengthen Medicaid and improve access to and quality of care provided.

Ensuring that beneficiaries can access covered services is necessary to the basic operation of the Medicaid program. Depending on the State and its Medicaid program structure, beneficiaries access their health care services using a variety of care delivery systems (for example, FFS, fully-capitated managed care, partially capitated managed care, etc.), including through demonstrations and waiver programs. In 2020, 70 percent of Medicaid beneficiaries were enrolled in comprehensive managed care plans; [10] the remaining individuals received all of their care or some services that have been carved out of managed care through FFS.

Current access regulations are neither comprehensive nor consistent across delivery systems or coverage authority (for example, State plan and demonstration authority). For example, regulations at 42 CFR 447.203 and 447.204 relating to access to care, service payment rates, and Medicaid provider participation in rate setting apply only to Medicaid FFS delivery systems and focus on ensuring that payment rates are consistent with the statutory requirements in section 1902(a)(30)(A) of the Act. The regulations do not apply to services delivered under managed care. These regulations are also largely procedural in nature and rely heavily on States to form an analysis and reach conclusions on the sufficiency of their own payment rates.

With a program as large and complex as Medicaid, access regulations need to be multi-factorial to promote consistent access to health care for all beneficiaries across all types of care delivery systems in accordance with statutory requirements. Strategies to enhance access to health care services should reflect how people move through and interact with the health care system. We view the continuum of health care access across three dimensions of a person-centered framework: (1) enrollment in coverage; (2) maintenance of coverage; and (3) access to services and supports. Within each of these dimensions, accompanying regulatory, monitoring, and/or compliance actions may be needed to ensure access to health care is achieved and maintained.

In the spring of 2022, we released a request for information (RFI) [11] to collect feedback on a broad range of questions that examined topics such as: challenges with eligibility and enrollment; ways we can use data available to measure, monitor, and support improvement efforts related to access to services; strategies we can implement to support equitable and timely access to providers and services; and opportunities to use existing and new access standards to help ensure that Medicaid and CHIP payments are sufficient to enlist enough providers.

Some of the most common feedback we received through the RFI related to ways that we can promote health equity through cultural competency. Commenters shared the importance that cultural competency plays in how beneficiaries access health care and in the quality of health services received by beneficiaries. The RFI respondents shared examples of actions that we could take, including collecting and analyzing health outcomes data by sociodemographic categories; establishing minimum standards for how States serve communities in ways that address cultural competency and language preferences; and reducing barriers to enrollment and retention for racial and ethnic minority groups.

In addition to the topic of cultural competency, commenters also commonly shared that they viewed reimbursement rates as a key driver of provider participation in Medicaid and CHIP programs. Further, commenters noted that aligning payment approaches and setting minimum standards for payment regulations and compliance across Medicaid and CHIP delivery systems, services, and benefits could help ensure that beneficiaries' access to services is as similar as possible across beneficiary groups, delivery systems, and programs.

As mentioned previously in this proposed rule, the first dimension of access focuses on ensuring that eligible people are able to enroll in the Medicaid program. Access to Medicaid enrollment requires that a potential beneficiary know if they are or may be eligible for Medicaid, be aware of Medicaid coverage options, and be able to easily apply for and enroll in coverage. The second dimension of access in this continuum relates to maintaining coverage once the beneficiary is enrolled in the Medicaid program initially. Maintaining coverage requires that eligible beneficiaries are able to stay enrolled in the program without interruption, or that they know how to and can smoothly transition to other health coverage, such as CHIP, Exchange coverage, or Medicare, when they are no longer eligible for Medicaid coverage but have become eligible for other health coverage programs. In September 2022, we published a proposed rule, *Streamlining the Medicaid, Children's Health Insurance Program, and Basic Health Program Application, Eligibility, Determination, Enrollment, and Renewal Processes* (87 FR 54760; hereinafter the ''Streamlining Eligibility & Enrollment proposed rule'') to simplify the processes for eligible individuals to enroll and retain eligibility in Medicaid, CHIP, and the Basic Health Program (BHP).

The third dimension, which is the focus of this proposed rule, is access to services and supports. This rule is focused on addressing additional critical elements of access: (1) potential access, which refers to a beneficiary's access to providers and services, whether or not the providers or services are used; (2) beneficiary utilization, which refers to beneficiaries' actual use of the providers and services available to them; and (3) beneficiaries' perceptions and experiences with the care they did or were not able to receive. These terms and definitions build upon previous efforts to examine how best to monitor access.[12]

We are engaging in an array of regulatory activities, including three rulemakings that are currently underway (more specifically, the Streamlining Eligibility & Enrollment proposed rule, a proposed rule, entitled

[9] Executive Order 14070: *https://www.federalregister.gov/documents/2022/04/08/2022-07716/continuing-to-strengthen-americans-access-to-affordable-quality-health-coverage.*

[10] MACPAC 2022 Analysis of T–MSIS data February 2022. Exhibit 30. Percentage of Medicaid Enrollees in Managed Care by State and Eligibility Group *https://www.macpac.gov/wp-content/uploads/2022/12/EXHIBIT-30.-Percentage-of-Medicaid-Enrollees-in-Managed-Care-by-State-and-Eligibility-Group-FY-2020.pdf.*

[11] CMS Request for Information: Access to Coverage and Care in Medicaid & CHIP. February 2022. For a full list of question from the RFI, see *https://www.medicaid.gov/medicaid/access-care/downloads/access-rfi-2022-questions.pdf.*

[12] Kenney, Genevieve M., Kathy Gifford, Jane Wishner, Vanessa Forsberg, Amanda I. Napoles, and Danielle Pavliv. ''Proposed Medicaid Access Measurement and Monitoring Plan.'' Washington, DC: The Urban Institute. August 2016. Accessed at *https://www.urban.org/sites/default/files/publication/88081/2001143-medicaid-access-measurement-and-monitoring-plan_0.pdf.*

Medicaid and Children's Health Insurance Program (CHIP) Managed Care Access, Finance, and Quality, on managed care including matters of access, and this proposed rule on access). Additionally, we are taking non-regulatory activities to improve beneficiary access to care (for example, best practices toolkits and technical assistance to States) to improve access to health care services across Medicaid delivery systems.

As noted earlier, we issued the Streamlining Eligibility & Enrollment proposed rule to address the first two dimensions of access to health care: (1) enrollment in coverage and (2) maintenance of coverage. Through that proposed rule, we sought to streamline Medicaid, CHIP and BHP eligibility and enrollment processes, reduce administrative burden on States and applicants/enrollees toward a more seamless eligibility and enrollment process, and increase the enrollment and retention of eligible individuals.

The managed care proposed rule seeks to improve access to care and quality outcomes for Medicaid and CHIP beneficiaries enrolled in managed care by: creating standards for timely access to care and States' monitoring and enforcement efforts; reducing burden for some State directed payments and certain quality reporting requirements; adding new standards that would apply when States use in lieu of services and settings (ILOSs) to promote effective utilization, and specifying the scope and nature of ILOS; specifying medical loss ratio (MLR) requirements, and establishing a quality rating system for Medicaid and CHIP managed care plans.

Through the managed care proposed rule and this proposed rule (Ensuring Access to Medicaid Services), we propose additional requirements to address the third dimension of the health care access continuum: access to services. The proposed requirements outlined later in this section focus on improving access to services in Medicaid by utilizing tools such as FFS rate transparency, standardized reporting for HCBS, and improving the process for interested parties, especially Medicaid beneficiaries, to provide feedback to State Medicaid agencies and for Medicaid agencies to respond to the feedback (also known as a feedback loop).

Through a combination of these three proposed rules, we seek to address a range of access-related challenges that impact how beneficiaries are served by Medicaid across all of its delivery systems. FFP would be available for expenditures that might be necessary to implement the activities States would need to undertake to comply with the provisions of the proposed rules, if finalized.

Finally, we also believe it is important to acknowledge the role of health equity within this proposed rule. Medicaid plays a disproportionately large role in covering health care for people of color in this country.[13] Consistent with E.O. 13985 on Advancing Racial Equity and Support for Underserved Communities Through the Federal Government (January 20, 2021),[14] which calls for advancing equity for underserved populations, we are working to ensure our programs consistently provide high-quality care to all beneficiaries, and thus advance health equity, consistent with the goals and objectives we have outlined in the CMS Framework for Health Equity 2022–2032 [15] and the HHS Equity Action Plan.[16] That effort includes increasing our understanding of the needs of those we serve to ensure that all individuals have access to equitable care and coverage.

We recognize that each State faces a unique set of challenges related to the resumption of its normal program acvitities after the end of the COVID–19 public health emergency (PHE). More specifically, the expiration of the continuous enrollment condition authorized by the Families First Coronavirus Response Act (FFCRA) presents the single largest health coverage transition event since the first open enrollment period of the Affordable Care Act. As a condition of receiving a temporary 6.2 percentage point Federal Medical Assistance Percentage (FMAP) increase under the FFCRA, States have been required to maintain enrollment of nearly all Medicaid enrollees. This continuous enrollment condition expired on March 31, 2023, and States now have 12 months to initiate and 14 months to complete renewals for all individuals enrolled in Medicaid, CHIP and the Basic Health Program. Additionally, many other temporary authorities adopted by States during the COVID–19 PHE will expire at the end of the PHE, and States will be returning to regular operations across their programs. The resumption of normal Medicaid operations is generally referred to as ''unwinding'' and the 12-month period for States to initiate all outstanding eligibility actions that were delayed because of the FFCRA continuous enrollment condition is called the ''unwinding period.'' CMS considered States' unwinding responsibilities when proposing the effective dates for the proposals in this rule, but, as noted below, we seek State feedback on whether our proposals strike the correct balance.

As we contemplate the timing of a final rule, we are considering adopting an effective date of 60 days following publication of the final rule and separate compliance dates for various provisions, which we note where relevant in our discussion of specific proposals in this proposed rule. We seek comment on whether an effective date of 60 days following publication would be appropriate when combined with later dates for compliance for some provisions. We also seek comment on the timeframe that would be most achievable and appropriate for compliance with each proposed provision and whether the compliance date should vary by provision.

B. Medical Care Advisory Committees (MCAC)

We obtained feedback during various public engagement activities conducted with States and other interested parties, which supports research findings that the beneficiary perspective and lived Medicaid experience [17] should be considered when making policy decisions related to Medicaid programs.[18] [19] A 2022 report from the

[13] Guth, M. and Artiga, S. Medicaid and Racial Health Equity March 2022. Accessed at *https://www.kff.org/medicaid/issue-brief/medicaid-and-racial-health-equity/.*

[14] Executive Order 13985: *https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/20/executive-order-advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government/.*

[15] CMS Framework for Health Equity 2022–2032: *https://www.cms.gov/files/document/cms-framework-health-equity.pdf.*

[16] HHS Equity Action Plan. April 2022. Accessed at *https://www.hhs.gov/sites/default/files/hhs-equity-action-plan.pdf.*

[17] Lived experience refers to ''representation and understanding of an individual's human experiences, choices, and options and how those factors influence one's perception of knowledge'' based on one's own life. In this context, we refer to people who have been enrolled in Medicaid currently or in the past. Accessed at *https://aspe.hhs.gov/lived-experience#:~:text=In%20the%20context%20of%20ASPE%E2%80%99s%20research%2C%20people%20with,programs%20that%20aim%20to%20address%20the%20issue%20%28s%29.*

[18] Zhu JM, Rowland R, Gunn R, Gollust S, Grande DT. Engaging Consumers in Medicaid Program Design: Strategies from the States. Milbank Q. 2021 Mar;99(1):99–125. doi: 10.1111/1468–0009.12492. Epub 2020 Dec 15. PMID: 33320389; PMCID: PMC7984666. Accessed at *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7984666/.*

[19] Key Findings from the Medicaid MCO Learning Hub Discussion Group Series and Roundtable—Focus on Member Engagement and the Consumer Voice. NORC at the University of Chicago. Jan 2021. Accessed at *https://www.norc.org/PDFs/Medicaid%20Managed%20Care%20Organization%20Learning%20Hub/MMCOLearningHub_MemberEngagement.pdf.*

HHS Assistant Secretary of Planning and Evaluation (ASPE) noted that including people with lived experience in the policy-making process can lead to a deeper understanding of the conditions affecting certain populations, facilitate identification of possible solutions, and avoid unintended consequences of potential policy or program changes that could negatively impact the people the program aims to serve.[20] We have concluded that beneficiary perspectives need to be central to operating a high-quality health coverage program that consistently meets the needs of all its beneficiaries.

However, effective community engagement is not as simple as planning a meeting and requesting feedback. To create opportunities that facilitate true engagement, it is important to understand and honor strengths and assets that exist within communities; recognize and solicit the inclusion of diverse voices; dedicate resources to ensuring that engagement is done in culturally meaningful ways; ensure timelines, planning processes, and resources that support equitable participation; and follow up with communities to let them know how their input was utilized. Ensuring optimal health outcomes for all beneficiaries served by a program through the design, implementation, and operationalization of policies and programs requires intentional and continuous effort to engage people who have historically been excluded from the process.

Section 1902(a)(4) of the Act is a longstanding statutory provision that, as implemented in part in regulations currently codified at 42 CFR 431.12,[21] requires States to have a Medical Care Advisory Committee (MCAC) in place to advise the State Medicaid agency about health and medical care services. Under section 1903(a)(7) of the Act, expenditures made by the State agency to operate the MCAC are eligible for Federal administrative match.

The current MCAC regulations at § 431.12 require States to establish such a committee, and describe high-level requirements related to the composition of the committee, the scope of topics to be discussed, and the support the Committee can receive from the State in its administration. Due to the lack of specificity in the current regulations, these regulations have not been consistently implemented across States. For example, there is no mention of how States should approach meeting periodicity or meeting structure in ways that are conducive to including a variety of Medicaid interested parties. There is also no mention in the regulations about how States can build accountability through transparency with their interested parties by publicly sharing meeting dates, membership lists, and the outcomes of these meetings. The regulations also limit the MCAC discussions to topics about health and medical care services—which in turn limits the benefits of using the MCAC as a vehicle that can provide States with varied ideas, suggestions, and experiences on a range of issues (medical and non-medical) related to the effective administration of the Medicaid program.

As such, we have determined the requirements governing MCACs need to be more robust to ensure all States are using these committees optimally to realize a more effective and efficient Medicaid program that is informed by the experiences of beneficiaries, their caretakers, and other interested parties. The current regulations have been in place without change for over 40 years.[22] Over the last four decades, we have learned that the current MCAC requirements are insufficient in ensuring that the beneficiary perspective is meaningfully represented on the MCAC. Recent research regarding soliciting input from individuals with lived experience, including our recent discussions with States about their MCAC, provide a unique opportunity to re-examine the purpose of this committee and update the policies to reflect four decades of program experience.

In 2022, we gathered feedback from various public engagement activities conducted with States, other interested parties, and directly from a subset of State Medicaid agencies that described a wide variation in how States are operating MCACs today. The feedback suggested that some MCACs operate simply to meet the broad Federal requirements. As discussed previously in this section, we have discovered that our current regulations do not further the statutory goal of meaningfully engaging Medicaid beneficiaries and other low-income people in matters related to the operation of the Medicaid program. Meaningful engagement can help develop relationships and establish trust between the communities served and the Medicaid agency to ensure States receive important information concerning how to best provide health coverage to their beneficiary populations. The current MCAC regulations establish the importance of broad feedback from interested parties, but they lack the specificity that can ensure States use MCACs in ways that facilitate that feedback.

The current regulation requires that MCACs must include Medicaid beneficiaries as committee members. However, the regulations do not mention or account for the reality that other interested parties can stifle beneficiary contribution in a group setting. For example, when there are a small number of beneficiary representatives in large committees with providers, health plans, and professional advocates, it can be uncomfortable and intimidating for beneficiaries to share their perspective and experience. Based on these reasons, several States already use beneficiary-only groups that feed into larger MCACs.

Improvements to the MCACs are critical to ensuring a robust and accurate understanding of beneficiaries' challenges to health care access. The current regulations value State Medicaid agencies having a way to get feedback from interested parties on issues related to the Medicaid program. However, the current regulations lack specificity related to how MCACs can be used to benefit the Medicaid program more expressly by more fully promoting the beneficiary voice. MCACs need to provide a forum for beneficiaries and people with lived experience with the Medicaid program to share their experiences and challenges with accessing health care, and to assist States in understanding and better addressing those challenges. These committees also represent unique opportunities for States to include representation by members that reflect the demographics of their Medicaid program to ensure that the program is best serving the needs of all beneficiaries, but not all States are utilizing that opportunity.

The proposed rule seeks to strike a balance that reflects how States currently use advisory committees (such as MCACs or standalone beneficiary groups). We know that some States approach these committees as a way to meet a Federal requirement while other States are using them in much more innovative ways. As a middle ground, the proposed rule seeks to: (1) address the gaps in the current regulations described previously in this section; and (2) establish requirements to implement

[20] Syreeta Skelton-Wilson et al., ''Methods and Emerging Strategies to Engage People with Lived Experience,'' Office of the Assistant Secretary for Planning and Evaluation (ASPE), U.S. Department of Health and Human Services, January 4, 2022, *https://aspe.hhs.gov/reports/lived-experience-brief*.

[21] The regulatory provision was originally established in 36 FR 3793 at 3870.

[22] 43 FR 45091 at 45189.

more effective advisory committees. States would select members in a way that reflects a wide range of Medicaid interested parties (covering a diverse set of populations and interests relevant to the Medicaid program), place a special emphasis on the inclusion of the beneficiary perspective, and create a meeting environment where each voice is empowered to participate equally.

The changes we propose in this rule are rooted in best practices learned from experience and from current State examples of community engagement that support getting the type of feedback and experiences from beneficiaries, their caretakers, providers, and other interested parties that can then be used to positively impact care delivered through the Medicaid program.

Accordingly, the proposed rule includes changes that, if finalized, would support the implementation of the principles of bi-directional feedback, transparency, and accountability. We propose changes to the features of the new committee that could most effectively ensure member engagement, including the staff and logistical support that is required for beneficiaries and individuals representing beneficiaries to meaningfully participate in these committees. We also propose changes to expand the scope of topics to be addressed by the committee, address committee membership composition, prescribe the features of administration of the committee, establish requirements of an annual report, and underscore the importance of beneficiary engagement through the addition of a related beneficiary-only group.

C. Home and Community-Based Services (HCBS)

While Medicaid programs are required to provide medically necessary nursing facility services for most eligible individuals age 21 or older, coverage for home and community-based services (HCBS) is a State option.[23] As a result of this ''institutional bias,'' Medicaid reimbursement for LTSS was primarily spent on institutional care, historically, with very little spending for HCBS.[24] However, over the past several decades, States have used several Medicaid authorities,[25] as well as CMS-funded grant programs,[26] to develop a broad range of HCBS to provide alternatives to institutionalization for eligible Medicaid beneficiaries and to advance person-centered care. Consistent with many beneficiaries' preferences for where they would like to receive their care, HCBS have become a critical component of the Medicaid program and are part of a larger framework of progress toward community integration of older adults and people with disabilities that spans efforts across the Federal government. In fact, total Medicaid HCBS expenditures surpassed the long-standing benchmark of 50 percent of LTSS expenditures in FY 2013 and has remained higher than 50 percent since then, reaching 55.4 percent in FY 2017 and 58.6 percent in FY 2019.[27] A total of 30 States spent at least 50 percent of Medicaid LTSS expenditures on HCBS in FY 2019.

Furthermore, HCBS play an important role in States' efforts to achieve compliance with the Americans with Disabilities Act (ADA) of 1990, section 504 of the Rehabilitation Act of 1973 (section 504),[28] section 1557 of the Affordable Care Act, and the Supreme Court's decision in *Olmstead* v. *L.C.,*[29] in which the Court held that unjustified segregation of persons with disabilities is a form of unlawful discrimination under the ADA [30] and States must ensure that persons with disabilities are served in the most integrated setting appropriate to their needs.[31] Section 9817 of the American Rescue Plan Act of 2021 (ARP) (Pub. L. 117–2) recently provided a historic investment in Medicaid HCBS by providing qualifying States with a temporary 10 percentage point increase to the FMAP for certain Medicaid expenditures for HCBS that States must use to implement or supplement the implementation of one or more activities to enhance, expand, or strengthen HCBS under the Medicaid program.[32]

Medicaid coverage of HCBS varies by State and can include a combination of medical and non-medical services, such as case management, homemaker, personal care, adult day health, habilitation (both day and residential), and respite care services. HCBS programs serve a variety of targeted population groups, such as older adults, and children and adults with intellectual or developmental disabilities, physical disabilities, mental health/substance use disorders, and complex medical needs. HCBS programs provide opportunities for Medicaid beneficiaries to receive services in their own homes and communities rather than in institutions.

CMS and States have worked for decades to support the increased availability and provision of high-quality HCBS for Medicaid beneficiaries. While there are quality and reporting requirements for Medicaid HCBS, the requirements vary across authorities and are often inadequate to provide the necessary information for ensuring that HCBS are provided in a high-quality manner that best protects the health and welfare of beneficiaries. Consequently, quality measurement and reporting expectations are not consistent across and within services, but instead vary depending on the authorities under which States are delivering services. Additionally, States have flexibility to determine the quality measures they use in their HCBS programs. While we support State flexibility, a lack of

[23] Murray, Caitlin, Alena Tourtellotte, Debra Lipson, and Andrea Wysocki. ''Medicaid Long Term Services and Supports Annual Expenditures Report: Federal Fiscal Year 2019.''Chicago, IL: Mathematica, December, 2021. Accessed at *https://www.medicaid.gov/medicaid/long-term-services-supports/downloads/ltssexpenditures2019.pdf.*

[24] Centers for Medicare and Medicaid Services. November 2020. Long-Term Services and Supports Rebalancing Toolkit. Accessed at *https://www.medicaid.gov/medicaid/long-term-services-supports/downloads/ltss-rebalancing-toolkit.pdf.*

[25] These authorities include Medicaid State plan personal care services and Social Security Act (the Act) section 1915(c) waivers, section 1915(i) State plan HCBS, section 1915(j) self-directed personal assistant services, and section 1915(k) Community First Choice. See *https://www.medicaid.gov/medicaid/home-community-based-services/home-community-based-services-authorities/index.html* for more information on these authorities. Some States also use demonstration authority under section 1115(a) of the Act to cover and test home and community-based service strategies. See *https://www.medicaid.gov/medicaid/section-1115-demonstrations/index.html for more information.*

[26] Federally funded grant programs include the Money Follows the Person (MFP) demonstration program, which was initially authorized by the Deficit Reduction Act of 2005 (Pub. L. 109–171). The MFP program was recently extended under the Consolidated Appropriations Act, 2021 (Pub. L. 116–260), which allowed new States to join the demonstration and made statutory changes affecting MFP participant eligibility criteria, allowing grantees to provide community transition services under MFP earlier in an eligible individual's inpatient stay.

[27] Murray, Caitlin, Alena Tourtellotte, Debra Lipson, and Andrea Wysocki. ''Medicaid Long Term Services and Supports Annual Expenditures Report: Federal Fiscal Year 2019.'' Chicago, IL: Mathematica, December 9, 2021. Accessed at *https://www.medicaid.gov/medicaid/long-term-services-supports/downloads/ltssexpenditures 2019.pdf.*

[28] HHS interprets section 504 and Title II of the ADA similarly regarding the integration mandate and the Department of Justice generally interprets the requirements under section 504 consistently with those under Title II of the ADA.

[29] 527 U.S. 581 (1999).

[30] Medicaid and the Olmstead Decision. Accessed at *https://www.medicaid.gov/about-us/program-history/medicaid-50th-anniversary/entry/47688.*

[31] Medicaid and the Olmstead Decision. Accessed at *https://www.medicaid.gov/about-us/program-history/medicaid-50th-anniversary/entry/47688.*

[32] Information on State activities to expand, enhance, or strengthen HCBS under ARP section 9817 can be found on Medicaid.gov at *https://www.medicaid.gov/medicaid/home-community-based-services/guidance/strengthening-and-investing-home-and-community-based-services-for-medicaid-beneficiaries-american-rescue-plan-act-of-2021-section-9817/index.html.*

standardization has resulted in thousands of metrics and measures currently in use across States, with different metrics and measures often used for different HCBS programs within the same State. As a result, CMS and States are limited in the ability to compare HCBS quality and outcomes within and across States or to compare the performance of HCBS programs for different populations.

In addition, although there are differences in rates of disability among demographic groups, there are very limited data currently available to assess disparities in HCBS access, utilization, quality, and outcomes. Few States have the data infrastructure to systematically or routinely report data that could be used to assess whether disparities exist in HCBS programs. This lack of available data also prevents CMS and States from implementing interventions to make improvements in HCBS programs designed to consistently meet the needs of all beneficiaries.

Compounding these concerns have been notable and high-profile instances of abuse and neglect in recent years, which have been shown to result from poor quality care and inadequate oversight of HCBS in Medicaid. For example, a 2018 report, ''Ensuring Beneficiary Health and Safety in Group Homes Through State Implementation of Comprehensive Compliance Oversight,'' [33] (''Joint Report''), which was jointly developed by the US Department of Health and Human Services' Administration for Community Living (ACL), Office for Civil Rights (OCR), and the Office of Inspector General (OIG), found systemic problems with health and safety policies and procedures being followed in group homes and that failure to comply with these policies and procedures left beneficiaries in group homes at risk of serious harm. In addition, while existing regulations provide safeguards for all Medicaid beneficiaries in the event of a denial of Medicaid eligibility or an adverse benefit determination by the State Medicaid agency and, where applicable, by the beneficiary's managed care plan, there are no safeguards related to other issues that HCBS beneficiaries may experience, such as the failure of a provider to comply with the HCBS settings requirements or difficulty accessing the services in the person-centered service plan unless the individual is receiving those services through a Medicaid managed care arrangement.

Finally, through our regular interactions with State Medicaid agencies, provider groups, and beneficiary advocates, we observed that all these interested parties routinely cite a shortage of direct care workers and high rates of turnover in direct care workers among the greatest challenges in ensuring access to high-quality, cost-effective HCBS for people with disabilities and older adults. Some States have also indicated that a lack of direct care workers is preventing them from transitioning individuals from institutions to home and community-based settings. While workforce shortages have existed for years, they have been exacerbated by the COVID–19 pandemic, which has resulted in higher rates of direct care worker turnover (for instance, due to higher rates of worker-reported stress), an inability of some direct care workers to return to their positions prior to the pandemic (for instance, due to difficulty accessing child care or concerns about contracting COVID–19 for people with higher risk of severe illness), workforce shortages across the health care sector, and wage increases in types of retail and other jobs that tend to draw from the same pool of workers.[34] [35] [36]

To address the list of challenges outlined in this section, we are proposing new Federal requirements in this proposed rule to improve access to care, quality of care, and health and quality of life outcomes; promote health equity for people receiving Medicaid-covered HCBS; and ensure that there are safeguards in place for beneficiaries who receive HCBS through FFS delivery systems. We seek comment on other areas for rulemaking consideration. The proposed requirements are also intended to promote public transparency related to the administration of Medicaid HCBS programs.

D. Fee-for-Service (FFS) Payment

Section 1902(a)(30)(A) of the Act requires States to ''assure that payments are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area.'' Regulations at § 447.203 require States to develop and submit to CMS an access monitoring review plan (AMRP) for a core set of services. Currently, the regulations rely on available State data to support a determination that the State's payment rates are sufficient to ensure access to care in Medicaid FFS that is at least as great for beneficiaries as is generally available to the general population in the geographic area, as required under section 1902(a)(30)(A) of the Act.

In the May 6, 2011, **Federal Register**, we published the ''Medicaid Program; Methods for Assuring Access to Covered Medicaid Services'' proposed rule (76 FR 26341; hereinafter ''2011 proposed rule''), which outlined a data-driven process for States with Medicaid services paid through a State plan under FFS to follow in order to document their compliance with section 1902(a)(30)(A) of the Act. We finalized the 2011 proposed rule in the November 2, 2015, **Federal Register** when we published the ''Medicaid Program; Methods for Assuring Access to Covered Medicaid Services'' final rule with comment period (80 FR 67576; hereinafter ''2015 final rule with comment period''). Among other requirements, the 2015 final rule with comment period required States to develop and submit to CMS an AMRP for certain Medicaid services that is updated at least every 3 years. Additionally, the rule required that when States submit a SPA to reduce or restructure provider payment rates, they must consider the data collected through the AMRP and undertake a public process that solicits input on the potential impact of the proposed reduction or restructuring of Medicaid FFS payment rates on beneficiary access to care. We published the ''Medicaid Program; Deadline for Access Monitoring Review Plan Submissions'' final rule in the April 12, 2016 **Federal Register** (81 FR 21479; hereinafter ''2016 final rule'') with a revised deadline for States' AMRPs to be submitted to us.

Following enactment, numerous States have expressed concern regarding the administrative burden associated with the 2015 final rule with comment period requirements, especially those

[33] Ensuring Beneficiary Health and Safety in Group Homes Through State Implementation of Comprehensive Compliance Oversight. US Department of Human Services, Office of the Inspector General, Administration for Community Living, and Office for Civil Rights. January 2018. Accessed at *https://oig.hhs.gov/reports-and-publications/featured-topics/group-homes/group-homes-joint-report.pdf.*

[34] MACPAC Issue Brief. State Efforts to Address Medicaid Home- and Community-Based Services Workforce Shortages. March 2022. Accessed at *https://www.macpac.gov/wp-content/uploads/2022/03/MACPAC-brief-on-HCBS-workforce.pdf.*

[35] Campbell, S., A. Del Rio Drake, R. Espinoza, K. Scales. 2021. Caring for the future: The power and potential of America's direct care workforce. Bronx, NY: PHI *http://phinational.org/wp-content/uploads/2021/01/Caring-for-the-Future-2021-PHI.pdf.*

[36] American Network of Community Options and Resources (ANCOR). 2021. The state of America's direct support workforce 2021. Alexandria, VA: ANCOR. Accessed at *https://www.ancor.org/sites/default/files/the_state_of_americas_direct_support_workforce_crisis_2021.pdf.*

States with high rates of beneficiary enrollment in managed care. In an attempt to address some of the States' concerns regarding unnecessary administrative burden, we issued a State Medicaid Director letter (SMDL) on November 16, 2017 (SMDL #17–004), which clarified the circumstances in which provider payment reductions or restructurings would likely not result in diminished access to care, and therefore, would not require additional analysis and monitoring procedures described in the 2015 final rule with comment period.[37] Subsequently, in the March 23, 2018 **Federal Register**, we published the ''Medicaid Program; Methods for Assuring Access to Covered Medicaid Services-Exemptions for States With High Managed Care Penetration Rates and Rate Reduction Threshold'' proposed rule (83 FR 12696; hereinafter ''2018 proposed rule''), which would have exempted States from requirements to analyze certain data or monitor access when the vast majority of their covered beneficiaries receive services through managed care plans. That proposed rule, if it had been finalized, would have provided similar flexibility to all States when they make nominal rate reductions or restructurings to FFS payment rates. Based on the responses received during the public comment period, we decided not to finalize the proposed exemptions.

In the July 15, 2019 **Federal Register**, we published the ''Medicaid Program; Methods for Assuring Access to Covered Medicaid Services-Rescission'' proposed rule (84 FR 33722; hereinafter ''2019 proposed rule'') to rescind the regulatory access requirements at §§ 447.203(b) and 447.204, and concurrently issued a CMCS Informational Bulletin [38] stating the agency's intention to establish a new access strategy. Based on the responses we received during the public comment period, we decided not to finalize the 2019 proposed rule, and instead continue our efforts and commitment to develop a data-driven strategy to understand access to care in the Medicaid program.

States have continued to question whether the AMRP process is the most effective or accurate reflection of access to care in a State's Medicaid program, and requested we provide additional clarity on the data necessary to support compliance with section 1902(a)(30)(A) of the Act. In reviewing the information that States presented through the AMRPs, we also have questioned whether the data and analysis consistently address the primary access-related question posed by section 1902(a)(30)(A) of the Act—namely, whether rates are sufficient to ensure access to care at least as great as that enjoyed by the general population in geographic areas. The unstandardized nature of the AMRPs, which largely defer to States to determine appropriate data measures to review and monitor when documenting access to care, have made it difficult to assess whether any single State's analysis demonstrates compliance with section 1902(a)(30)(A) of the Act.

While the AMRPs were intended to be a useful guide to States in the overall process to monitor beneficiary access, they are generally limited to access in FFS delivery systems and focus on targeted payment rate changes rather than the availability of care more generally or population health outcomes (which may be indicative of the population's ability to access care). Moreover, the AMRP processes are largely procedural in nature and not targeted to specific services for which access may be of particular concern, requiring States to engage in triennial reviews of access to care for certain broad categories of Medicaid services—primary care services, physician specialist services, behavioral health services, pre and post-natal obstetric services, and home health services. Although the 2016 final rule reasonably discussed that the selected service categories intended to be indicators for available access in the overall Medicaid FFS system, the categories do not easily translate to the services authorized under section 1905(a) of the Act, granting States deference as to how broadly or narrowly to apply the AMRP analysis to services within their programs. For example, the category ''primary care services'' could encompass several of the Medicaid service categories described within section 1905(a) of the Act and, without clear guidance on which section 1905(a) services categories, qualified providers, or procedures we intended States to include within the AMRP analyses. States were left to make their own interpretations in analyzing access to care under the 2016 final rule.

Similarly, a number of the AMRP data elements, both required and suggested within the 2016 final rule, may be overly broad, subject to interpretation, or difficult to obtain. Specifically, under the 2016 final rule provisions, States are required to review: the extent to which beneficiary needs are fully met; the availability of care through enrolled providers to beneficiaries in each geographic area, by provider type and site of service; changes in beneficiary utilization of covered services in each geographic area; the characteristics of the beneficiary population (including considerations for care, service and payment variations for pediatric and adult populations and for individuals with disabilities); and actual or estimated levels of provider payment available from other payers, including other public and private payers, by provider type and site of service. Though service utilization and provider participation are relatively easy measures to source and track using existing Medicaid program data, an analysis of whether beneficiary needs are fully met is at least somewhat subjective and could require States to engage in a survey process to complete. Additionally, while most Medicaid services have some level of equivalent payment data that can be compared to other available public payer data, such as Medicare, private pay information may be proprietary and difficult to obtain. Therefore, many States struggled to meet the regulatory requirement comparing Medicaid program rates to private payer rates because of their inability to obtain private payer data.

Due to these issues, States produced varied AMRPs through the triennial process that were, as a whole, difficult to interpret or to use in assessing compliance with section 1902(a)(30)(A) of the Act. In isolation, a State's specific AMRP most often presented data that could be meaningful as a benchmark against changes within a State's Medicaid program, but did not present a case for Medicaid access consistent with the general population in geographic areas. Frequently, the data and information within the AMRPs were presented without a formal determination or attestation from the State that the information presented established compliance with section 1902(a)(30)(A) of the Act. Because the States' AMRPs generally varied to such a great degree, there was also little to glean in making State-to-State comparisons of performance on access measures, even for States with geographic and demographic similarities.

Based on results of the triennial AMRPs, we were uncertain of how to make use of the information presented within them other than to make them publicly available. We published the

[37] State Medicaid Director Letter #17–0004 Re: Medicaid Access to Care Implementation Guidance. Accessed at *https://www.medicaid.gov/federal-policy-guidance/downloads/smd17004.pdf* (November 2017).

[38] CMCS Informational Bulletin: Comprehensive Strategy for Monitoring Access in Medicaid, Accessed at *https://www.medicaid.gov/federal-policy-guidance/downloads/CIB071119.pdf* (July 2019).

AMRPs on *Medicaid.gov* but had little engagement with States on the content or results of the AMRPs since much of the information within the plans could not meaningfully answer whether access in Medicaid programs satisfied the requirements of section 1902(a)(30)(A) of the Act. Additionally, we received little feedback from providers, beneficiaries, or advocates on whether or how interested parties made use of the triennial AMRPs. However, portions of the 2016 final rule related to public awareness and feedback on changes to Medicaid payment rates and the analysis that we received from individual States proposing to make rate changes was of great benefit in determining approvals of State payment change proposals. Specifically, the portion of the AMRP process where States update their plans to describe data and measures to serve as a baseline against which they monitor after reducing or restructuring Medicaid payments allows States to document consistency with section 1902(a)(30)(A) of the Act at the time of SPA submission, usually as an assessment of how closely rates align with Medicare rates, and to understand the impact of reductions through data monitoring after SPA approval.

Under this proposed rule, we are proposing to balance elimination of unnecessary Federal and State administrative burden with robust implementation of the Federal and State shared obligation to ensure that Medicaid payment rates are set at levels sufficient to ensure access to care for beneficiaries consistent with section 1902(a)(30)(A) of the Act. The provisions of this proposed rule, as discussed in more detail later, would better achieve this balance through improved transparency of Medicaid FFS payment rates, through publication of a comparative payment rate analysis to Medicare and payment rate disclosures, and through a more targeted and defined approach to evaluating data and information when States propose to reduce or restructure their Medicaid payment rates. Payment rate transparency is a critical component of assessing compliance with section 1902(a)(30)(A) of the Act. In addition, payment rate transparency helps to ensure that interested parties have basic information available to them to understand Medicaid payment levels and the associated effects of payment rates on access to care so that they may raise concerns to State Medicaid agencies via the various forms of public processes discussed within this proposed rule. Along with improved payment rate transparency and disclosures as well as comparative payment rate analyses, we are proposing a more efficient process for States to undertake when submitting rate reduction or restructuring SPAs to CMS for review. As we move toward aligning our Medicaid access to care strategy across FFS and managed care delivery systems, we will consider additional rulemaking to help ensure that Medicaid payment rate information is appropriately transparent and rates are fully consistent with broad access to care across delivery systems, so that interested parties have a more complete understanding of Medicaid payment rate levels and resulting access to care for beneficiaries.

II. Provisions of the Proposed Regulations

A. Medicaid Advisory Committee and Beneficiary Advisory Group (§ 431.12)

Current § 431.12 requires States to have a MCAC to advise the State Medicaid agency about health and medical care services. The current regulations are intended to ensure that State Medicaid agencies have a way to receive feedback from interested parties on issues related to the Medicaid program. However, the current regulations lack specificity related to how these committees can be used to ensure the proper and efficient administration of the Medicaid program more expressly by more fully promoting beneficiary perspectives.

Under the authority of section 1902(a)(4) of the Act, section 1902(a)(19) of the Act, and our general rulemaking authority in section 1102 of the Act, we propose to update § 431.12 to replace the current MCAC requirements with a committee framework designed to ensure the proper and efficient administration of the Medicaid program and to better ensure that care and services under the Medicaid program will be provided in a manner consistent with the best interests of the beneficiaries. If finalized, States would be required to establish and operate the newly named Medicaid Advisory Committee (MAC) and a Beneficiary Advisory Group (BAG). The MAC and its corresponding BAG would serve as vehicles for bi-directional feedback between interested parties and the State on matters related to the effective administration of the Medicaid program. With this proposal, FFP, or Federal match, for Medicaid administrative activities would remain available to States for expenditures related to MAC and BAG activities in the same manner as the former MCAC.

We propose to amend the title and paragraph (a) of § 431.12 to update the name of the existing MCAC to the MAC, and to add the requirement for States to establish and operate a dedicated advisory group comprised of Medicaid beneficiaries, the BAG. Our goal is that the committee and its corresponding advisory group would advise the State not only on issues related to health and medical services, as the MCAC did, but also on matters related to policy development and to the effective administration of the Medicaid program consistent with the language of section1902(a)(4)(B) of the Act, which requires a State plan to meaningfully engage Medicaid beneficiaries and other low-income people in the administration of the plan. While the Medicaid program covers medical services, the program is increasingly also covering services designed to address beneficiaries' social determinants of health and their health-related social needs more generally. Therefore, having a discussion with the MAC about topics that are not directly related to covered services may be necessary to ensure that beneficiaries are able to meaningfully access these services. Expanding the scope of the current committee is necessary to align the actions of the committee with the expanding scope of the Medicaid program, consistent with section 1902(a)(4)(B) of the Act, because the MAC creates a formalized way for interested parties and beneficiary representatives to provide feedback to the State about issues related to the Medicaid program and the services it covers and to help ensure that the program operates efficiently and as it was designed to operate.

Every State will vary in the types of topics that would benefit from the interested parties' feedback, so discretion on which topics will be discussed with the MAC will be left to the State. Depending on the priorities of the State in a given year, States may find it helpful to bring to the MAC issues related to, for example, grievances, consumer experience survey ratings, design of a new program, or other like topics. Proposed mandates for these entities are described later in this section under proposed paragraph (g). We further propose conforming updates to paragraph (b) regarding the State plan requirements, to reflect the proposed MAC and BAG and the expanded mandate proposed in this proposed rule. The interested parties advisory group, proposed and described in the FFS sections of this proposed rule, to advise States on rate setting for certain HCBS

is not related to the MAC or BAG outlined here. We note in that section that a State would be able utilize its MAC and BAG to provide recommendations for payment rates, thereby satisfying the requirements of that proposal. However, the MAC and BAG requirements proposed here, if finalized, are wholly separate from the interested parties advisory group, regardless of whether that proposal is finalized as well.

We propose to update paragraph (c) of § 431.12 regarding appointment of committee members to specify that the members of the MAC and BAG must be appointed by the agency director or higher State authority on a rotating, continuous basis. Under our proposals, committee and advisory group members would serve a specific amount of time, the length of which will be determined by each State and noted in its bylaws. After a committee or advisory group member term has been completed, the State will appoint a new member, thus ensuring that MAC and BAG memberships rotate continuously. We propose the State be required to make public its process and bylaws for recruitment and appointment of members of the MAC and BAG and post the list of both sets of members on the State's website. Under our proposal, the website page where this information is located must be easily accessible by the public. These updates align with how advisory committees similar to the MAC and BAG are run, and the changes are designed to provide additional details to support States' operation of the MAC and BAG. Further, these updates facilitate transparency, improving the current regulations, which do not mention nor promote transparency of information related the MCAC with the public. We believe that transparency of information can lead to enhanced accountability on the part of the State to making its MAC and BAG as effective as possible.

Advisory committees and groups can be most effective when they represent a wide range of perspectives and experiences. The current MAC regulations only provide high level descriptions of types of members that should be selected. Since we know that each State environment is different, in the proposed rule, we continue to provide the State with discretion on how large the MAC and BAG should be, but we outline in more detail the types of categories of members that can best reflect the needs of a Medicaid program. We believe that diversely populated MACs and BAGs can provide States with access to a broad range of perspectives, and importantly, beneficiaries' perspective, which can positively impact the administration of the Medicaid program.

We encourage States to take into consideration, as part of their member selection process, the demographics of the Medicaid population in their State. Keeping diverse representation in mind as a goal for the MAC membership can be a way for States to acknowledge that specific populations and those receiving critically important services be appropriately represented on the MAC. For example, in making the MAC appointments, the State may want to balance the representation of the MAC according to geographic areas of the State and the demographics of the Medicaid program of the State. The State may want to consider geographical diversity (for example, urban, rural, tribal) when making its membership selections. The State could also consider demographic representation of its membership by including members representing or serving Medicaid beneficiaries the following categories: (1) children's health care; (2) behavioral health services; (3) preventive care and reproductive health services; (4) health or service issues pertaining specifically to people over age 65; and (5) health or service issues pertaining specifically to people with disabilities. By offering these considerations, we seek to support States in their efforts to eliminate differences in health care access and outcomes experienced by diverse populations enrolled in Medicaid. Our aim is to support several of the priorities for operationalizing health equity across CMS programs as outlined in the CMS Framework for Health Equity (2022–2032) and the HHS Equity Action Plan which is consistent with E.O. 13985 which calls for advancing equity for underserved populations.

As we considered effective ways to better integrate the beneficiary perspective into decisions related the Medicaid program, we also recognized that a diverse and representative set of interested parties should be reflected in the composition of each State's MAC. We propose to amend paragraph (d) of § 431.12 regarding committee membership to account for both membership and composition, and to require the MAC membership include members from the BAG, described later in this section, who are currently or have been Medicaid beneficiaries, and individuals with direct experience supporting Medicaid beneficiaries (for example, family members or caregivers [39] of those enrolled in Medicaid); as well as advocacy groups; providers or administrators of Medicaid services; representatives of managed care plans or State health plan associations representing such managed care plans; and representatives from other State agencies that serve Medicaid beneficiaries. This proposal is consistent with the language of section 1902(a)(4)(B) of the Act, which requires a State plan to meaningfully engage Medicaid beneficiaries and other low-income people in the administration of the plan. The change we propose would support States to set up MACs that align with section 1902(a)(4)(B) of the Act since they would now have to select the membership composition to reflect the community members who represent the interests of Medicaid beneficiaries. The State also benefits from having a way to hear how the Medicaid program can be responsive to its beneficiaries' and the Medicaid community's needs.

Specifically, in paragraph (d)(1) of § 431.12, we propose that at least 25 percent of the MAC must be individuals with lived Medicaid beneficiary experience from the BAG. This means that the BAG would be comprised of people who: (1) are currently or have been Medicaid beneficiaries and (2) individuals with direct experience supporting Medicaid beneficiaries (family members or caregivers of those enrolled in Medicaid). We selected 25 percent as a threshold to reflect the importance of including the beneficiary perspective in the administration of the Medicaid program and to ensure that the beneficiary perspective has equitable representation in the feedback provided by the MAC. We did not select a higher percentage because we acknowledge that States will benefit from a MAC that includes representation from a diverse set of interested parties who work in areas related to Medicaid but are not beneficiaries, their family members or their caregivers. We seek comment on the 25 percent requirement.

As noted earlier, representation from the remaining committee members would be left to the States' discretion. Rather than prescribing specific percentages for each category, we only propose to require representation from each category as part of the MAC. The specific percentage of each of category (other than the BAG members) relative to the whole committee can be determined by each State. This approach would provide States with flexibility to determine how to best represent the unique landscape of each State's Medicaid program. We seek comment on what should be the minimum percentage requirement that MAC members be current/past Medicaid

[39] Caregivers can be paid or unpaid.

beneficiaries or individuals with direct experience supporting Medicaid beneficiaries (such as family members or caregivers of those enrolled in Medicaid).

States need to know how to deliver care to its beneficiaries. In addition to hearing directly from beneficiaries, the State can gain insights into how to effectively administer its program, from other groups of the Medicaid community. Categorically, we propose in paragraph (d)(2) that the rest of the MAC must include representation from each category: (1) members of State or local consumer advocacy groups or other community-based organizations that represent the interests of, or provide direct service, to Medicaid beneficiaries; (2) clinical providers or administrators who are familiar with the health and social needs of Medicaid beneficiaries and with the resources available and required for their care; (3) representatives from participating Medicaid managed care plans or the State health plan association representing such plans, as applicable; and (4) representatives from other State agencies serving Medicaid beneficiaries, as ex-officio members.

States are determining which types of providers to include under the clinical providers or administrators category, we recommend they consider a wide range of providers or administrators that are experienced with the Medicaid program including, but not limited to: (1) primary care providers (internal or family medicine physicians or nurse practitioners or physician assistants that practice primary care); (2) behavioral health providers (that is, mental health and substance use disorder providers); (3) reproductive health service providers, including maternal health providers; (4) pediatric providers; (5) dental and oral health providers; (6) community health, rural health clinic or Federally Qualified Health Center (FQHC) administrators; (7) individuals providing long-term care services and supports; and (8) direct care workers [40] who can be individuals with direct experience supporting Medicaid beneficiaries (such as family members or caregivers). Direct care workers also include community health workers who assist Medicaid beneficiaries in navigating access to needed services and care managers, care coordinators, or service coordinators who assist Medicaid beneficiaries with complex care needs.

We have also identified health plans as an important contributor to the MAC, but we acknowledge that not all States that have managed care delivery systems. We know many Medicaid health plans administer similar committees and thus allow for States to tailor health plan representation based on its managed care market. For example, States can fulfil this category with only one or with multiple plans operating in the State. In addition, we also give States the flexibility to meet the health plan representation requirements with either participating Medicaid managed care plans or the State health plan association representing such plans, as applicable.

The proposed language in paragraph (d)(2)(D) broadens the type of representatives from other State agencies that are required to be on the committee from the similar MCAC requirement. The current MCAC regulation requires membership by ''the director of the public welfare department or the public health department, whichever does not head the Medicaid agency.'' By expanding the definition of external agency representation to be broader than the welfare or public health department, we would give States more flexibility in representing the Medicaid program's interests based on States' unique circumstances and organizational structure. States can work with sister State agencies to determine who should participate in the MAC (for example, foster care agency, mental health agency, department of public health). We also propose that these representatives be part of the committee as ex-officio members, not as full members of the MAC. While we believe it will be essential to have these State-interested parties present for program coordination and information-sharing, we believe the formal representation of the MAC should be comprised of beneficiaries, advocates, community organizations, and providers that serve Medicaid beneficiaries.

We propose to replace paragraph (e) of § 431.12; in paragraph (e) to require that States create a BAG, a dedicated beneficiary advisory group that will meet separately from the MAC. Currently, the requirements governing MCACs require the presence of beneficiaries in committee membership but do little to ensure their contributions are considered or their voices heard. For example, current paragraph (e) describes committee participation and requires the committee ''[further] the participation of beneficiary members in the agency program.'' This requirement provides little guidance toward this goal and creates an environment where a beneficiary may not feel comfortable participating despite the opportunity being afforded in its technical sense. We believe adding the creation of the BAG will result in providing the State with increased access to the beneficiary perspective. This proposal directly addresses and provides the mechanism (the BAG) through which States can meet the language of section 1902(a)(4)(B) of the Act, which requires a State plan to meaningfully engage Medicaid beneficiaries and other low-income people in the administration of the plan.

As such, the creation of a separate beneficiary-only advisory group aligns with what we learned from multiple interviews with State Medicaid agencies and other Medicaid interested parties (for example, Medicaid researchers, former Medicaid officials) conducted over the course of 2022 on the effective operation of the existing MCACs. Interested parties described the importance of having a comfortable, supportive, and trusting environment that facilitates beneficiaries' ability to speak freely on matters most important to them. It is equally important that the BAG have a subset of its members that also sit on the State's MAC to ensure that the beneficiary perspective and experience are heard directly. We noted earlier that some States may already have highly effective BAG-type groups operating as part of their Medicaid program. These groups may represent specific constituencies such as children with complex medical needs or older adults or may be participants in a specific waiver. In these instances, States may utilize these groups to satisfy the proposed requirements of this rule, provided the BAG-type group membership includes the MAC members described in paragraph (d)(1). Those States must appoint members from the BAG-type group to serve on the MAC to facilitate this crossover.

Specifically, at paragraph (e)(1), we propose that the MAC members described in proposed paragraph (d)(1) must also be members of the BAG. This proposed requirement would facilitate the bi-directional communication essential to effective beneficiary

[40] CMS defines direct care workers as: a registered nurse, licensed practical nurse, nurse practitioner, or clinical nurse specialist who provides nursing services to Medicaid-eligible individuals receiving home and community-based services; (2) A licensed or certified nursing assistant who provides such services under the supervision of a registered nurse, licensed practical nurse, nurse practitioner, or clinical nurse specialist; (3) A direct support professional; (4) A personal care attendant; (5) A home health aide; or (6) Other individuals who are paid to provide services to address activities of daily living or instrumental activities of daily living, behavioral supports, employment supports, or other services to promote community integration directly to Medicaid-eligible individuals receiving home and community-based services.

engagement and allow for meaningful representation of diverse voices across the MAC and BAG. In paragraph (e)(2), we propose that the BAG meetings occur in advance of each MAC meeting to ensure BAG member preparation for each MAC discussion. BAG meetings would also be subject to requirements we propose in paragraph (f)(5), described later in this section, that the BAG meetings must occur virtually, in-person, or through a hybrid option to maximize member attendance. We plan to expound on best practices for engaging beneficiary participation in committees like the MAC in future guidance.

We propose at subsection (f) an administrative framework for the MAC and BAG to ensure transparency and a meaningful feedback loop to the public and among the members of the committee and group. Interested parties' feedback and recent reports [41] [42] published on meaningful beneficiary engagement illuminate the need for more transparent and standardized processes across States to drive participation from key interested parties and to facilitate the opportunity for participation from a diverse set of members and the community. Further, we believe that in order for the State to comply with the language of section 1902(a)(4)(B) of the Act, which requires a State plan to meaningfully engage Medicaid beneficiaries and other low-income people in the administration of the plan, it needs to be responsive to the needs of its beneficiaries. To be responsive to the needs of its beneficiaries, the State needs to be able to gather feedback from a variety of people that touch the Medicaid program, and the MAC and BAG will serve as the vehicle through which States can obtain this feedback.

Specifically, in paragraph (f)(1), we propose to require State agencies to develop and post publicly on their website bylaws for governance of the MAC and BAG, current lists of MAC and BAG memberships, and past meeting minutes for both the committee and group. In paragraph (f)(2), we propose to require State agencies to develop and post publicly a process for MAC and BAG member recruitment and appointment, and for selection of MAC and BAG leadership. In paragraph (f)(3), we propose to require State agencies to develop, publicly post, and implement a regular meeting schedule for the MAC and BAG. The requirement specifies the MAC and BAG must each meet at least once per quarter and hold off-cycle meetings as needed. In paragraph (f)(4), we propose that, at least two MAC meetings per year must be opened to the public. For the MAC meetings that are open to the public, the meeting agenda must include a dedicated time for public comment to be heard by the MAC. Further, the State must also adequately notify the public of the date, location, and time of these type (public) of MAC meetings at least 30 calendar days in advance. None of the BAG meetings are not required to be open to the public, unless the State's BAG members decide otherwise. The same requirements would apply to States whose BAG meetings were determined, by its membership, to be open to the public. We seek comment on this approach.

In paragraph (f)(5), we propose to require that States offer in-person and virtual attendance options to maximize member participation at MAC and BAG meetings. We acknowledge that interested parties may face a range of technological and internet accessibility limitations, and that at a minimum, States will need to provide a telephone dial-in option for MAC and BAG meetings. While we understand that in-person interaction can sometimes assist in building trusted relationships, we also recognize that accommodations for members and the public to participate virtually is important, particularly since the beginning of the COVID–19 pandemic. We invite comment on ways to best strike this balance. We address technical and logistical challenges in paragraph (f)(5) and address effective communication and language access and meeting accessibility in subsequent paragraphs.

With respect to in-person meetings, we propose in paragraph (f)(6) to require that States ensure meeting times and locations for MAC and BAG meetings are selected to maximize participant attendance, which may vary by meeting. For example, States may determine, by consulting with its MAC and BAG members that holding meetings in various locations throughout the State may result in better attendance. In addition, they may ask the committee and group members about which times and weekdays may be more favorable than others and hold meetings at those times accordingly. States must also use the publicly posted meeting minutes, which lists attendance by members, as a way to gauge which meeting times and locations garner maximum participate attendance. Finally, in paragraph (f)(7), we propose to require State agencies to facilitate participation of beneficiaries by ensuring that meetings are accessible to people with disabilities, that reasonable modifications are provided when necessary to ensure access and enable meaningful participation, that communication with individuals with disabilities is as effective as with others, that reasonable steps are taken to provide meaningful access to individuals with Limited English Proficiency, and that meetings comply with the requirements at § 435.905(b) and applicable regulations implementing the ADA, section 504 of the Rehabilitation Act, and section 1557 of the Affordable Care Act at 28 CFR part 35 and 45 CFR parts 84 and 92.

We propose to revise paragraph (g) to detail an expansion of the topics on which the MAC and BAG should provide feedback to the Medicaid agency from the prior MCAC requirements. In researching other States' MACs, we know that some already use the MACs to get feedback from interested parties, including beneficiaries, on a variety of topics relating to the effective and efficient administration of the Medicaid program. The changes we propose aim to strike a balance that reflects some States' current practices without putting strict limitations on specific topics for discussion to all States. Broadening the scope of the topics that the MAC and BAG discuss will benefit the State by giving greater insight into how it is currently delivering care for its beneficiaries and thereby assist in identifying ways to improve the way the Medicaid program is administered.

The State will use this engagement with the MAC and BAG to ensure that the beneficiary and interested parties' voices are considered and to allow the opportunity to adjust course based on the feedback provided by the committee and group members. Topics of discussion are to be based on State need and determined in collaboration with the MAC to address matters related to policy development and matters related to the effective administration of the Medicaid program. These topics could include new policy or program developments; changes to services; coordination of care and quality of

[41] Resources for Integrated Care and Community Catalyst, ''Listening to the Voices of Dually Eligible Beneficiaries: Successful Member Advisory Councils'', 2019. Retrieved from *https://www.resourcesforintegratedcare.com/listening_to_voices_of_dually_eligible_beneficiaries/.*

[42] Centers for Medicare & Medicaid Services.(n.d.). Person & Family Engagement Strategy: Sharing with Our Partners. Retrieved from: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/Downloads/Person-and-Family-Engagement-Strategic-Plan-12-12-16.pdf#:~:text=person%E2%80%99s%20priorities%2C%20goals%2C%20needs%20and%20values.%E2%80%9D%20Using%20these,to%20guide%20all%20clinical%20decisions%20and%20drives%20genuine.*

services; eligibility, enrollment, and renewal processes; the review of communications to beneficiaries by the State Medicaid agency and Medicaid managed care plans; the provision of culturally and linguistically appropriate services, health equity, disparities, and biases in the Medicaid program; and other issues that impact the provision or outcomes of health and medical care services in the Medicaid program as identified by the MAC, the BAG, or the State.

We propose new paragraph (h) to expand on existing State responsibilities for managing the MAC and BAG regarding staff assistance, participation, and financial support. We understand from States and other interested parties, that many States already provide staffing and financial support to their MACs in ways that meet or going beyond what we propose through our updated requirements. We believe that expanding upon the current standards regarding State responsibility for planning and executing the functions of the MAC and BAG will ensure consistent and ongoing standards to further beneficiaries' and interested parties' engagement. For example, we know that when any kind of interested parties group meets, all members of that group need to fully understand the topics being discussed in order to meaningfully engage in that discussion. This is particularly relevant when the topics of discussion are complex or based in specific terminology as Medicaid related issues often can be.

We believe that when States provide their MACs and BAGs with additional staffing support that can explain, provide background materials, and meet with the members in preparation for the larger discussions, the members have a greater chance to provide more meaningful feedback and ensure that members are adequately prepared to engage in these discussions. The proposed changes to the requirements seek to create environments that support meaningful engagement by the members of these groups whose feedback can then be used by States to support the efficient administration of their Medicaid program. We anticipate providing additional guidance on model practices, recruitment strategies, and ways to facilitate beneficiary participation, and we invite comments on effective strategies to ensure meaningful interested parties' engagement that in turn can facilitate full beneficiary participation.

Under the current MCAC regulations in § 431.12(f), each State is required to provide the committee with staff assistance from the agency, independent technical assistance as needed to enable it to make effective recommendations, and financial arrangements, if necessary, to make possible the participation of beneficiary members. The changes we propose include adding requirements regarding recruitment, meeting scheduling, recordkeeping, and support for beneficiary members. The overlap with the current regulation would mean much of the work to implement our proposals, if finalized, would already be occurring.

The proposed requirement for beneficiary support, including financial support, is similar to current requirements, such as using dedicated staff to support beneficiary attendance at both the MAC and BAG meetings and providing financial assistance to facilitate meeting attendance by beneficiary members, as needed. Staff may support beneficiary attendance through outreach to the Medicaid beneficiary MAC and BAG members throughout the membership period to provide information and answer questions; identify barriers and supports needed to facilitate attendance at MAC and BAG meetings; and facilitate access to those supports. We are not proposing changes to existing financial support requirements. However, we are proposing an additional requirement that at least one member of the State agency's executive staff attend all MAC and BAG meetings to provide an opportunity for beneficiaries and representatives of the State's leadership to interact directly.

In the spirit of transparency and to ensure compliance with the updated regulations, we propose new paragraph (i) to require that the MAC, with support from the State and in accordance with the requirements proposed at this section, submit an annual report to the State. The BAG perspective and feedback will be embedded in the report, since the Group is represented on the MAC. The State, in turn, would be required to review the report and include responses to recommendations in the report. Prior to finalizing the report, the State must allow the MAC to perform a final review. Once the MAC completes its final review, the State must publish it by posting it on its website. The proposed requirements of this section seek to both ensure transparency while also facilitating a feedback loop and view into the impact of the committee and group's recommendations. We invite comment on additional ways to ensure that the State can create a feedback loop with the MAC and BAG.

Finally, we propose no changes to, and thus maintain, the current regulatory language on FFP from current paragraph (g) to support committee and group administration, to appear in new paragraph (j) with conforming edits for new committee and group names.

This requirement, if finalized, would be effective 60 days after the effective date of the final rule, which would provide States with 1 year to implement these requirements. We seek comment on whether 1 year is too much or not enough time for States to implement the updates in this regulation in an effective manner. We understand that States may need to modify their current MCACs to reflect the updated requirements and may also need to create the BAG and recruit members to participate, if they do not already have a similar entity already in place.

B. Home and Community-Based Services (HCBS)

We are proposing both to amend and add new Federal HCBS requirements to improve access to care, quality of care, and beneficiary health and quality of life outcomes, while consistently meeting the needs of all beneficiaries receiving Medicaid-covered HCBS. This preamble discusses our proposed changes in the context of current law.

We have previously received questions from States with demonstration projects under section 1115 of the Act that include HCBS about the applicability of other HCBS regulatory requirements. As a result, we are identifying that, consistent with the applicability of other HCBS regulatory requirements to such demonstration projects, the proposed requirements for section 1915(c) waiver programs and section 1915(i), (j), and (k) State plan services included in this proposed rule, if finalized, would apply to such services included in approved section 1115 demonstration projects, unless we explicitly waive one or more of the requirements as part of the approval of the demonstration project. We are not proposing to apply the requirements for section 1915(c) waiver programs and section 1915(i), (j), and (k) State plan services in this proposed rule to the Program of All-Inclusive Care of the Elderly (PACE) authorized under sections 1894 and 1934 of the Act, as the existing requirements for PACE either already address or exceed the requirements outlined in this proposed rule, or are substantially different from those for section 1915(c) waiver programs and section 1915(i), (j), and (k) State plan services.

1. Person-Centered Service Plans (42 CFR 441.301(c), 441.450(c), 441.540(c), and 441.725(c))

Section 1915(c)(1) of the Act requires that services provided through section 1915(c) waiver programs be provided under a written plan of care (hereinafter referred to as ''person-centered service plans'' or ''service plans''). Existing Federal regulations at § 441.301(c) address the person-centered planning process and include a requirement at § 441.301(c)(3) that the person-centered service plan be reviewed and revised, upon reassessment of functional need, at least every 12 months, when the individual's circumstances or needs change significantly, or at the request of the individual.

In 2014, we released guidance for section 1915(c) waiver programs [43] (hereinafter the ''2014 guidance'') that included expectations for State reporting of State-developed performance measures to demonstrate compliance with section 1915(c) of the Act and the implementing regulations in part 441, subpart G, through six assurances, including assurances related to person-centered service plans. The 2014 guidance indicated that States should conduct systemic remediation and implement a Quality Improvement Project when they score below an 86 percent threshold on any of their performance measures. The six assurances identified in the 2014 guidance were the following:

1. *Level of Care:* The State demonstrates that it implements the processes and instrument(s) specified in its approved waiver for evaluating/reevaluating an applicant's/waiver participant's level of care consistent with care provided in a hospital, nursing facility, or Intermediate Care Facility for Individuals with Intellectual Disabilities;

2. *Service Plan:* The State demonstrates it has designed and implemented an effective system for reviewing the adequacy of service plans for waiver participants;

3. *Qualified Providers:* The State demonstrates that it has designed and implemented an adequate system for assuring that all waiver services are provided by qualified providers;

4. *Health and Welfare:* The State demonstrates it has designed and implemented an effective system for assuring waiver participant health and welfare;

5. *Financial Accountability:* The State demonstrates that it has designed and implemented an adequate system for insuring financial accountability of the waiver program; and

6. *Administrative Authority:* The Medicaid Agency retains ultimate administrative authority and responsibility for the operation of the waiver program by exercising oversight of the performance of waiver functions by other State and local/regional non-State agencies (if appropriate) and contracted entities.[44]

We are proposing a different approach for States to demonstrate that they meet the statutory requirements in section 1915(c) of the Act and the regulatory requirements in part 441, subpart G, including the requirements regarding assurances around service plans. The proposed approach is based on feedback CMS obtained during various public engagement activities conducted with States and other interested parties over the past several years about the reporting discussed in the 2014 guidance, as well as feedback received through the RFI [45] discussed earlier about the need to standardize reporting and set minimum standards for HCBS. Accordingly, the proposed HCBS requirements in this rulemaking are intended to establish a new strategy for oversight, monitoring, quality assurance, and quality improvement for section 1915(c) waiver programs. The proposed approach focuses on priority areas that have been identified by States, oversight entities, consumer advocacy organizations, and other interested parties. The priority areas are person-centered planning, health and welfare, access, beneficiary protections, and quality improvement. As part of this approach, we propose to establish new minimum performance requirements and new reporting requirements for section 1915(c) waiver programs that are intended to supersede and fully replace the reporting requirements and the 86 percent performance level threshold for performance measures described in the 2014 guidance. Further, to ensure consistency and alignment across HCBS authorities, we propose to apply the proposed requirements for section 1915(c) waiver programs to section 1915(i), (j), and (k) State plan services as appropriate.

Under section 1902(a)(19) of the Act, States must provide safeguards to assure that eligibility for Medicaid-covered care and services will be determined and provided in a manner that is consistent with simplicity of administration and that is in the best interest of Medicaid beneficiaries. While the needs of some individuals who receive HCBS may be relatively stable over some time periods, individuals who receive HCBS experience changes in their functional needs and individual circumstances, such as the availability of natural supports or a desire to choose a different provider, that necessitate revisions to the person-centered service plan to remain as independent as possible or to prevent adverse outcomes. The requirements to reassess functional need and to update the person-centered service plan based on the results of the reassessment, when circumstances or needs change significantly, or at the request of the individual are important safeguards that are in the best interest of beneficiaries because they ensure that an individual's section 1915(c) waiver program services change to meet the beneficiary's needs most appropriately as those needs change. Section 2402(a) of the Affordable Care Act (Pub. L. 111–148 and Pub. L. 111–152) requires the Secretary of HHS to ensure that all States receiving Federal funds for HCBS, including Medicaid, develop HCBS systems that are responsive to the needs and choices of beneficiaries receiving HCBS, maximize independence and self-direction, provide support and coordination to facilitate the participant's full engagement in community-life, and achieve a more consistent and coordinated approach to the administration of policies and procedures across public programs providing HCBS.[46] In particular, section 2402(a)(1) of the Affordable Care Act requires States to allocate resources for services in a manner that is responsive to the changing needs and choices of beneficiaries receiving HCBS and to provide strategies for beneficiaries receiving such services to maximize their independence, while section 2402(a)(2) of the Affordable Care Act requires States to provide beneficiaries who need HCBS with the support and coordination needed to design a plan based on individual preferences and

[43] Modifications to Quality Measures and Reporting in § 1915(c) Home and Community-Based Waivers. March 2014. Accessed at *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/3-cmcs-quality-memo-narrative_0_2.pdf.*

[44] Performance measures were required for delegated functions unless the delegated functions were covered by performance measures associated with other assurances.

[45] CMS Request for Information: Access to Coverage and Care in Medicaid & CHIP. February 2022. For a full list of question from the RFI, see *https://www.medicaid.gov/medicaid/access-care/downloads/access-rfi-2022-questions.pdf.*

[46] Section 2402(a) of the Affordable Care Act—Guidance for Implementing Standards for Person-Centered Planning and Self-Direction in Home and Community-Based Services Programs. Accessed at *https://acl.gov/sites/default/files/news%202016-10/2402-a-Guidance.pdf.*

personal goals that support their full engagement in community life.

Effective State implementation of the person-centered planning process is integral to ensuring compliance with section 2402 of the Affordable Care Act. This is because this process is how States identify and document the service needs and choices of people receiving HCBS, plan for delivering individualized services that promote independence and self-direction, effectively coordinate services and supports necessary for community living, and ensure that the services and supports that people receive are responsive to their changing needs and choices. Each component of the person-centered planning process, including the functional assessment, developing and implementing the person-centered service plan, and periodically reassessing and updating of the service plan, are essential to ensuring States' compliance with sections 2402(a)(1) and (2) of the Affordable Care Act.

Since the release of the 2014 guidance, we have received feedback from States, the OIG, ACL, and OCR, and other interested parties on how crucial person-centered planning is in the delivery of care and the significance of the person-centered service plan for the assurance of health and welfare for section 1915(c) waiver program participants. The importance of the person-centered planning process to the assurance of health and welfare is supported by the existing regulatory requirements for section 1915(c) waivers, which indicate, at § 441.301(c)(2)(vi), that person-centered service plans must ''reflect risk factors and measures in place to minimize them, including individualized back-up plans and strategies when needed'' and, at § 441.301(c)(2)(xiii)(H), that person-centered service plans must ''include an assurance that interventions and supports will cause no harm to the individual.'' As such, if States fail to conduct the required reassessment and updating of the person-centered service plan, they could increase the risk of harm for beneficiaries by not identifying risk factors and measures to minimize them and by not taking the steps necessary to assure that interventions and supports will not cause harm.

To ensure a more consistent application of person-centered service plan requirements across States and to protect the health and welfare of section 1915(c) waiver participants, we propose under our authority at sections 1915(c)(1) and 1902(a)(19) of the Act and section 2402(a)(1) and (2) of the Affordable Care Act, to codify a minimum performance level to demonstrate that States meet the requirements at § 441.301(c)(3). Specifically, at new § 441.301(c)(3)(ii)(A), we propose to require that States demonstrate that a reassessment of functional need was conducted at least annually for at least 90 percent of individuals continuously enrolled in the waiver for at least 365 days. We also propose, at new § 441.301(c)(3)(ii)(B), to require that States demonstrate that they reviewed the person-centered service plan and revised the plan as appropriate based on the results of the required reassessment of functional need at least every 12 months for at least 90 percent of individuals continuously enrolled in the waiver for at least 365 days.

We considered whether to propose to codify the minimum 86 percent performance level that was outlined in the 2014 guidance, instead of the minimum 90 percent performance level we are now proposing. The minimum 86 percent performance level was intended to provide States with a reasonable threshold for demonstrating compliance with the requirements at § 441.301(c)(3). However, since we released the 2014 guidance, we have heard from many interested parties that a minimum 86 percent performance level may not be sufficient to demonstrate that a State is meeting these requirements. The key concern expressed is that this performance level provides States with more latitude than is necessary to account for unexpected delays in the timeframe for conducting reassessments and updating service plans, as States should assume that some delays are likely and account for them as part of their reassessment and service planning processes. Further, media and anecdotal reports indicate that re-assessment and care planning processes are often delayed without valid reasons, which suggests that beneficiaries may be at risk for preventable harm due to unnecessary delays in person-centered planning processes and that we should establish a more stringent threshold for States to demonstrate compliance with the requirements at § 441.301(c)(3). In response to the feedback we have received since 2014, we are proposing a slight increase to the minimum performance level outlined in the 2014 guidance. This proposed minimum performance level is intended to strengthen person-centered planning requirements based on feedback we have received, while also recognizing that there may be legitimate reasons why assessment and care planning processes occasionally are not completed timely in all instances.

We also considered whether to propose allowing good cause exceptions to the minimum performance level in the event of a natural disaster, public health emergency, or other event that would negatively impact a State's ability to achieve a minimum 90 percent performance level. In the end, we decided not to propose good cause exceptions because the minimum 90 percent performance level is intended to account for various scenarios that might impact a State's ability to achieve these minimum performance levels. Further, there are existing disaster authorities that States could utilize to request a waiver of these requirements in the event of a public health emergency or a disaster. We invite comment on these proposals.

At § 441.301(c)(3), we are also proposing to move the sentence beginning with ''The person-centered service plan must be reviewed . . .'' to a new paragraph at § 441.301(c)(3)(i) and to reposition the regulatory text under the proposed title, *Requirement.* In addition, we are proposing to revise the regulatory text at the renumbered paragraph, which currently says, ''The person-centered service plan must be reviewed, and revised upon reassessment of functional need as required by § 441.365(e), at least every 12 months, when the individual's circumstances or needs change significantly, or at the request of the individual'' to read, ''The State must ensure that the person-centered service plan is reviewed, and revised, as appropriate, based upon the reassessment of functional need as required by § 441.365(e), at least every 12 months, when the individual's circumstances or needs change significantly, or at the request of the individual.'' We are proposing this revision to the regulatory text so that it is clearer that the State is the required actor under § 441.301(c)(3). We are also proposing this revision to the regulatory text so that it is clear that changes to the person-centered service plan are not required if the reassessment does not indicate a need for changes. With this proposed revision to the regulatory text, a State could, for instance, meet the requirement that the person-centered service plan was reviewed and revised as appropriate based on the results of the required reassessment of functional need by documenting that there were no changes in functional needs or the individual's circumstances upon reassessment that necessitated changes to the service plan.

Section 2402(a)(3)(A) of the Affordable Care Act requires States to improve coordination among, and the regulation of, all providers of Federally and State-funded HCBS programs to achieve a more consistent administration of policies and procedures across HCBS programs. In the context of Medicaid coverage of HCBS, it should not matter whether the services are covered directly on an FFS basis or by a managed care entity to its enrollees. The requirement for ''consistent administration'' should require consistency between these two modes of service delivery. Accordingly, we are proposing to specify that a State must ensure compliance with the requirements in § 441.301(c)(3), with respect to HCBS delivered under both FFS and managed care delivery systems. To ensure consistency in person-centered service plan requirements between FFS and managed care delivery systems, we propose to add the requirements at § 441.301(c)(3) to 42 CFR 438.208(c).

We also propose updates to existing language describing the person-centered planning process specific to section 1915(c) waivers. Current language describes the role of an individual's authorized representative as if every waiver participant will require an authorized representative, which is not the case and has been a source of confusion for States and providers. We propose to remove extraneous language from the regulation text at § 441.301(c)(1) to now read: ''The individual, or if applicable, the individual and the individual's authorized representative, will lead the person-centered planning process. When the term 'individual' is used throughout this section, it includes the individual's authorized representative if applicable. In addition, the person-centered planning process: . . .'' This proposed language brings the section 1915(c) waiver regulatory text in line with person-centered planning process language in both the section 1915(j) and (k) State plan options.

We recognize that many States may need time to implement these proposed requirements, including time to amend provider agreements or managed care contracts, make State regulatory or policy changes, implement process or procedural changes, update information systems for data collection and reporting, or conduct other activities to implement these requirements. As a result, we are proposing at § 441.301(c)(3)(iii) to make the performance levels under § 441.301(c)(3)(ii) effective 3 years after the effective date of § 441.301(c)(3) (in other words, 3 years after the effective date of the final rule) in FFS delivery systems. For States with managed care delivery systems under the authority of sections 1915(a), 1915(b), 1932(a), or 1115(a) of the Act that include HCBS in the managed care organization's (MCO), prepaid inpatient health plan's (PIHP), or prepaid ambulatory health plan's (PAHP) contract, we are proposing to provide States until the first managed care plan contract rating period that begins on or after 3 years after the effective date of the final rule to implement these requirements. This time period is based on feedback from States and other interested parties that it could take 2 to 3 years to amend State regulations and work with their State legislatures, if needed, as well as to revise policies, operational processes, information systems, and contracts to support implementation of the proposals outlined in this section. We also considered this proposed timeframe based on all of the HCBS proposals outlined in this proposed rule as whole. We invite comments on whether this timeframe is sufficient, whether we should require a shorter timeframe (2 years) or longer timeframe (4 years) to implement these provisions, and if an alternate timeframe is recommended, the rationale for that alternate timeframe. As noted previously, the proposed requirements at § 441.301(c)(3), in combination with new proposed reporting requirements at § 441.311(b)(3) and other proposed requirements identified throughout this proposed rule, are intended to supersede and fully replace the reporting requirements and the required minimum 86 percent performance level for performance measures described in the 2014 guidance. We expect that States may implement some of the requirements proposed in this proposed rule in advance of the effective date. We will work with States to phase-out the requirements in the 2014 guidance as they implement the future requirements that become part of the final rule to reduce unnecessary burden and to avoid duplicative or conflicting reporting requirements.

As discussed earlier in this section of the preamble, section 2402(a)(3)(A) of the Affordable Care Act requires States to improve coordination among, and the regulation of, all providers of Federally and State-funded HCBS programs to achieve a more consistent administration of policies and procedures across HCBS programs. In accordance with the requirement of section 2402(a)(3)(A) of the Affordable Care Act for States to achieve a more consistent administration of policies and procedures across HCBS programs and because HCBS State plan options have similar person-centered planning and service plan requirements, we are proposing to incorporate these new requirements within the applicable HCBS regulatory sections. Specifically, we propose to apply the proposed requirements at § 441.301(c)(3) to section 1915(j), (k), and (i) State plan services by cross-referencing at §§ 441.450(c), 441.540(c), and 441.725(c), respectively. Consistent with our proposal for section 1915(c) waivers, we propose these requirements under section 1902(a)(19) of the Act, which authorizes safeguards necessary to assure that eligibility for care and services under the Medicaid program will be determined, and such care and services will be provided, in a manner consistent with the best interest of beneficiaries. We believe the same reasons for proposing these requirements for section 1915(c) waivers are equally applicable for these other HCBS authorities and are also responsive to feedback we have received from States and interested parties over the years requesting consistency of requirements across HCBS authorities. We request comment on the application of these provisions to section 1915(i), (j), and (k) authorities.

Finally, we considered whether to also apply these proposed requirements to section 1905(a) ''medical assistance'' State plan personal care, home health, and case management services. However, we are not proposing that these requirements apply to any section 1905(a) State plan services at this time, based on State feedback that States do not have the same data collection and reporting capabilities for these services as they do for other HCBS at section 1915(c), (i), (j), and (k), and because the person-centered planning and service plan requirements for section 1905(a) services are substantially different from those for section 1915(c), (i), (j), and (k) services. Specifically, there are requirements for a ''comprehensive assessment and periodic reassessment of individual needs'' and ''development (and periodic revision) of a specific care plan based on the information collected through the assessment'' under § 440.169(d) for the provision of case management services. There are also requirements for a ''plan of treatment'' (or, at the option of the State, a ''service plan'') under § 440.167 for the provision of personal care services. However, §§ 440.169(d) and 440.167 do not include specific timeframes that could be used to establish minimum

performance thresholds that would be similar to those proposed for section 1915(c) waivers. A face-to-face encounter within the 90 days before or within the 30 days after the start of the services is required at § 440.70(f)(1) for the initiation of home health services, and a written plan of care that the ordering practitioner reviews every 60 days for services is required under § 440.70(a)(2) for the provision of home health services. However, the proposed minimum thresholds for section 1915(c) waiver services would be incompatible with the required timeframes under § 440.70(a)(2) and (f)(1). Person-centered planning and service plan requirements are not required by Medicaid for other section 1905(a) services, although we recommend that States implement person-centered planning process for all HCBS. We note that the vast majority of HCBS is delivered under section 1915(c), (i), (j), and (k) authorities, while only a small percentage of HCBS nationally is delivered under section 1905(a) State plan authorities. However, the small overall percentage includes large numbers of people with mental health needs who receive case management. We request comment on whether we should establish similar person-centered planning and service plan requirements for section 1905(a) State plan personal care, home health, and case management services.

2. Grievance System (§§ 441.301(c)(7), 441.464(d)(2)(v), 441.555(b)(2)(iv), and 441.745(a)(1)(iii))

As discussed earlier in section II.B.1., of this preamble, section 2402(a) of the Affordable Care Act requires the Secretary of HHS to ensure that all States receiving Federal funds for HCBS, including Medicaid HCBS, develop HCBS systems that are responsive to the needs and choices of beneficiaries receiving HCBS, maximize independence and self-direction, provide support and coordination to assist with a community-supported life, and achieve a more consistent and coordinated approach to the administration of policies and procedures across public programs providing HCBS.[47] Among other things, section 2402(a)(3)(B)(ii) of the Affordable Care Act requires development and monitoring of an HCBS complaint system. Further, section 1902(a)(19) of the Act requires States to provide safeguards to assure that eligibility for Medicaid-covered care and services will be determined and provided in a manner that is consistent with simplicity of administration and the best interest of Medicaid beneficiaries.

Federal regulations at 42 CFR part 431, subpart E require States to provide Medicaid applicants and beneficiaries with an opportunity for a fair hearing before the State Medicaid agency in certain circumstances, including for a termination, suspension, or reduction of Medicaid eligibility, or for a termination, suspension, or reduction in benefits or services. These fair hearing rights apply to all Medicaid applicants and beneficiaries, including those receiving HCBS regardless of the delivery system. Under 42 CFR part 438, subpart F, Medicaid managed care plans must have in place: an appeal system that allows a Medicaid managed care enrollee to request an appeal, which is a review by the Medicaid managed care plan of an adverse benefit determination issued by the plan; and a grievance system, which allows a Medicaid managed care enrollee to file an expression of dissatisfaction with the plan about any matter other than an adverse benefit determination. Note that if a Medicaid managed care enrollee exhausts the Medicaid managed care plan's appeals process, the enrollee may request a fair hearing before the State Medicaid agency. Medicaid managed care enrollees cannot request a fair hearing for grievances because grievances are not generally related to the direct provision of services. Section 1902(a)(3) of the Act provides for the opportunity for a State fair hearing when a ''claim for medical assistance under the plan is denied or is not acted upon with reasonable promptness.'' This structure creates a disparity for FFS HCBS beneficiaries, as it does not provide for a venue to raise concerns about issues that HCBS beneficiaries may experience which are not subject to the fair hearing process, such as the failure of a provider to comply with the HCBS settings requirements at § 441.301(c)(4) (note that these are issues for which a managed care enrollee could file a grievance with their plan).

Under our authority at section 1902(a)(19) of the Act and section 2402(a)(3)(B)(ii) of the Affordable Care Act, we propose to require at new § 441.301(c)(7) that States establish grievance procedures for Medicaid beneficiaries receiving section 1915(c) waiver program services through an FFS delivery system. Specifically, we propose at § 441.301(c)(7) that States must establish a procedure under which a beneficiary can file a grievance related to the State's or a provider's compliance with the person-centered planning and service plan requirements at §§ 441.301(c)(1) through (3) and the HCBS settings requirements at §§ 441.301(c)(4) through (6). This proposal is based on feedback obtained during various public engagement activities conducted with interested parties over the past several years about the need for beneficiary grievance processes in section 1915(c) waiver programs related to these requirements. However, to avoid duplication with the grievance requirements at part 438, subpart F, we are not proposing to apply this requirement to establish a grievance procedure to managed care delivery systems. We note, though, that the proposals in this section are similar to requirements for managed care grievance requirements found at part 438, subpart F, with any differences reflecting changes appropriate for FFS systems. The proposed requirements included at § 441.301(c)(7) in this proposed rule are focused specifically on grievance systems and do not establish new fair hearing system requirements, as appeals of adverse eligibility and/or benefit or service determinations are addressed by existing fair hearing requirements at 42 CFR part 431, subpart E. We welcome comments on any additional changes we should consider in this section.

As discussed earlier in this section of the preamble, section 2402(a)(3)(B)(ii) of the Affordable Care Act requires development and monitoring of an HCBS complaint system. In addition, section 2402(a)(3)(A) of the Affordable Care Act requires the Secretary of HHS to ensure that all States receiving Federal funds for HCBS, including Medicaid HCBS, develop HCBS systems that achieve a more consistent and coordinated approach to the administration of policies and procedures across public programs providing HCBS. As such, we believe the requirement for States to establish grievance procedures for Medicaid beneficiaries receiving section 1915(c) waiver program services through a FFS delivery system are necessary to comply with the HCBS complaint system requirements at section 2402(a)(3)(B)(ii) and to ensure consistency in the administration of HCBS between managed care and FFS delivery systems. Further, in the absence of a grievance system requirement for FFS HCBS programs, States may not have established processes and systems for people receiving section 1915(c) waiver program services through FFS delivery

[47] Section 2402(a) of the Affordable Care Act—Guidance for Implementing Standards for Person-Centered Planning and Self-Direction in Home and Community-Based Services Programs. Accessed at *https://acl.gov/sites/default/files/news%202016-10/2402-a-Guidance.pdf.*

systems to express dissatisfaction with or voice concerns related to States' compliance with the person-centered planning and service plan requirements at § 441.301(c)(1) through (3) and the HCBS settings requirements at § 441.301(c)(4) through (6), as such concerns are not subject to the existing fair hearing process at 42 CFR part 431 subpart E. As a result, we believe the proposal for a grievance system for FFS HCBS programs is necessary to assure that care and services will be provided in a manner that is in the best interests of the beneficiaries, as required by section 1902(a)(19) of the Act.

We have specifically focused this requirement on States' and providers' compliance with the person-centered planning and service plan requirements at § 441.301(c)(1) through (3) and the HCBS settings requirements at § 441.301(c)(4) through (6) because of the critical role that person-centered planning and the service plan play in appropriate care delivery for people receiving HCBS. Additionally, we have focused the grievance system requirements on the HCBS settings requirements because of the importance of the HCBS settings requirements to ensuring that HCBS beneficiaries have full access to the benefits of community living and are able to receive services in the most integrated setting appropriate to their needs. Beneficiary advocates and other interested parties have also indicated to us that these are especially important areas for which to ensure that grievance processes are in place for all Medicaid beneficiaries receiving HCBS. Further, focusing the grievance systems requirements on the person-centered planning and service plan requirements at § 441.301(c)(1) through (3) and the HCBS settings requirements at § 441.301(c)(4) through (6) helps to ensure that the proposed grievance requirements do not duplicate or conflict with existing fair hearing requirements at part 431, subpart E, as HCBS settings requirements and person-centered planning requirements are outside the scope of the fair hearing requirements.

At § 441.301(c)(7)(ii)(A), we propose to define ''grievance'' as an expression of dissatisfaction or complaint related to the State's or a provider's compliance with the person-centered planning and service plan requirements at § 441.301(c)(1) through (3) and the HCBS settings requirements at § 441.301(c)(4) through (6), regardless of whether the beneficiary requests that remedial action be taken to address the area of dissatisfaction or complaint. At § 441.301(a)(7)(ii)(B), we also propose to define ''grievance system'' as the processes the State implements to handle grievances, as well as the processes to collect and track information about them. To ensure consistency in the administration of HCBS between managed care and FFS delivery systems, we based these definitions on the definitions at part 438, subpart F.

At § 441.301(c)(7)(iii)(A) through (C), we propose new general requirements for States' grievance procedures. Specifically, at § 441.301(c)(7)(iii)(A), we propose to require that a beneficiary or authorized representative be permitted to file a grievance. Under the proposal, another individual or entity may file a grievance on a beneficiary's behalf, so long as the beneficiary or authorized representative provides written consent. Our proposal would not permit a provider to file a grievance that would violate conflict of interest guidelines, which States are required to have in place under § 441.540(a)(5). At § 441.301(c)(7)(iii)(A), we also propose to specify that all references to beneficiary in the regulatory text of this section includes the beneficiary's representative, if applicable.

At § 441.301(c)(7)(iii)(B)(1) through (7), we propose to require States to:

- Have written policies and procedures for their grievance processes that at a minimum meet the requirements of this proposed section and serve as the basis for the State's grievance process;
- Provide beneficiaries with reasonable assistance in completing the forms and procedural steps related to grievances and to ensure that the grievance system is consistent with the availability and accessibility requirements at § 435.905(b);
- Ensure that punitive action is not threatened or taken against an individual filing a grievance;
- Accept grievances, requests for expedited resolution of grievances, and requests for extensions of timeframes from beneficiaries;
- Provide beneficiaries with notices and other information related to the grievance system, including information on their rights under the grievance system and on how to file grievance, and ensure that such information is accessible for individuals with disabilities and individuals who are limited English proficient in accordance with § 435.905(b);
- Review grievance resolutions with which beneficiaries are dissatisfied; and
- Provide information on the grievance system to providers and subcontractors approved to deliver services under section 1915(c) of the Act.

At § 441.301(c)(7)(iii)(C)(1) through (5), we propose to require that the processes for handling grievances must:

- Allow beneficiaries to file a grievance either orally or in writing;
- Acknowledge receipt of each grievance;
- Ensure that decisions on grievances are not made by anyone previously involved in review or decision-making related to the problem or issue for which the beneficiary has filed a grievance or a subordinate of such an individual, are made by individuals with appropriate expertise, and are made by individuals who consider all of the information submitted by the beneficiary related to the grievance;
- Provide beneficiaries with a reasonable opportunity, face-to-face (including through the use of audio or video technology) and in writing, to present evidence and testimony and make legal and factual arguments related to their grievance;
- Provide beneficiaries, free of charge and in advance of resolution timeframes, with their own case files and any new or additional evidence used or generated by the State related to the grievance; and
- Provide beneficiaries, free of charge, with language services, including written translation and interpreter services in accordance with 435.905(b), to support their participation in grievance processes and their use of the grievance system.

At § 441.301(c)(7)(iv)(A), we propose to require that the beneficiary be able to file a grievance at any time. At § 441.301(c)(7)(iv)(B), we propose to require that beneficiaries be permitted to request expedited resolution of a grievance, whenever there is a substantial risk that resolution within standard timeframes will adversely affect the beneficiary's health, safety, or welfare, such as if, for example, a beneficiary cannot access personal care services authorized in the person-centered service plan.

At § 441.301(c)(7)(v), we propose resolution and notification requirements for grievances. Specifically, at § 441.301(c)(7)(v)(A), we propose to require that States resolve and provide notice of resolution related to each grievance as quickly as the beneficiary's health, safety, and welfare requires and within State-established timeframes that do not exceed the standard and expedited timeframes proposed in § 441.301(c)(7)(v)(B). At § 441.301(c)(7)(v)(B)(1), we propose to require that standard resolution of a grievance and notice to affected parties must occur within 90 calendar days of receipt of the grievance. At

§ 441.301(c)(7)(v)(B)(2), we propose to require that expedited resolution of a grievance and notice must occur within 14 calendar days of receipt of the grievance.

At § 441.301(c)(7)(v)(C), we propose that States be permitted to extend the timeframes for the standard resolution and expedited resolution of grievances by up to 14 calendar days if the beneficiary requests the extension, or the State documents that there is need for additional information and how the delay is in the beneficiary's interest. At § 441.301(c)(7)(v)(D), we propose to require that States make reasonable efforts to give the beneficiary prompt oral notice of the delay, give the beneficiary written notice, within 2 calendar days of determining a need for a delay but no later than the timeframes in paragraph (c)(7)(v)(B), of the reason for the decision to extend the timeframe, and resolve the grievance as expeditiously as the beneficiary's health condition requires and no later than the date the extension expires, if the State extends the timeframe for a standard resolution or an expedited resolution.

We note that the proposed requirements at § 441.301(c)(7)(iv)(B) that beneficiaries be permitted to request expedited resolution of a grievance and at § 441.301(c)(7)(v)(B)(2) related to the timeframe for expedited resolution of a grievance and notice differ from the current grievance system requirements for Medicaid managed care plans at part 438, subpart F, which do not include specific requirements for an expedited resolution of a grievance. We invite comment on whether part 438, subpart F should be amended to include the proposed requirements at § 441.301(c)(7)(iv)(B) and at § 441.301(c)(7)(v)(B)(*2*).

Proposed § 441.301(c)(7)(vi) describes proposed requirements related to the notice of resolution for beneficiaries. Specifically, at § 441.301(c)(7)(vi)(A), we propose to require that States establish a method for written notice to beneficiaries and that the method meet the availability and accessibility requirements at § 435.905(b). At § 441.301(c)(7)(vi)(B), we propose to require that States make reasonable efforts to provide oral notice of resolution for expedited resolutions.

Proposed § 441.301(c)(7)(vii) lists proposed recordkeeping requirements related to grievances. Specifically, at § 441.301(c)(7)(vii)(A), we propose to require that States maintain records of grievances and review the information as part of their ongoing monitoring procedures. At § 441.301(c)(7)(vii)(B)(*1*) through (*6*), we propose to require that the record of each grievance must contain the following information at a minimum: a general description of the reason for the grievance, the date received, the date of each review or review meeting (if applicable), resolution and date of the resolution of the grievance (if applicable), and the name of the beneficiary for whom the grievance was filed. Further, at § 441.301(c)(7)(vii)(C), we propose to require that grievance records be accurately maintained and in a manner that would be available upon our request.

We recognize that many States may need time to implement these requirements, including to amend provider agreements, make State regulatory or policy changes, implement process or procedural changes, update information systems for data collection and reporting, or conduct other activities to implement these requirements. However, we also recognize that the absence of a grievance system in FFS HCBS systems poses a substantial risk of harm to beneficiaries. As a result, we are proposing at § 441.301(c)(7)(viii) that the requirement at § 441.301(c)(7) be effective 2 years after the effective date of the final rule. A 2-year time period after the effective date of the final rule for States to implement these requirements reflects our attempt to balance two competing challenges: (1) the fact that there is a gap in existing regulations for FFS HCBS grievance processes related to important HCBS beneficiary protection issues involving person-centered planning and HCBS settings requirements; and (2) feedback from States and other interested parties that it could take 1 to 2 years to amend State regulations and work with their State legislatures, if needed, as well as to revise policies, operational processes, information systems, and contracts to support implementation of the proposals outlined in this section. We also considered all of the HCBS proposals outlined in this proposed rule as whole. We invite comments on overall burden for States to meet the requirements of this section, whether this timeframe is sufficient, whether we should require a shorter timeframe (1 year to 18 months) or longer timeframe (3 to 4 years) to implement these provisions, and if an alternate timeframe is recommended, the rationale for that alternate timeframe.

As discussed earlier in section II.B.1. of this preamble, section 2402(a)(3)(A) of the Affordable Care Act requires States to improve coordination among, and the regulation of, all providers of Federally and State-funded HCBS programs to achieve a more consistent administration of policies and procedures across HCBS programs. In accordance with the requirement of section 2402(a)(3)(A) of the Affordable Care Act for States to achieve a more consistent administration of policies and procedures across HCBS programs and because HCBS State plan options also must comply with the HCBS Settings Rule and with similar person-centered planning and service plan requirements, we are proposing to incorporate these grievance requirements within the applicable regulatory sections. Specifically, we propose to apply these proposed requirements in § 441.301(c)(7) to sections 1915(j), (k), and (i) State plan services by cross-referencing at §§ 441.464(d)(2)(v), 441.555(b)(2)(iv), and 441.745(a)(1)(iii), respectively.

Consistent with our proposal for section 1915(c) waivers, we propose to apply the proposed grievance requirements in § 441.301(c)(7) to sections 1915(j), (k), and (i) State plan services based on our authority under section 1902(a)(19) of the Act to assure that there are safeguards for beneficiaries and our authority at section 2402(a)(3)(B)(ii) of the Affordable Care Act to require a complaint system for beneficiaries. We believe the same arguments for proposing these requirements for section 1915(c) waivers are equally applicable to these other HCBS authorities. We request comment on the application of the grievance system provisions to section 1915(i), (j), and (k) authorities. We note that in the language added to § 441.464(d)(2)(v), we identify that the proposed grievance requirements apply when self-directed personal assistance services authorized under section 1915(j) include services under a section 1915(c) waiver program. As described later in this section of this proposed rule, we have not proposed to apply these requirements to section 1905(a) services; section 1905(a) personal care services are the other service authorized under section 1915(j) authorities to be self-directed.

We considered whether to also apply the proposed requirements to section 1905(a) ''medical assistance'' State plan personal care, home health, and case management services. However, we are not proposing that these requirements apply to any section 1905(a) State plan services because section 1905(a) services are not required to comply with HCBS settings requirements and because the person-centered planning and service plan requirements for most section 1905(a) services are substantially different from those for section 1915(c), (i), (j), and (k) services. Further, the vast majority of HCBS is delivered under section 1915(c), (i), (j), and (k) authorities, while only a small percentage of HCBS nationally is delivered under section 1905(a) State plan authorities. We request comment on whether we should establish grievance requirements for section 1905(a) State plan personal care, home health, and case management services.

3. Incident Management System (§§ 441.302(a)(6), 441.464(e), 441.570(e), and 441.745(a)(1)(v))

Section 1902(a)(19) of the Act requires States to provide safeguards as may be necessary to assure that eligibility for care and services will be determined, and that ''such care and services will be provided,'' in a manner consistent with simplicity of administration and ''the best interests of the recipients.'' Section 1915(c)(2)(A) of the Act and current Federal regulations at § 441.302(a) require that States have in place necessary safeguards to protect the health and welfare of individuals receiving section 1915(c) waiver program services. Further, as discussed previously in section II.B.1. of this preamble, section 2402(a) of the Affordable Care Act requires the Secretary of HHS to ensure that all States receiving Federal funds for HCBS, including Medicaid, develop HCBS systems that are responsive to the needs and choices of beneficiaries receiving HCBS, maximize independence and self-direction, provide support and coordination to assist with a community-supported life, and achieve a more consistent and coordinated approach to the administration of policies and procedures across public programs providing HCBS.[48] Among other things, section 2402(a)(3)(B)(ii) of the Affordable Care Act requires development and oversight of a system to qualify and monitor providers.

As noted earlier in section II.B.1. of this preamble we released guidance for section 1915(c) waiver programs in 2014 which noted that States should report on State-developed performance measures to demonstrate that they meet six assurances, including a Health and Welfare assurance for States to demonstrate that they have designed and implemented an effective system for assuring waiver participant health and welfare. Specifically, the 2014 guidance highlighted, related to the Health and Welfare assurance, the following:

- The State demonstrates on an ongoing basis that it identifies, addresses, and seeks to prevent instances of abuse, neglect, exploitation, and unexplained death;
- The State demonstrates that an incident management system is in place that effectively resolves incidents and prevents further similar incidents to the extent possible;
- The State policies and procedures for the use or prohibition of restrictive interventions (including restraints and seclusion) are followed;
- The State establishes overall health care standards and monitors those standards based on the responsibility of the service provider as stated in the approved waiver.

Consistent with the expectations for other performance measures, the 2014 guidance noted that States should conduct systemic remediation and implement a Quality Improvement Project when they score below 86 percent on any of their Health and Welfare performance measures.

Despite States implementing these statutory and regulatory requirements to protect the health and welfare of individuals receiving section 1915(c) waiver program services, and States' adherence to related subregulatory guidance, there have been notable and high-profile instances of abuse and neglect in recent years that highlight the risks associated with poor quality care and with inadequate oversight of HCBS in Medicaid. For example, a 2018 report, ''Ensuring Beneficiary Health and Safety in Group Homes Through State Implementation of Comprehensive Compliance Oversight,'' [49] (referred to as the Joint Report, developed by ACL, OCR, and the OIG), found systemic problems with health and safety policies and procedures being followed in group homes and that failure to comply with these policies and procedures left beneficiaries in group homes at risk of serious harm.

In addition, in 2016 and 2017, OIG released several reports on their review of States' compliance with Federal and State requirements regarding critical incident reporting and monitoring.[50] [51] [52] OIG found that several States did not comply with Federal waiver and State requirements for reporting and monitoring critical incidents involving individuals receiving HCBS through waivers. In particular, they reported that:

- Critical incidents were not reported correctly;
- Adequate training to identify appropriate action steps for reported critical incidents or reports of abuse or neglect was not provided to State staff;
- Appropriate data sets to trend and track critical incidents were not accessible to State staff; and
- Critical incidents were not clearly defined, making it difficult to identify potential abuse or neglect.

In 2016, we conducted three State audits based at least in part on concerns regarding health and welfare and media coverage on abuse, neglect, or exploitation issues.[53] We found that these three States had not been meeting their section 1915(c) waiver assurances, similar to findings reported by the OIG. In two cases, for the incidents of concern, tracking and trending of critical incidents were not present. Further, in at least two of the States, staffing at appropriate levels was identified as an issue.

In January 2018, the United States Government Accountability Office (GAO) released a report on a study of 48 States that covered assisted living services.[54] The GAO found large

[48] Section 2402(a) of the Affordable Care Act—Guidance for Implementing Standards for Person-Centered Planning and Self-Direction in Home and Community-Based Services Programs. Accessed at *https://acl.gov/sites/default/files/news%202016-10/2402-a-Guidance.pdf.*

[49] Ensuring Beneficiary Health and Safety in Group Homes Through State Implementation of Comprehensive Compliance Oversight. US Department of Human Services, Office of the Inspector General, Administration for Community Living, and Office for Civil Rights. January 2018. Accessed at *https://oig.hhs.gov/reports-and-publications/featured-topics/group-homes/group-homes-joint-report.pdf.*

[50] HHS OIG. ''Connecticut did not comply with Federal and State requirements for critical incidents involving developmentally disabled Medicaid beneficiaries.'' May 2016. Accessed at *https://oig.hhs.gov/oas/reports/region1/11400002.pdf.*

[51] HHS OIG. ''Massachusetts did not comply with Federal and State requirements for critical incidents involving developmentally disabled Medicaid beneficiaries.'' July 2016. Accessed at *https://oig.hhs.gov/oas/reports/region1/11400008.pdf.*

[52] HHS OIG. ''Maine did not comply with Federal and State requirements for critical incidents involving Medicaid beneficiaries with developmental disabilities.'' August 2017. Accessed at *https://oig.hhs.gov/oas/reports/region1/11600001.pdf.*

[53] Presentation by CMS for Advancing States: Quality in the HCBS Waiver—Health and Welfare. See: *http://www.nasuad.org/sites/nasuad/files/Final%20Quality%20201.pdf.*

[54] Government Accountability Office. ''Medicaid assisted living services—improved Federal

inconsistencies between States in their definition of a critical incident and their system's ability to report, track, and collect information on critical incidents that have occurred. States also varied in their oversight methods as well as the type of information they were reviewing as part of this oversight. The GAO recommended that requiring States to report information on incidents (such as the type and severity of incidents and the number of incidents) would strengthen the effectiveness of State and Federal oversight.

In July 2019, we issued a survey to States that operate section 1915(c) waivers, requesting information on their approach to administering incident management systems. The goal of the survey was to obtain a comprehensive understanding of how States organize their incident management system to best respond to, resolve, monitor, and prevent critical incidents in their waiver programs. The survey found that:

- Definitions of critical incidents vary across States and, in some cases, within States for different HCBS programs or populations;
- Some States do not use standardized forms for reporting incidents, thereby impeding the consistent collection of information on critical incidents;
- Some States do not have electronic incident management systems, and, among those that do, many use systems with outdated electronic platforms that are not linked with other State systems, leading to the systems operating in silos and the need to consolidate information across disparate systems; and
- Many States cited the lack of communication within and across State agencies, including with investigative agencies, as a barrier to incident resolution.

Additionally, during various public engagement activities conducted with interested parties over the past several years, we have heard that ensuring access to HCBS requires that we must first ensure health and safety systems are in place across all States, a theme underscored by the Joint Report.

Based on these findings and reports, under the authorities at sections 1902(a)(19) and 1915(c)(2)(A) of the Act and section 2402(a)(3)(B)(ii) of the Affordable Care Act, we propose a new requirement at § 441.302(a)(6) to require that States provide an assurance that they operate and maintain an incident management system that identifies, reports, triages, investigates, resolves, tracks, and trends critical incidents. This proposal is intended to ensure standardized requirements for States regarding incidents that harm or place a beneficiary at risk of harm and is based on our experience working with States as part of the section 1915(c) waiver program and informed by the incident management survey described previously in this section of the proposed rule. In the absence of an incident management system, people receiving section 1915(c) waiver program services are at risk of preventable or intentional harm. As such, we believe that such a system to identify and address incidents of abuse, neglect, exploitation, or other harm during the course of service delivery is in the best interest of and necessary for protecting the health and welfare of individuals receiving section 1915(c) waiver program services.

At § 441.302(a)(6)(i)(A) through (G), we propose new requirements for States' incident management systems. Specifically, at § 441.302(a)(6)(i)(A), we propose to establish a minimum standard definition of a critical incident to include, at a minimum, verbal, physical, sexual, psychological, or emotional abuse; neglect; exploitation including financial exploitation; misuse or unauthorized use of restrictive interventions or seclusion; a medication error resulting in a telephone call to or a consultation with a poison control center, an emergency department visit, an urgent care visit, a hospitalization, or death; or an unexplained or unanticipated death, including but not limited to a death caused by abuse or neglect. Currently, there is no standardized Federal definition for the type of events or instances that States should consider a critical incident that must be reported by a provider to the State and considered for an investigation by the State to assess whether the incident was the result of abuse, neglect, or exploitation, and whether it could have been prevented. The proposed definition at § 441.302(a)(6)(i)(A) is based on internal analyses of data and information obtained through a CMS survey of States' incident management systems, commonalities across definitions, and common gaps in States' definitions of critical incidents (for instance, that many States do not consider sexual assault to be a critical incident). We request comment on whether there are specific types of events or instances of serious harm to section 1915(c) waiver participants, such as identity theft or fraud, that would not be captured by the proposed definition and that should be included, and whether the inclusion of any specific types of events or instances of harm in the proposed definition would lead to the overidentification of critical incidents.

At § 441.302(a)(6)(i)(B), we propose to require that States have electronic critical incident systems that, at a minimum, enable electronic collection, tracking (including of the status and resolution of investigations), and trending of data on critical incidents. We request comment on the burden associated with requiring States to have electronic critical incident systems and whether there is specific functionality, such as unique identifiers, that should be required or encouraged for such systems. Although we are not proposing to require States to do so, States are also encouraged to advance the interoperable exchange of HCBS data and support quality improvement activities by adopting standards in 45 CFR, part 170 and other relevant standards identified in the Interoperability Standards Advisory (ISA).[55] We also remind States that enhanced FFP is available at a 90 percent FMAP for the design, development, or installation of improvements of mechanized claims processing and information retrieval systems, in accordance with applicable Federal requirements.[56] Enhanced FFP at a 75 percent FMAP is also available for operations of such systems, in accordance with applicable Federal requirements.[57] However, we note that receipt of these enhanced funds is conditioned upon States meeting a series of standards and conditions to ensure investments are efficient and effective.[58]

At § 441.302(a)(6)(i)(C), we propose to require States to require providers to report to States any critical incidents that occur during the delivery of section 1915(c) waiver program services as specified in a waiver participant's person-centered service plan, or any critical incidents that are a result of the

oversight of beneficiary health and welfare is needed.'' January 2018. Accessed at *https://www.gao.gov/assets/690/689302.pdf.*

[55] Relevant standards adopted by HHS and identified in the ISA include the USCDI (*https://www.healthit.gov/isa/united-states-core-data-interoperability-uscdi*), eLTSS (*https://www.healthit.gov/isa/documenting-care-plans-person-centered-services),* and Functional Assessment Standardized Items (*https://www.healthit.gov/isa/representing-patient-functional-status-andor-disability*).

[56] See section 1903(a)(3)(A)(i) and § 433.15(b)(3), 80 FR 75817–75843; *https://www.medicaid.gov/state-resourcecenter/faq-medicaid-and-chip-affordable-care-act-implementation/downloads/affordable-care-act-faq-enhancedfunding-for-medicaid.pdf; https://www.medicaid.gov/federal-policy-guidance/downloads/SMD16004.pdf.*

[57] See section 1903(a)(3)(B) and § 433.15(b)(4).

[58] See § 433.112 (b, 80 FR 75841; *https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-C/part-433/subpart-C.*

failure to deliver authorized services. Based on the findings of the Joint Report, as well as the OIG and GAO reports cited earlier, settings in which residential habilitation and day habilitation services are provided, and services provided in a beneficiary's private home by a provider should be of particular focus. We believe that such a requirement will help to specify provider expectations for reporting critical incidents and to ensure that harm that occurs because of the failure to deliver services will be appropriately identified as a critical incident.

At § 441.302(a)(6)(i)(D), we propose to require that States use claims data, Medicaid Fraud Control Unit data, and data from other State agencies such as Adult Protective Services or Child Protective Services to the extent permissible under applicable State law to identify critical incidents that are unreported by providers and occur during the delivery of section 1915(c) waiver program services, or as a result of the failure to deliver authorized services. We believe that such data can play an important role in identifying serious instances of harm to waiver program participants, which may be unreported by a provider, such as a death that occurs as a result of choking of an individual with a developmental disability residing in a group home, or a burn that occurs because a provider failed to appropriately supervise someone with dementia and that results in an emergency department visit. We request comment on whether States should be required to use these data sources to identify unreported critical instances, and whether there are other specific data sources that States should be required to use to identify unreported critical incidents.

At § 441.302(a)(6)(i)(E), we propose to require that States share information, consistent with the regulations in 42 CFR part 431, subpart F, on the status and resolution of investigations. We expect this data sharing could be accomplished through the use of information sharing agreements, with other entities in the State responsible for investigating critical incidents, if the State refers critical incidents to other entities for investigation. We also propose, at § 441.302(a)(6)(i)(F), to require States to separately investigate critical incidents if the investigative agency fails to report the resolution of an investigation within State-specified timeframes. These proposed requirements are intended to ensure that the failure to effectively share information between State agencies or other entities in the State responsible for investigating incidents does not impede a State's ability to effectively identify, report, triage, investigate, resolve, track, and trend critical incidents, particularly where there could be evidence of serious harm or a pattern of harm to a section 1915(c) waiver program participant for which a provider is responsible.

As noted in section II.B.1. of this proposed rule, in 2014, we released guidance for section 1915(c) waiver programs in which we indicated that States should report on State-developed performance measures across several domains, including to demonstrate that the State designed and implemented an effective system for assuring waiver participant health and welfare. Specifically, the 2014 guidance noted that States should demonstrate: on an ongoing basis that they identify, address, and seek to prevent instances of abuse, neglect, exploitation, and unexplained death; that an incident management system is in place that effectively resolves those incidents and prevents further similar incidents to the extent possible; State policies and procedures for the use or prohibition of restrictive interventions (including restraints and seclusion) are followed; and overall health care standards are established and monitored. The 2014 guidance also indicated that States should conduct systemic remediation and implement a Quality Improvement Project when they score below 86 percent on any of their performance measures.

Section 1902(a)(6) of the Act requires State Medicaid agencies to make such reports, in such form and containing such information, as the Secretary may from time to time require, and to comply with such provisions as the Secretary may from time to time find necessary to assure the correctness and verification of such reports. Under our authority at section 1902(a)(6) of the Act, we propose to modernize the health and welfare reporting by requiring all States to report on the same Federally prescribed quality measures as opposed to the State-developed measures, which naturally vary State by State. Specifically, at new § 441.302(a)(6)(i)(G), we propose to require that States meet the reporting requirements at § 441.311(b)(1) related to the performance of their incident management systems. We discuss these reporting requirements in our discussion of proposed § 441.311(b)(1). Further, under our authority at sections 1915(c)(2)(A) and 1902(a)(19) of the Act, we propose to codify a minimum performance level to demonstrate that States meet the requirements at § 441.302(a)(6). Specifically, at new § 441.302(a)(6)(ii)(A) through (C), we propose to require that States demonstrate that an investigation was initiated, within State-specified timeframes, for no less than 90 percent of critical incidents; an investigation was completed and the resolution of the investigation was determined, within State-specified timeframes, for no less than 90 percent of critical incidents; and corrective action was completed, within State-specified timeframes, for no less than 90 percent of critical incidents that require corrective action.

While we expect States to meet State-specified timeframes for initiating investigations, completing investigations and determining resolution, and completing corrective action plans for all critical incidents, we are proposing to establish a minimum 90 percent performance level in each of these areas in recognition of the various scenarios that may impact a State's ability to meet these timeframes for each critical incident (for example, some critical incidents may require more complex investigations than others, an illness may delay the interview of an important witness to the incident).

We considered whether to codify the minimum 86 percent performance level that was established in the 2014 guidance, instead of the minimum 90 percent performance level we have proposed. The minimum 86 percent performance level was intended to provide States with a reasonable threshold for demonstrating compliance with the requirements at § 441.302(a)(6). However, we have conducted extensive oversight and received significant feedback from external parties since we released the 2014 guidance. Our findings from the oversight and feedback have led us to conclude that the minimum 86 percent performance level may not be sufficient to demonstrate a State is meeting these requirements because it provides States with more latitude than is necessary to account for unexpected delays in the timeframes for investigating and addressing critical incidents. Further, findings from our 2016 audits and 2019 survey, feedback from States, OIG, ACL, OCR, and other interested parties, and media and anecdotal reports document the harm that beneficiaries can experience when States fail to investigate and address critical incidents and indicate that we should establish a more stringent threshold for States to demonstrate compliance with the requirements at § 441.302(a)(6). As a result, we are proposing an increase to the minimum performance level in the 2014 guidance. This proposed minimum performance level is intended to

strengthen health and welfare reporting requirements based on feedback and evidence we have received, while also recognizing that there may be legitimate reasons for delays in investigating and addressing critical incidents.

We also considered whether to propose allowing good cause exceptions to the minimum performance level in the event of a natural disaster, public health emergency, or other event that would negatively impact a State's ability to achieve a minimum 90 percent performance level. In the end, we are not proposing good cause exceptions because the minimum 90 percent performance level is intended to account for various scenarios that might impact a State's ability to achieve these performance levels. Further, as noted earlier with the person-centered service plan requirements in section II.B.1. of this preamble, there are existing disaster authorities that States could utilize to request a waiver of these requirements in the event of a public health emergency or a disaster.

At § 441.302(a)(6)(iii), we propose to apply these requirements to services delivered under FFS or managed care delivery systems. As discussed earlier in section II.B.1. of this preamble, section 2402(a)(3)(A) of the Affordable Care Act requires States to improve coordination among, and the regulation of, all providers of Federally and State-funded HCBS programs to achieve a more consistent administration of policies and procedures across HCBS programs. In the context of Medicaid coverage of HCBS, it should not matter whether the services are covered directly on a FFS basis or by a managed care entity to its enrollees. The requirement for ''consistent administration'' should require consistency between these two modes of service delivery. We accordingly are proposing to identify that a State must ensure compliance with the requirements in § 441.302(a)(6) with respect to HCBS delivered both under FFS and managed care delivery systems.

As noted throughout the HCBS proposals in this rule, we recognize that many States may need time to implement these requirements, including to amend provider agreements or managed care contracts, make State regulatory or policy changes, implement process or procedural changes, update information systems for data collection and reporting, or conduct other activities to implement these requirements. As a result, we are proposing at § 441.302(a)(6)(iii) to provide States with 3 years to implement these requirements in FFS delivery systems following effective date of the final rule. For States with managed care delivery systems under the authority of sections 1915(a), 1915(b), 1932(a), or 1115(a) of the Act and that include HCBS in the MCO's, PIHP's, or PAHP's contract, we are proposing to provide States until the first managed care plan contract rating period that begins on or after 3 years after the effective date of the final rule to implement these requirements. This time period is based on feedback from States and other interested parties that it could take 2 to 3 years to amend State regulations and work with their State legislatures, if needed, as well as to revise policies, operational processes, information systems, and contracts to support implementation of the proposals outlined in this section. We also considered all of the HCBS proposals outlined in proposed rule as whole. We invite comments on whether this timeframe is sufficient, whether we should require a shorter timeframe (2 years) or longer timeframe (4 years) to implement these provisions, and if an alternate timeframe is recommended, the rationale for that alternate timeframe.

Again, the proposed requirements at §§ 441.302(a)(6)(iii) and 441.311(b)(1), in combination with other proposed requirements identified throughout this proposed rule, are intended to supersede and fully replace the reporting expectations and the minimum 86 percent performance level for State's performance measures described in the 2014 guidance. We expect that States may implement some of the requirements proposed in this proposed rule in advance of the effective date. To reduce unnecessary burden and to avoid duplicative or conflicting reporting requirements, we will work with States to phase-out the 2014 guidance as they implement these proposed requirements should a final rule be adopted.

Additionally, as discussed earlier in section II.B.1. of this preamble, section 2402(a)(3)(A) of the Affordable Care Act requires States to improve coordination among, and the regulation of, all providers of Federally and State-funded HCBS programs to achieve a more consistent administration of policies and procedures across HCBS programs. In accordance with the requirement of section 2402(a)(3)(A) of the Affordable Care Act for States to achieve a more consistent administration of policies and procedures across HCBS programs and because of the importance of assuring health and welfare for other HCBS State plan options, we are proposing to incorporate these incident management requirements within the applicable regulatory sections. Specifically, we propose to apply the proposed requirements § 441.302(a)(6) to section 1915(j), (k), and (i) State plan services by cross-referencing at §§ 441.570(e), 441.464(e), and 441.745(a)(1)(v), respectively. Consistent with our proposal for section 1915(c) waivers, we propose these requirements based on our authority under section 1902(a)(19) of the Act to assure that there are safeguards for beneficiaries. We believe the same arguments for proposing these requirements for section 1915(c) waivers are equally applicable for these other HCBS authorities. We request comment on the application of these provisions across section 1915(i), (j), and (k) authorities. To accommodate the addition of new language at § 441.464(e) and (f) (discussed later in section II.B.5. of this proposed rule), we are proposing to renumber existing § 441.464(e) as § 441.464(g) and existing § 441.464(f) as § 441.464(h).

Finally, we considered whether to also apply the proposed incident management system and critical incident reporting and performance threshold requirements to section 1905(a) ''medical assistance'' State plan personal care, home health, and case management services. However, we are not proposing that these requirements apply to any section 1905(a) State plan services based on State feedback that they do not have the same data collection and reporting capabilities in place for section 1905(a) services as they do for section 1915(c), (i), (j), and (k) services. Further, the vast majority of HCBS is delivered under section 1915(c), (i), (j), and (k) authorities, while only a small percentage of HCBS nationally is delivered under section 1905(a) State plan authorities. We request comment on whether we should establish similar health and welfare requirements for section 1905(a) State plan personal care, home health, and case management services.

4. Reporting (§ 441.302(h))

Proposed § 441.311, described in section II.B.7. of this proposed rule, establishes a new *Reporting Requirements* section. As discussed earlier in section II.B.1. of this preamble, section 2402(a)(3)(A) of the Affordable Care Act requires HHS to promulgate regulations to ensure that States develop HCBS systems that are designed to improve coordination among, and the regulation of, all providers of Federally and State-funded HCBS programs to achieve a more consistent administration of policies and procedures across HCBS programs.

In addition to supporting States with achieving a more consistent administration of policies and procedures across HCBS programs in accordance with the requirement of section 2402(a)(3)(A) of the Affordable Care Act, we believe that standardizing reporting across HCBS authorities will streamline and simplify reporting for providers, improve States' and CMS's ability to assess HCBS quality and performance, and better enable States to improve the quality of HCBS programs through the availability of comparative data. Further, section 1902(a)(6) of the Act requires State Medicaid agencies to make such reports, in such form and containing such information, as the Secretary may from time to time require, and to comply with such provisions as the Secretary may from time to time find necessary to assure the correctness and verification of such reports.

To avoid duplicative or conflicting reporting requirements at § 441.302(h), we propose to amend § 441.302(h) by removing the following language: ''annually''; ''The information must be consistent with a data collection plan designed by CMS and must address the waiver's impact on -''; and by removing paragraphs (1) and (2) under § 441.302(h). Further, we propose to add '', including the data and information as required in § 441.311'' at the end of the new amended text, ''Assurance that the agency will provide CMS with information on the waiver's impact.'' By making these changes, we are consolidating reporting expectations in one new section at proposed § 441.311, described in section II.B.7. of this proposed rule, under our authority at section 1902(a)(6) of the Act and section 2402(a)(3)(A) of the Affordable Care Act. As noted earlier in section II.B.1. of this proposed rule, this reporting will supersede existing reporting for section 1915(c) waivers and standardize reporting across section 1915 HCBS authorities.

5. HCBS Payment Adequacy (§§ 441.302(k), 441.464(f), 441.570(f), 441.745(a)(1)(vi))

Section 1902(a)(30)(A) of the Act requires State Medicaid programs to ensure that payments to providers are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available to beneficiaries at least to the extent as to the general population in the same geographic area. Access to most HCBS generally requires hands-on and in-person services to be delivered by direct care workers. Direct care workers are referred to by various names, such as direct support professionals, personal care attendants, and home health aides, within and across States. They perform a variety of roles, including nursing services, assistance with activities of daily living (such as mobility, personal hygiene, eating) and instrumental activities of daily living (such as cooking, grocery shopping, managing finances), behavioral supports, employment supports, and other services to promote community integration for older adults and people with disabilities. We discuss the definition of direct care workers in more detail below in the context of our proposed definition of direct care workers.

Direct care workers typically earn low wages and receive limited benefits,[59] [60] [61] contributing to a shortage of direct care workers and high rates of turnover in this workforce, which can limit access to and impact the quality of HCBS. Workforce shortages can also reduce the cost-effectiveness of services for State Medicaid agencies that take into account the actual cost of delivering services when determining Medicaid payment rates, such as by increasing the reliance on overtime and temporary staff, which have higher hourly costs than non-overtime wages paid to permanent staff. Further, an insufficient supply of HCBS providers can prevent individuals from transitioning from institutions to home and community-based settings and from receiving HCBS that can prevent institutionalization. HCBS is, on average, less costly than institutional services,[62] [63] and most older adults and people with disabilities strongly prefer to live in the community. Accordingly, limits on the availability of HCBS lessen the ability for State Medicaid programs to deliver LTSS in a cost-effective, beneficiary friendly manner.

Shortages of direct care workers and high rates of turnover also reduce the quality of HCBS. For instance, workforce shortages can prevent individuals from receiving needed services and, in turn, lead to poorer outcomes for people who need HCBS. Insufficient staffing can also make it difficult for providers to achieve quality standards.[64] High rates of turnover can reduce quality of care,[65] including through the loss of experienced and qualified workers and by reducing continuity of care people receiving HCBS,[66] which is associated with the reduced likelihood of improvement in function among people receiving home health aide services.[67]

While workforce shortages have existed for years, the COVID–19 pandemic has exacerbated the problem, leading to higher rates of direct care worker turnover (for instance, due to higher rates of worker-reported stress), an inability of some direct care workers to return to their positions prior to the pandemic (for instance, due to difficulty accessing child care or concerns about contracting COVID–19 for people with higher risk of severe illness), workforce shortages across the health care sector, and wage increases in retail and other jobs that tend to draw from the same pool of workers as some HCBS.[68] [69] [70]

[59] MACPAC Issue Brief. State Efforts to Address Medicaid Home- and Community-Based Services Workforce Shortages. March 2022. Accessed at *https://www.macpac.gov/wp-content/uploads/2022/03/MACPAC-brief-on-HCBS-workforce.pdf.*

[60] Campbell, S., A. Del Rio Drake, R. Espinoza, K. Scales. 2021. Caring for the future: The power and potential of America's direct care workforce. Bronx, NY: PHI *http://phinational.org/wp-content/uploads/2021/01/Caring-for-the-Future-2021-PHI.pdf.*

[61] We recognize that there are workforce shortages that may impact access to other Medicaid-covered services aside from HCBS. We are focusing in this proposed rule on addressing workforce shortages in HCBS and continue to assess the feasibility and potential impact of other actions to address workforce shortages in other parts of the health care sector.

[62] Reaves, E.L., & Musumeci, M.B. December 15, 2015. *Medicaid and Long-Term Services and Supports: A Primer.* Kaiser Family Foundation. Accessed at *https://www.kff.org/medicaid/report/medicaid-and-long-term-services-and-supports-a-primer/.*

[63] Kim, M–Y, Weizenegger, E., & Wysocki, A. July 22, 2022. *Medicaid Beneficiaries Who Use Long-Term Services and Supports: 2019.* Chicago, IL: Mathematica. Accessed at *https://www.medicaid.gov/medicaid/long-term-services-supports/downloads/ltss-user-brief-2019.pdf.*

[64] American Network of Community Options and Resources (ANCOR). 2021. The state of America's direct support workforce 2021. Alexandria, VA: ANCOR. Accessed at *https://www.ancor.org/sites/default/files/the_state_of_americas_direct_support_workforce_crisis_2021.pdf.*

[65] Newcomer R, Kang T, Faucett J. Consumer-directed personal care: comparing aged and non-aged adult recipient health-related outcomes among those with paid family versus non-relative providers. Home Health Care Serv Q. 2011;30(4):178–97.

[66] Campbell, S., A. Del Rio Drake, R. Espinoza, K. Scales. 2021. Caring for the future: The power and potential of America's direct care workforce. Bronx, NY: PHI *http://phinational.org/wp-content/uploads/2021/01/Caring-for-the-Future-2021-PHI.pdf.*

[67] Russell D, Rosati RJ, Peng TR, Barrón Y, Andreopoulos E . Continuity in the provider of home health aide services and the likelihood of patient improvement in activities of daily living. Home Health Care Manage Pract. 2013;25(1):6–12.

[68] MACPAC Issue Brief. State Efforts to Address Medicaid Home- and Community-Based Services Workforce Shortages. March 2022. Accessed at *https://www.macpac.gov/wp-content/uploads/2022/03/MACPAC-brief-on-HCBS-workforce.pdf.*

[69] Campbell, S., A. Del Rio Drake, R. Espinoza, K. Scales. 2021. Caring for the future: The power and potential of America's direct care workforce. Bronx, NY: PHI *http://phinational.org/wp-content/uploads/2021/01/Caring-for-the-Future-2021-PHI.pdf.*

Further, demand for direct care workers is expected to continue rising due to the growing needs of the aging population, the changing ability of aging caregivers to provide supports, a broader societal shift away from institutional services and towards services that are integrated in the community, and a decline in the number of younger workers available to provide services.[71] [72] [73] As discussed previously in section II.B.1. of this proposed rule, section 2402(a) of the Affordable Care Act requires the Secretary of HHS to ensure that all States receiving Federal funds for HCBS, including Medicaid, develop HCBS systems that are responsive to the needs and choices of beneficiaries receiving HCBS, maximize independence and self-direction, provide coordination for and support each person's full engagement in community life, and achieve a more consistent and coordinated approach to the administration of policies and procedures across public programs providing HCBS.[74] In particular, section 2402(a)(1) of the Affordable Care Act requires States to allocate resources for services in a manner that is responsive to the changing needs and choices of beneficiaries receiving HCBS, while section 2402(a)(3)(B)(iii) of the Affordable Care Act requires States to oversee and monitor HCBS system functions to assure a sufficient number of qualified direct care workers to provide self-directed personal assistance services. To comply with sections 2402(a)(1) and 2402(a)(3)(B)(iii) of the Affordable Care Act, States must have a sufficient direct care workforce to be able to deliver services that are responsive to the changing needs and choices of beneficiaries, and, specifically, a sufficient number of qualified direct care workers to provide self-directed personal assistance services.

Consistent with section 1902(a)(30)(A) of the Act and sections 2402(a)(1) and 2402(a)(3)(B)(iii) of the Affordable Care Act, we propose to require that State Medicaid agencies demonstrate that payment rates for certain HCBS authorized under section 1915(c) of the Act are sufficient to ensure a sufficient direct care workforce (defined and explained later in this section of the proposed rule) to meet the needs of beneficiaries and provide access to services in accordance with the amount, duration, and scope specified in the person-centered service plan, as required under § 441.301(c)(2). We believe that this proposal supports the economy, efficiency, and quality of HCBS authorized under section 1915(c) of the Act, by ensuring that a sufficient portion of State FFS and managed care payments for HCBS go directly to compensation of the direct care workforce. While many States have already voluntarily established such minimums for payments authorized under section 1915(c) of the Act,[75] we believe a Federal standard would support ongoing access to, and quality and efficiency of, HCBS.

This proposal is designed to affect the inextricable link between sufficient payments being received by the direct care workforce and access to and, ultimately, the quality of HCBS received by Medicaid beneficiaries. We believe that this proposal would not only benefit direct care workers but also individuals receiving Medicaid HCBS because supporting and stabilizing the direct care workforce will result in better qualified employees, lower turnover, and a higher quality of care. The direct care workforce must be able to attract and retain qualified workers in order for beneficiaries to access providers of the services they have been assessed to need and for the direct care workforce to be comprised of workers with the training, expertise, and experience to meet the diverse and often complex HCBS needs of individuals with disabilities and older adults. Without access to a sufficient pool of direct care providers, individuals are forced to forgo having their needs met or addressed by workers without sufficient training, expertise, or experience to meet their unique needs, both of which could lead to worsening health and quality of life outcomes, loss of independence, and institutionalization.[76] [77] [78] [79] Further, we believe that ensuring adherence to a Federal standard of the percentage of Medicaid payments going to direct care workers is a concrete step in recruitment and retention efforts to stabilize this workforce by enhancing salary competitiveness in the labor market. In the absence of such requirements, we are unable to support and stabilize the direct care workforce because we are unable to ensure that the payments are used primarily and substantially to pay for care and services provided by direct care workers. Therefore, at § 441.302(k)(3)(i), we propose to require that at least 80 percent of all Medicaid payments, including but not limited to base payments and supplemental payments, with respect to the following services be spent on compensation to direct care workers: homemaker services, home health aide services, and personal care services.[80]

This proposal is based on feedback from States that have implemented similar requirements for payments for certain HCBS under section 9817 of the ARP [81] or other State-led initiatives.

[70] American Network of Community Options and Resources (ANCOR). 2021. The state of America's direct support workforce 2021. Alexandria, VA: ANCOR. Accessed at *https://www.ancor.org/sites/default/files/the_state_of_americas_direct_support_workforce_crisis_2021.pdf.*

[71] MACPAC Issue Brief. State Efforts to Address Medicaid Home- and Community-Based Services Workforce Shortages. March 2022. Accessed at *https://www.macpac.gov/wp-content/uploads/2022/03/MACPAC-brief-on-HCBS-workforce.pdf.*

[72] Campbell, S., A. Del Rio Drake, R. Espinoza, K. Scales. 2021. Caring for the future: The power and potential of America's direct care workforce. Bronx, NY: PHI *http://phinational.org/wp-content/uploads/2021/01/Caring-for-the-Future-2021-PHI.pdf.*

[73] Centers for Medicare and Medicaid Services. November 2020. Long-Term Services and Supports Rebalancing Toolkit. Accessed at *https://www.medicaid.gov/medicaid/long-term-services-supports/downloads/ltss-rebalancing-toolkit.pdf.*

[74] Section 2402(a) of the Affordable Care Act—Guidance for Implementing Standards for Person-Centered Planning and Self-Direction in Home and Community-Based Services Programs. Accessed at *https://acl.gov/sites/default/files/news%202016-10/2402-a-Guidance.pdf.*

[75] For instance, as part of their required activities to enhance, expand, or strengthen HCBS under ARP section 9817, some States have required that a minimum percentage of rate increases and supplemental payments go to the direct care workforce. See *https://www.medicaid.gov/medicaid/home-community-based-services/guidance/strengthening-and-investing-home-and-community-based-services-for-medicaid-beneficiaries-american-rescue-plan-act-of-2021-section-9817/index.html* for more information on ARP section 9817.

[76] MACPAC Issue Brief. State Efforts to Address Medicaid Home- and Community-Based Services Workforce Shortages. March 2022. Accessed at *https://www.macpac.gov/wp-content/uploads/2022/03/MACPAC-brief-on-HCBS-workforce.pdf.*

[77] Campbell, S., A. Del Rio Drake, R. Espinoza, K. Scales. 2021. Caring for the future: The power and potential of America's direct care workforce. Bronx, NY: PHI *http://phinational.org/wp-content/uploads/2021/01/Caring-for-the-Future-2021-PHI.pdf.*

[78] American Network of Community Options and Resources (ANCOR). 2021. The state of America's direct support workforce 2021. Alexandria, VA: ANCOR. Accessed at *https://www.ancor.org/sites/default/files/the_state_of_americas_direct_support_workforce_crisis_2021.pdf.*

[79] Chong, N., I. Akorbirshoev, J. Caldwell, H.S. Kaye, and M. Mitra. 2021. The relationship between unmet need for home and community-based services and health and community living outcomes. Disability Health Journal. Accessed at *https://www.sciencedirect.com/science/article/abs/pii/S1936657421001953.*

[80] We note that section 2402(a) of the Affordable Care Act applies broadly to all HCBS programs and services funded by HHS. Further, section 2402(a) does not include limits on the scope of services, HCBS authorities, or other factors related to its use of the term HCBS. Therefore, we believe that there is no indication that personal care, homemaker, and home health aide services would fall outside the scope of section 2402(a).

[81] Information on State activities to expand, enhance, or strengthen HCBS under ARP section

Continued

These States have reported to us through various public engagement activities that similar requirements have had their intended effect of ensuring that a sufficient portion of the payment for Medicaid HCBS goes to compensation for the direct care workforce. These States have also indicated an 80 percent threshold is an appropriate threshold that takes into account the expected portion of payments that are necessary for provider administrative and other costs, aside from direct care worker compensation, although our research indicates that some States have successfully implemented other thresholds, ranging from a low of around 75 percent [82] to a high of 90 percent. We have also focused this requirement on homemaker services, home health aide services, and personal care services because they are services for which we expect that the vast majority of payment should be comprised of compensation for direct care workers. These are services that would most commonly be conducted in individuals' homes and general community settings. As such, there should be low facility or other indirect costs associated with the services. We request comment on the following options for the minimum percentage of payments that must be spent on compensation to direct care workers for homemaker services, home health aide services, and personal care services: (1) 75 percent; (2) 85 percent; and (3) 90 percent. If an alternate minimum percentage is recommended, we request that commenters provide the rationale for that minimum percentage.

We considered whether the proposed requirements at § 441.302(k)(3)(i) related to the percent of payments going to the direct care workforce should apply to other services, such as adult day health, habilitation, day treatment or other partial hospitalization services, psychosocial rehabilitation services, and clinic services for individuals with chronic mental illness. However, these services may have facility or other indirect costs for which we do not have adequate information to determine a minimum percent of the payment that should be spent on compensation for the direct care workforce. We request comment on whether the proposed requirements at § 441.302(k)(3)(i) related to the percent of payments going to the direct care workforce should apply to other services listed at § 440.180(b). In particular, in recognition of the importance of services provided to individuals with intellectual or developmental disabilities, we request comment on whether the proposed requirements at § 441.302(k)(3)(i) related to the percent of payments going to the direct care workforce should apply to residential habilitation services, day habilitation services, and home-based habilitation services.

We also request comment on the following options for the minimum percentage of payments that must be spent on compensation to direct care workers for each specific service that this provision should apply if this provision should apply to other services at § 440.180(b): (1) 65 percent; (2) 70 percent; (3) 75 percent; and (4) 80 percent. Specifically, we request that commenters respond separately on the minimum percentage of payments for services delivered in a non-residential community-based facility, day center, senior center, or other dedicated physical space, which would be expected to have higher other indirect costs and facility costs built into the Medicaid payment rate than other HCBS. If an alternate minimum percentage is recommended, we request that commenters provide the rationale for that minimum percentage.

We further clarify that we are requesting comment on a different range of options for the other services at § 440.180(b) than for the services at § 440.180(b)(2) through (4) because we expect that some of the other services at § 440.180(b), such as adult day health and day habilitation services, may have higher other indirect costs and facility costs than the services at § 440.180(b)(2) through (4). We also request that commenters respond separately on the minimum percentage of payments for facility-based residential services and other facility-based round-the-clock services that have other indirect costs and facility costs that would be paid for at least in part by room and board payments that Medicaid does not cover. If a minimum percentage is recommended for any services, we request that commenters provide the rationale for that minimum percentage.

At § 441.302(k)(1)(i), we propose to define compensation to include salary, wages, and other remuneration as defined by the Fair Labor Standards Act and implementing regulations (29 U.S.C. 201 *et seq.,* 29 CFR parts 531 and 778), and benefits (such as health and dental benefits, sick leave, and tuition reimbursement). In addition, we propose to define compensation to include the employer share of payroll taxes for direct care workers delivering services under section 1915(c) waivers. We considered whether to include training or other costs in our proposed definition of compensation. However, we determined that a definition that more directly assesses the financial benefits to workers would better ensure that a sufficient portion of the payment for services went to direct care workers, as it is unclear that the cost of training and other workforce activities is an appropriate way to quantify the benefit of those activities for workers. We request comment on whether the definition of compensation should include other specific financial and non-financial forms of compensation for direct care workers.

At § 441.302(k)(1)(ii), we propose to define direct care workers to include workers who provide nursing services, assist with activities of daily living (such as mobility, personal hygiene, eating) or instrumental activities of daily living (such as cooking, grocery shopping, managing finances), and provide behavioral supports, employment supports, or other services to promote community integration. Specifically, we propose to define direct care workers to include nurses (registered nurses, licensed practical nurses, nurse practitioners, or clinical nurse specialists) who provide nursing services to Medicaid-eligible individuals receiving HCBS, licensed or certified nursing assistants, direct support professionals, personal care attendants, home health aides, and other individuals who are paid to directly provide services to Medicaid beneficiaries receiving HCBS to address activities of daily living or instrumental activities of daily living, behavioral supports, employment supports, or other services to promote community integration. We further identify that our definition of direct care worker is intended to exclude nurses in supervisory or administrative roles who are not directly providing nursing services to people receiving HCBS.

Our definition of direct care worker is intended to broadly define such workers to ensure that the definition appropriately captures the diversity of roles and titles that direct care workers may have. We included workers with professional degrees, such as nurses, in our proposed definition because of the

9817 can be found on *Medicaid.gov* at *https://www.medicaid.gov/medicaid/home-community-based-services/guidance/strengthening-and-investing-home-and-community-based-services-for-medicaid-beneficiaries-american-rescue-plan-act-of-2021-section-9817/index.html.*

[82] Minnesota has established a minimum threshold of 72.5 percent, while Illinois has implemented a minimum threshold of 77 percent, for similar requirements for HCBS as we are proposing. See *https://www.revisor.mn.gov/statutes/cite/256B.85/pdf* and *https://casetext.com/regulation/illinois-administrative-code/title-89-social-services/part-240-community-care-program/subpart-t-financial-reporting/section-2402040-minimum-direct-service-worker-costs-for-in-home-service,* respectively, for more information.

important roles that direct care workers with professional degrees play in the care and services of people receiving HCBS, and because excluding workers with professional degrees may increase the complexity of reporting, and may unfairly punish States, managed care plans, and providers that disproportionately rely on workers with professional degrees in the delivery of HCBS. We also propose to define direct care workers to include: individuals employed by a Medicaid provider, State agency, or third party; contracted with a Medicaid provider, State agency, or third party; or delivering services under a self-directed service model. This proposed definition is in recognition of the varied service delivery models and employment relationships that can exist in HCBS waivers. We request comment on whether there are other specific types of direct care workers that should be included in the definition, and whether any of the types of workers listed should be excluded from the definition of direct care worker.

Section 1902(a)(6) of the Act requires State Medicaid agencies to make such reports, in such form and containing such information, as the Secretary may from time to time require, and to comply with such provisions as the Secretary may from time to time find necessary to assure the correctness and verification of such reports. At § 441.302(k)(2), under our authority at section 1902(a)(6) of the Act, we propose to require that States demonstrate that they meet the minimum performance level at § 441.302(k)(3)(i) through new Federal reporting requirements at § 441.311(e). We discuss these reporting requirements in our discussion of proposed § 441.311(e).

At § 441.302(k)(4), we propose to apply these requirements to services delivered under FFS or managed care delivery systems. As discussed earlier in section II.B.1. of this preamble, section 2402(a)(3)(A) of the Affordable Care Act requires States to improve coordination among, and the regulation of, all providers of Federally and State-funded HCBS programs to achieve a more consistent administration of policies and procedures across HCBS programs. In the context of Medicaid coverage of HCBS, it should not matter whether the services are covered directly on a FFS basis or by a managed care entity to its enrollees. The requirement for ''consistent administration'' should require consistency between these two modes of service delivery. We accordingly are proposing to specify that a State must ensure compliance with the requirements in § 441.302(k) with respect to HCBS delivered both under FFS and managed care delivery systems.

Similarly, because workforce shortages exist under other HCBS authorities, which include many of the same types of services to address activities of daily living or instrumental activities of daily living as under section 1915(c) waiver authority, we are proposing to incorporate these requirements within the applicable regulatory sections. Specifically, we propose to apply the proposed requirements at § 441.302(k) to section 1915(j), (k), and (i) State plan services by cross-referencing at §§ 441.464(f), 441.570(f), and 441.745(a)(1)(vi), respectively. Consistent with our proposal for section 1915(c) waivers, we propose these requirements based on our authority under section 1902(a)(30)(A) of the Act to ensure payments to HCBS providers are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available to beneficiaries at least to the extent as to the general population in the same geographic area. We believe the same arguments for proposing these requirements for section 1915(c) waivers are equally applicable for these other HCBS authorities. We request comment on the application of payment adequacy provisions across section 1915(i), (j), and (k) authorities. As noted earlier in section II.B.4. of this proposed rule, to accommodate the addition of new language at §§ 441.464(e) and 441.464(f), we are proposing to renumber existing § 441.464(e) as § 441.464(g) and existing § 441.464(f) as § 441.464(h). We request comment on whether we should exempt, from these requirements, services delivered using any self-directed service delivery model under any Medicaid authority.

We considered whether to also apply these proposed payment adequacy requirements to section 1905(a) ''medical assistance'' State plan personal care and home health services. However, we are not proposing that these requirements apply to any 1905(a) State plan services based on State feedback that they do not have the same data collection and reporting capabilities in place for section 1905(a) services as they do for section 1915(c), (i), (j), waiver programs and section 1915(i), (j), and (k) services. Further, the vast majority of HCBS is delivered under section 1915(c), (i), (j), and (k) authorities, while only a small percentage of HCBS nationally is delivered under section 1905(a) State plan authorities. We request comment on whether we should apply these requirements to section 1905(a) State plan personal care and home health services.

As noted throughout the HCBS provisions in this preamble, we recognize that many States may need time to implement these requirements, including to amend provider agreements or managed care contracts, make State regulatory or policy changes, implement process or procedural changes, update information systems for data collection and reporting, or conduct other activities to implement these proposed payment adequacy requirements. We expect that these activities will take longer than similar activities for other HCBS provisions in this proposed rule. Further, we expect that it will take a substantial amount of time for managed care plans and providers to establish the necessary systems, data collection tools, and processes necessary to collect the required information to report to States. As a result, we are proposing at § 441.302(k)(4), to provide States with 4 years to implement these requirements in FFS delivery systems following effective date of the final rule. For States with managed care delivery systems under the authority of sections 1915(a), 1915(b), 1932(a), or 1115(a) of the Act and that include HCBS in the MCO's, PIHP's, or PAHP's contract, we are proposing to provide States until the first managed care plan contract rating period that begins on or after 4 years after the effective date of the final rule to implement these requirements. Similar to our rationale in other sections, this proposed timeline reflects feedback from States and other interested parties that it could take 3 to 4 years for States to complete any necessary work to amend State regulations and work with their State legislatures, if needed, as well as to revise policies, operational processes, information systems, and contracts to support implementation of the proposals outlined in this section. We also considered the overall burden of the proposed rule as whole in proposing the effective date for the payment adequacy provision. We invite comments on the overall burden associated with implementing this section, whether this timeframe is sufficient, whether we should require a shorter timeframe (such as 3 years) or longer timeframe (such as 5 years) to implement the payment adequacy provisions and if an alternate timeframe is recommended, the rationale for that alternate timeframe.

6. Supporting Documentation Required (§ 441.303(f)(6))

As described in section II.B.7 of this proposed rule, discussing newly proposed reporting requirements, States vary in whether they maintain waiting lists for section 1915(c) waivers, and if a waiting list is maintained, how individuals may join the waiting list. Section 1915(c) of the Act authorizes States to set enrollment limits or caps on the number of individuals served in a waiver, and many States maintain waiting lists of individuals interested in receiving waiver services once a spot becomes available. While some States require individuals to first be determined eligible for waiver services to join the waiting list, other States permit individuals to join a waiting list after an expression of interest in receiving waiver services. This can overestimate the number of people who need Medicaid-covered HCBS because the waiting lists may include individuals who are not eligible for services. According to the Kaiser Family Foundation, over half of people on HCBS waiting lists live in States that do not screen people on waiting lists for eligibility.[83]

We have not previously required States to submit any information on the existence or composition of waiting lists, which has led to gaps in information on the accessibility of HCBS within and across States. Further, feedback obtained during various public engagement activities conducted with States and other interested parties over the past several years about reporting requirements for HCBS, as well as feedback received through the RFI[84] discussed earlier, indicate that there is a need to improve public transparency and processes related to States' HCBS waiting lists. In addition, we have found, over the past several years in particular, that some States are operating waiting lists for their section 1915(c) waiver programs even though they are serving fewer people than their CMS-approved enrollment limit or cap, and States are expected to enroll individuals up to their CMS-approved enrollment limit or cap before imposing a waiting list. However, because we do not routinely collect information on States' use of waiting lists and the number of people on waiting lists, we are unable to determine the extent to which States are operating such ''unauthorized'' waiting lists or to work with States to address these ''unauthorized'' waiting lists.

Section 1902(a)(6) of the Act requires State Medicaid agencies to make such reports, in such form and containing such information as the Secretary may from time to time require, and to comply with such provisions as the Secretary may from time to time find necessary to assure the correctness and verification of such reports. Based on the authority found at section 1902(a)(6) of the Act, we now propose to require information from States on waiting lists to improve public transparency and processes related to States' HCBS waiting lists and ensure that we are able to adequately oversee and monitor States' use of waiting lists in their section 1915(c) waiver programs. To address new proposed requirements at § 441.311(d)(1), described in the next section of the preamble, on State reporting on waiting lists, we propose to amend § 441.303(f)(6) by adding the following sentence to the end of the existing regulatory text: If the State has a limit on the size of the waiver program and maintains a list of individuals who are waiting to enroll in the waiver program, the State must meet the reporting requirements at § 441.311(d)(1).''

7. Reporting Requirements (§§ 441.311, 441.474(c), 441.580(i), and 441.745(a)(1)(vii))

Section 1902(a)(6) of the Act requires State Medicaid agencies to make such reports, in such form and containing such information, as the Secretary may from time to time require, and to comply with such provisions as the Secretary may from time to time find necessary to assure the correctness and verification of such reports. As discussed in section II.B.1. of this proposed rule, in 2014, we released guidance for section 1915(c) waiver programs in which we requested States to report on State-developed performance measures across several domains, as part of an overarching HCBS waiver quality strategy. The 2014 guidance established an expectation that States conduct systemic remediation and implement a Quality Improvement Project when they score below 86 percent on any of their performance measures. Under our authority at section 1902(a)(6) of the Act, we are proposing requirements at § 441.311, in combination with other proposed requirements identified throughout this proposed rule, to supersede and fully replace the reporting metrics and the minimum 86 percent performance level expectations for States' performance measures described in the 2014 guidance. We describe the basis and scope of this section in paragraph (a).

The reporting requirements proposed in this proposed rule represent consolidated feedback from States, consumer advocates, managed care plans, providers, and other HCBS interested parties on improving and enhancing section 1915(c) waiver performance to integrate nationally standardized quality measures into the reporting requirements, address gaps in existing reporting requirements related to access and the direct service workforce, strengthen health and welfare and person-centered planning reporting requirements, and eliminate annual performance measure reporting requirements that provide limited useful data for assessing State compliance with statutory and regulatory requirements. We believe that the proposed reporting requirements will allow us to better assess State compliance with the statutory and regulatory requirements for section 1915(c) waiver programs. As indicated at the end of this preamble section, we propose that the following reporting requirements also apply to State plan options authorized under section 1915(i), (j) and (k) of the Act, as well as to both FFS and managed care delivery systems.

a. Compliance Reporting

(1) Incident Management System Assessment

As noted earlier in section II.B.3. of this preamble, there have been notable and high-profile instances of abuse and neglect in recent years that highlight the risks associated with poor quality care and with inadequate oversight of HCBS in Medicaid, despite State efforts to implement statutory and regulatory requirements to protect the health and welfare of individuals receiving section 1915(c) waiver program services, and State adoption of related subregulatory guidance, requirements, and adopting subregulatory guidance. In addition, a July 2019 survey of States that operate section 1915(c) waivers found that:

- Definitions of critical incidents vary across States and, in some cases, within States for different HCBS programs or populations;
- Some States do not use standardized forms for reporting incidents, thereby impeding the consistent collection of information on critical incidents;
- Some States do not have electronic incident management systems, and, among those that do, many use systems

[83] Burns, A., M. O'Malley Watts, M. Ammula. A Look at Waiting lists for Home and Community-Based Services from 2016 to 2021. Kaiser Family Foundation. *https://www.kff.org/47f8e6f/.*

[84] CMS Request for Information: Access to Coverage and Care in Medicaid & CHIP. February 2022. For a full list of question from the RFI, see *https://www.medicaid.gov/medicaid/access-care/downloads/access-rfi-2022-questions.pdf.*

with outdated electronic platforms that are not linked with other State systems, leading to the systems operating in silos and the need to consolidate information across disparate systems; and

• Many States cited the lack of communication within and across State agencies, including with investigative agencies, as a barrier to incident resolution.

Based on these findings and reports, as well as feedback obtained during various public engagement activities conducted with interested parties over the past several years to standardize and strengthen health and welfare reporting requirements, we are proposing new requirements for States' incident management systems at § 441.302(a)(6), as discussed in section II.B.3. of this preamble. We believe that these proposed reporting requirements will allow us to better assess State compliance with the requirements at § 441.302(a)(6).

Relying on our authority at section 1902(a)(6) of the Act, at § 441.311(b), we propose to establish new compliance reporting requirements. Specifically, at § 441.311(b)(1)(i), we propose to require that States report every 24 months on the results of an incident management system assessment to demonstrate that they meet the requirements at § 441.302(a)(6) that the State operate and maintain an incident management system that identifies, reports, triages, investigates, resolves, tracks, and trends critical incidents, including that:

• The State define critical incidents to meet the proposed minimum standard definition at § 441.302(a)(6)(i)(A);

• The State have an electronic critical incident system that, at a minimum, enables electronic collection, tracking (including of the status and resolution of investigations), and trending of data on critical incidents as proposed at § 441.302(a)(6)(i)(B);

• The State require that providers report any critical incidents that occur during the delivery of section 1915(c) waiver program services as specified in a waiver participant's person-centered service plan, or are a result of the failure to deliver authorized services, as proposed at § 441.302(a)(6)(i)(C);

• The State use claims data, Medicaid Fraud Control Unit data, and data from other State agencies such as Adult Protective Services or Child Protective Services to the extent permissible under applicable State law to identify critical incidents that are unreported by providers and occur during the delivery of section 1915(c) waiver program services, or as a result of the failure to deliver authorized services, as proposed at § 441.302(a)(6)(i)(D);

• The State share information on reported incidents, the status and resolution of investigations, such as through the use of information sharing agreements, with other entities in the State responsible for investigating critical incidents, if the State refers critical incidents to other entities for investigation, as proposed at § 441.302(a)(6)(i)(E); and

• The State separately investigate critical incidents if the investigative agency fails to report the resolution of an investigation within State-specified timeframes as proposed at § 441.302(a)(6)(i)(F).

Given the risk of preventable and intentional harm to beneficiaries when effective incident management systems are not in place, documented instances of abuse and neglect among people receiving HCBS, and identified shortcomings and weaknesses of States' incident management systems discussed earlier, we believe the requirement for States to report every other year on the results of an incident management system assessment is in the best interest of and necessary for protecting the health and welfare of individuals receiving section 1915(c) waiver program services. In the absence of such a reporting requirement, we are unable to determine whether States have effective systems in place to identify and address incidents of abuse, neglect, exploitation, or other harm during the course of service delivery; ensure that States are protecting the health and welfare of individuals receiving section 1915(c) waiver program services; and safeguard people receiving section 1915(c) waiver program services from preventable or intentional harm.

In proposing an every other year timeframe for reporting, we were attempting to take into account the likely frequency of State changes to policies, procedures, and information systems, while also balancing State reporting burden and the potential risk to beneficiaries if States have incident management systems that are not compliant with the proposed requirements at § 441.302(a)(6). We believe every other year timeframe for reporting is sufficient to detect substantial changes to policies, procedures, and information systems and ensure that we have accurate information on States' incident management systems. We also propose, at § 441.311(b)(1)(ii), to allow States to reduce the frequency of reporting to up to once every 60 months for States with incident management systems that are determined to meet the requirements at proposed § 441.302(a)(6). We expect to provide States with technical assistance on how to meet the requirements at proposed § 441.302(a)(6). We invite comments on whether the timeframe for States to report on the results of the incident management system assessment is sufficient or if we should require reporting more frequently (every year) or less frequently (every 3 years). We also invite comment on whether we should require reporting more frequently (every 3 years or every 4 years) for States that are determined to have an incident management system that meets the requirements at § 441.302(a)(6). If an alternate timeframe is recommended, we request that commenters provide the rationale for that alternate timeframe.

(2) Critical Incidents

As discussed earlier in section II.B.4. of this proposed rule, at § 441.302(a)(6)(i)(A), we propose to require States to define critical incidents at a minimum as verbal, physical, sexual, psychological, or emotional abuse; neglect; exploitation including financial exploitation; misuse or unauthorized use of restrictive interventions or seclusion; a medication error resulting in a telephone call to or a consultation with a poison control center, an emergency department visit, an urgent care visit, a hospitalization, or death; or an unexplained or unanticipated death, including but not limited to a death caused by abuse or neglect.

Based on the same rationale as discussed previously in section II.B.7.a.(1) of this preamble related to the proposed incident management system assessment proposed reporting requirement, at § 441.311(b)(2), relying on our authority under section 1902(a)(6) of the Act, we propose to require that States report annually on the number and percent of critical incidents for which an investigation was initiated within State-specified timeframes; number and percent of critical incidents that are investigated and for which the State determines the resolution within State-specified timeframes; and number and percent of critical incidents requiring corrective action, as determined by the State, for which the required corrective action has been completed within State-specified timeframes. We intend to use the information generated from the proposed reporting requirements at § 441.311(b)(2)(ii) through (iv) to determine if States meet the requirements at § 441.302(a)(6)(ii). Given the risk of harm to beneficiaries when effective incident management

systems are not in place, documented instances of abuse and neglect among people receiving HCBS, and identified shortcomings and weaknesses of States' incident management systems discussed earlier, we believe the proposed requirement at § 441.311(b)(2) for States to report annually on critical incidents is in the best interest of and necessary for protecting the health and welfare of individuals receiving section 1915(c) waiver program services. We invite comments on the timeframe for States to report on the critical incidents, whether we should require reporting less frequently (every 2 years), and if an alternate timeframe is recommended, the rationale for the alternate timeframe.

(3) Person-Centered Planning

Under the authority of section 1902(a)(6) of the Act, we propose at § 441.311(b)(3) to require that States report annually to demonstrate that they meet the requirements at § 441.301(c)(3)(ii). Specifically, at § 441.311(b)(3)(i), we propose to require that States report on the percent of beneficiaries continuously enrolled for at least 365 days for whom a reassessment of functional need was completed within the past 12 months. At § 441.311(b)(3)(ii), we propose to require that States report on the percent of beneficiaries continuously enrolled for at least 365 days who had a service plan updated as a result of a re-assessment of functional need within the past 12 months. These proposed requirements are based on feedback obtained during various interested parties' engagement activities conducted with States and other interested parties over the past several years about the reporting discussed in the 2014 guidance. As discussed in section II.B.7. of this preamble, this feedback has indicated that we should strengthen person-centered planning reporting requirements, and eliminate annual performance measure reporting requirements that provide limited useful data for assessing State compliance with statutory and regulatory requirements. These proposed requirements are also based on feedback received through the RFI[85] discussed earlier about the need to standardize reporting and set minimum standards for HCBS.

As discussed in section II.B.1. of this preamble, we are proposing a revision to the regulatory text so that it is clear that changes to the person-centered service plan are not required if the re-assessment does not indicate a need for changes. As such, for the purpose of the reporting requirement at § 441.311(b)(3)(ii), beneficiaries will be considered to have had a service plan updated as a result of the re-assessment if it is documented that the required re-assessment did not indicate a need for changes.

For both of the metrics at § 441.301(c)(3), we propose to allow States to report on a statistically valid random sample of beneficiaries, rather than for all individuals continuously enrolled in the waiver program for at least 365 days. We invite comments on whether there are other specific compliance metrics related to person-centered planning that we should require States to report, either in place of or in addition to the metrics we proposed. We also invite comments on the timeframe for States to report on the person-centered planning, whether we should require reporting less frequently (every 2 years), and if an alternate timeframe is recommended, the rationale for the alternate timeframe.

(4) Type, Amount, and Cost of Services

As discussed previously in section II.B.4. of this preamble, we propose to amend § 441.302(h) to avoid duplicative or conflicting reporting requirements with the new *Reporting Requirements* section at proposed § 441.311. In particular, at § 441.302(h), we propose to remove paragraphs (1) and (2). At § 441.311(b)(4), we propose to add the language previously at § 441.302(h)(1). In doing so, we are proposing to retain the current requirement that States report on the type, amount, and cost of services and to include the reporting requirement in the new consolidated reporting section at § 441.311.

b. Reporting on the Home and Community-Based Services (HCBS) Quality Measure Set

At § 441.311(c), relying on our authority under section 1902(a)(6) of the Act, we propose to require that States report every other year on the HCBS Quality Measure Set, which is described later in section II.B.8. of the preamble. Specifically, we propose, at § 441.311(c)(1)(i), to require that States report every other year, according to the format and schedule prescribed by the Secretary through the process for developing and updating the HCBS Quality Measure Set described later in section II.B.8. of the preamble, on measures identified in the HCBS Quality Measure Set as mandatory measures for States to report or are identified as measures for which the Secretary will report on behalf of States, and, at § 441.311(c)(1)(ii), to allow States to report on measures in the HCBS Quality Measure Set that are not identified as mandatory, as described later in this section of this proposed rule. We are proposing every other year for State reporting in recognition of the fact that the current, voluntary HCBS Quality Measure Set is heavily comprised of survey-based measures, which are more burdensome, including for beneficiaries who would be the respondents for the surveys, and costlier to implement than other types of quality measures. Further, we believe that requiring reporting every other year, rather than annually, would better allow States to use the data that they report for quality improvement purposes, as it would provide States with sufficient time to implement interventions that would result in meaningful improvement in performance scores from one reporting period to another. We are also proposing this frequency in recognition of the overall burden of the proposed requirements.

As discussed earlier in section II.B.1. of this preamble, section 1902(a)(19) of the Act requires States to provide safeguards to assure that eligibility for Medicaid-covered care and services will be determined and provided in a manner that is consistent with simplification, simplicity of administration, and in the best interest of Medicaid beneficiaries. Because the delivery of high quality services is in the best interest of Medicaid beneficiaries, we propose at § 441.311(c)(1)(iii), under our authority at section 1902(a)(19) of the Act, to require States to establish performance targets, subject to our review and approval, for each of the measures in the HCBS Quality Measure Set that are identified as mandatory for States to report or are identified as measures for which we will report on behalf of States, as well as to describe the quality improvement strategies that they will pursue to achieve the performance targets for those measures.[86] We welcome comments on whether there should be a threshold of compliance that would exempt the State from developing improvement strategies, and if so, what that threshold should be.

At § 441.311(c)(1)(iv), we propose to allow States to establish State performance targets for other measures in the HCBS Quality Measure Set that are not identified as mandatory for States to report or as measures for which

[85] CMS Request for Information: Access to Coverage and Care in Medicaid & CHIP. February 2022. For a full list of question from the RFI, see *https://www.medicaid.gov/medicaid/access-care/downloads/access-rfi-2022-questions.pdf.*

[86] We note that compliance with CMS regulations and reporting requirements does not imply that a State has complied with the integration mandate of Title II of the ADA, as interpreted by the Supreme Court in the Olmstead Decision.

the Secretary will report on behalf of States as well as to describe the quality improvement strategies that they will pursue to achieve the performance targets for those targets.

At § 441.311(c)(2), we propose to report, on behalf of the States, on a subset of measures in the HCBS Quality Measure Set that are identified as measures for which we will report on behalf of States. Further, at § 441.311(c)(3), we propose to allow, but not require, States to report on measures that are not yet required but will be, and on populations for whom reporting is not yet required but will be phased-in in the future.

We invite comments on whether the timeframe for States to report on the measures in HCBS Quality Measure Set is sufficient, whether we should require reporting more frequently (every year) or less frequently (every 3 years), and if an alternate timeframe is recommended, the rationale for that alternate timeframe. We welcome comments on any additional changes we should consider in this section.

c. Access Reporting

As noted earlier in section II.B.6. of this preamble, feedback obtained during various public engagement activities conducted with States and other interested parties over the past several years about reporting requirements for HCBS, as well as feedback received through the RFI[87] discussed earlier, indicate that there is a need to improve public transparency and processes related to States' HCBS waiting lists and for standardized reporting on HCBS access, including timeliness of HCBS and the comparability to services received to eligibility for services.

At § 441.311(d)(1)(i), relying on our authority under section 1902(a)(6) of the Act, we propose to require that States provide a description annually on how they maintain the list of individuals who are waiting to enroll in a section 1915(c) waiver program, if they have a limit on the size of the waiver program and maintain a list of individuals who are waiting to enroll in the waiver program, as described in § 441.303(f)(6). We further propose to require that this description must include, but be not limited to, information on whether the State screens individuals on the waiting list for eligibility for the waiver program, whether the State periodically re-screens individuals on the waiver list for eligibility, and the frequency of re-screening if applicable. We also propose to require States to report, at § 441.311(d)(1)(ii), the number of people on the waiting list, if applicable, and, at § 441.311(d)(1)(iii), the average amount of time that individuals newly enrolled in the waiver program in the past 12 months were on the waiting list, if applicable. We invite comments on whether there are other specific metrics or reporting requirements related to waiting lists that we should require States to report, either in place of or in addition to the requirements we proposed. We also invite comments on the timeframe for States to report on their waiting lists, whether we should require reporting less frequently (every 2 or 3 years), and if an alternate timeframe is recommended, the rationale for that alternate timeframe.

At § 441.311(d)(2)(i), based on our authority under section 1902(a)(6) of the Act, we propose to require States report annually on the average amount of time from when homemaker services, home health aide services, or personal care services, as listed in § 440.180(b)(2) through (4), are initially approved to when services began, for individuals newly approved to begin receiving services within the past 12 months. We propose to focus on these specific services for this reporting requirement because of feedback from States, consumer advocates, managed care plans, providers, and other HCBS interested parties that timely access to these services is especially challenging and because the failure of States to ensure timely access to these services poses substantial risk to the health, safety, and quality of care of individuals residing independently and in other community-based residences. Having States report this information will assist us in our oversight of State HCBS programs by helping us target our technical assistance and monitoring efforts. We request comment on whether this requirement should apply to additional services authorized under section 1915(c) of the Act.

For this metric, we propose to allow States to report on a statistically valid random sample of individuals newly approved to begin receiving these services within the past 12 months, rather than for all individuals newly approved to begin receiving these services within the past 12 months. We invite comments on the timeframe for States to report on this metric, whether we should require reporting less frequently (every 2 or 3 years), and if an alternate timeframe is recommended, the rationale for that alternate timeframe. We also invite comments on whether there are other specific metrics related to the amount of time that it takes for eligible individuals to begin receiving homemaker services, home health aide services, or personal care services that we should require States to report, either in place of or in addition to the metric we proposed.

At § 441.311(d)(2)(ii), also based on our authority under section 1902(a)(6) of the Act, we propose to require States to report annually on the percent of authorized hours for homemaker services, home health aide services, or personal care services, as listed in § 440.180(b)(2) through (4), that are provided within the past 12 months. For this metric, we further propose to allow States to report on a statistically valid random sample of individuals authorized to receive these services within the past 12 months, rather than all individuals authorized to receive these services within the past 12 months. We invite comments on the timeframe for States to report on this metric, whether we should require reporting less frequently (every 2 or 3 years), and if an alternate timeframe is recommended, the rationale for that alternate timeframe. We also invite comments on whether there are other specific metrics related to individuals' use of authorized homemaker services, home health aide services, or personal care services that we should require States to report, either in place of or in addition to the metric we proposed. We further request comment on whether this requirement should apply to additional services authorized under section 1915(c) of the Act.

d. Payment Adequacy

At § 441.311(e), we propose new reporting requirements for section 1915(c) waivers, under our authority at section 1902(a)(6) of the Act, for States to demonstrate that they meet the proposed *HCBS Payment Adequacy* requirements at § 441.302(k). Specifically, we propose that States report annually on the percent of payments for homemaker, home health aide, and personal care services, as listed at § 440.180(b)(2) through (4), that are spent on compensation for direct care workers. As discussed in section II.B.5. of this preamble, we have focused this requirement on homemaker services, home health aide services, and personal care services because they are services for which we expect that the vast majority of payment should be comprised of compensation for direct care workers and for which there would be low facility or other indirect costs. These are services that would most commonly be conducted in individuals' homes and general community settings.

[87] CMS Request for Information: Access to Coverage and Care in Medicaid & CHIP. February 2022. For a full list of question from the RFI, see: *https://www.medicaid.gov/medicaid/access-care/downloads/access-rfi-2022-questions.pdf.*

As such, there should be low facility or other indirect costs associated with the services.

We considered whether the proposed reporting requirements at § 441.311(e) related to the percent of payments going to the direct care workforce should apply to other services, such as adult day health, habilitation, day treatment or other partial hospitalization services, psychosocial rehabilitation services and clinic services for individuals with chronic mental illness. As discussed in section II.B.5. of this preamble, these services may have facility or other indirect costs for which we do not have adequate information to determine a minimum percent of the payment that should be spent on compensation for the direct care workforce and, as a result, we are not proposing to apply *HCBS Payment Adequacy* requirements at § 441.302(k) to services other than homemaker, home health aide, and personal care services, as listed at § 440.180(b)(2) through (4). However, we are requesting comment on whether the proposed requirements at § 441.302(k)(3)(i) related to the percent of payments going to the direct care workforce should apply to other services listed at § 440.180(b). In particular, we are requesting comment on whether the proposed requirements at § 441.302(k)(3)(i) related to the percent of payments going to the direct care workforce should apply to residential habilitation services, day habilitation services, and home-based habilitation services. As a result, we are also requesting comment whether States should be required to report annually on the percent of payments for other services listed at § 440.180(b) that are spent on compensation for direct care workers and, in particular, on the percent of payments for residential habilitation services, day habilitation services, and home-based habilitation services that are spent on compensation for direct care workers.

We further propose that States separately report for each service subject to the reporting requirement and, within each service, separately report on payments for services that are self-directed. We considered whether other reporting requirements such as a State assurance or attestation or an alternative frequency of reporting could be used to determine State compliance with the requirement at § 441.302(k) and decided that the proposed requirement would be most effective to demonstrate State compliance. We request comment on whether we should allow States to provide an assurance or attestation, subject to audit, that they meet the requirement in place of reporting on the percent of payments, and whether we should reduce the frequency of reporting to every other year.

The intent of this proposed requirement is for States to report in the aggregate for each service across all of their services across all programs as opposed to separately report for each waiver or HCBS program. As an alternative, we considered whether to require reporting at the delivery system, HCBS waiver program, or population level. However, we are not proposing to require additional levels of reporting because we expect that it would increase reporting burden for States without providing us with additional information necessary for determining whether States meet the requirements at § 441.302(k). We request comment on whether we should require States to report on the percent of payments for certain HCBS that are spent on compensation for direct care workers at the delivery system, HCBS waiver program, or population level. In addition, we considered whether to require States to report on median hourly wage and on compensation by category, including salary, wages, and other remuneration; benefits; and payroll taxes. We believe that such information would be valuable for better monitoring workforce compensation and its impact on workforce shortages and turnover and access to services for Medicaid beneficiaries. While such information should be readily accessible for providers, we have not proposed requiring these types of reporting, as collecting and aggregating such information would increase State burden. We request comment on whether we should require States to report on median hourly wage and on compensation by category. We considered whether to allow States, at their option, to exclude, from their reporting to CMS but not from the proposed requirement at § 441.302(k) related to the percent of payments that are spent on compensation for direct care workers, payments to providers of agency-directed services that have low Medicaid revenues or serve a small number of Medicaid beneficiaries, based on Medicaid revenues for the service, number of direct care workers serving Medicaid beneficiaries, or the number of Medicaid beneficiaries receiving the service. We considered this option as a way to reduce State, managed care plan, and provider data collection and reporting burden based on the experience of States that have implemented similar reporting requirements. However, we are concerned that such an option could discourage providers from serving Medicaid beneficiaries or increasing the number of Medicaid beneficiaries or amount of Medicaid revenues. We request comment on whether we should allow States the option to exclude, from their reporting to CMS, payments to providers of agency directed services that have low Medicaid revenues or serve a small number of Medicaid beneficiaries, based on Medicaid revenues for the service, number of direct care workers serving Medicaid beneficiaries, or the number of Medicaid beneficiaries receiving the service.

We also request comment on whether we should establish a specific limit on this exclusion and, if so, the specific limit we should establish, such as to limit the exclusion to providers in the lowest 5th, 10th, 15th, or 20th percentile of providers in terms Medicaid revenues for the service, number of Medicaid beneficiaries served, or number of direct care workers serving Medicaid beneficiaries.

We also considered whether to allow States to exclude payments for self-directed services from this reporting requirement, based on feedback obtained during various interested parties' engagement activities conducted with States and other interested parties over the past several years related to HCBS workforce shortages that indicate that compensation for direct care workers in self-directed models tends to be higher and may comprise a higher percentage of the payments for services than other HCBS, and that administrative costs account for a small percentage of the cost of self-directed services. However, we have decided that payments for self-directed services by States should be included in these reporting requirements. This decision not to exclude them was based on the importance of ensuring a sufficient direct care workforce for self-directed services, the experience of States that have applied similar requirements to report on the percent of payments for to self-directed services that are spent on compensation for direct care workers, and the lack of conclusive data indicating that compensation for direct care workers meets or exceeds the proposed 80 percent threshold. We request comment on whether we should allow States to exclude payments for self-directed services from these reporting requirements.

e. Effective Date

We recognize that many States may need time to implement these reporting requirements, including to amend provider agreements or managed care contracts, make State regulatory or

policy changes, implement process or procedural changes, update information systems for data collection and reporting, or conduct other activities to implement these requirements. As a result, we are proposing at § 441.311(f)(1) to provide States with 3 years to implement the compliance reporting requirements at § 441.311(b), the HCBS Quality Measure Set reporting requirements at § 441.311(c), and the access reporting requirements at § 441.311(d) in FFS delivery systems following the effective date of the final rule. For States with managed care delivery systems under the authority of sections 1915(a), 1915(b), 1932(a), or 1115(a) of the Act and that include HCBS in the MCO's, PIHP's, or PAHP's contract, we are proposing to provide States until the first managed care plan contract rating period that begins on or after 3 years after the effective date of the final rule to implement these requirements. This time period is based on feedback from States and other interested parties that it could take 2 to 3 years to amend State regulations and work with their State legislatures, if needed, as well as to revise policies, operational processes, information systems, and contracts to support implementation of these proposed reporting requirements. We also have considered all of the HCBS proposals outlined in this proposed rule as whole. We invite comments on whether this timeframe is sufficient, whether we should require a shorter timeframe (2 years) or longer timeframe (4 years) to implement these provisions, and if an alternate timeframe is recommended, the rationale for that alternate timeframe.

In addition, we are proposing at § 441.311(f)(2) to provide States with 4 years to implement the payment adequacy reporting requirements at § 441.311(e) in FFS delivery systems following the effective date of the final rule. For States with managed care delivery systems under the authority of sections 1915(a), 1915(b), 1932(a), or 1115(a) of the Act and that include HCBS in the MCO's, PIHP's, or PAHP's contract, we are proposing to provide States until the first managed care plan contract rating period that begins on or after 4 years after the effective date of the final rule to implement these requirements. This time period is intended to align with the effective date for the HCBS payment adequacy requirements at § 441.302(k), which are discussed in section II.B.5. of this preamble. It is also based on feedback from States and other interested parties that it could take 3 to 4 years to amend State regulations and work with their State legislatures, if needed, as well as to revise policies, operational processes, information systems, and contracts to support implementation of these reporting requirements. We also have considered all of the HCBS proposals outlined in this proposed rule as whole. We invite comments on whether this timeframe is sufficient, whether we should require a shorter timeframe (3 years) or longer timeframe (5 years) to implement these provisions, and if an alternate timeframe is recommended, the rationale for that alternate timeframe.

At § 441.311(f), we propose to apply all of the reporting requirements described in § 441.311 to services delivered under FFS and managed care delivery systems. As discussed earlier in section II.B.1. of this preamble, section 2402(a)(3)(A) of the Affordable Care Act requires States to improve coordination among, and the regulation of, all providers of Federally and State-funded HCBS programs to achieve a more consistent administration of policies and procedures across HCBS programs, and as noted in the Medicaid context this would include consistent administration between FFS and managed care programs. We accordingly are proposing to specify that a State must ensure compliance with the requirements in § 441.302(a)(6) with respect to HCBS delivered both under FFS and managed care delivery systems.

As discussed earlier in section II.B.1. of this preamble, the proposed requirements at § 441.311, in combination with other proposed requirements identified throughout this proposed rule, are intended to supersede and fully replace the reporting expectations and the minimum 86 percent performance level for State's performance measures described in the 2014 guidance, also discussed earlier in section II.B.1. of this preamble. We expect that States may implement some of the requirements proposed in this proposed rule in advance of any effective date. If the rule is finalized, we will work with States to phase out the 2014 guidance as they implement the requirements in the future final rule to reduce unnecessary burden and to avoid duplicative or conflicting reporting requirements.

In accordance with the requirement of section 2402(a)(3)(A) of the Affordable Care Act for States to achieve a more consistent administration of policies and procedures across HCBS programs, and because these reporting requirements are relevant to other HCBS authorities, we are proposing to incorporate these requirements within the applicable regulatory sections for other HCBS authorities. Specifically, we propose to apply the requirements at § 441.311 to section 1915(j), (k), and (i) State plan services by cross-referencing at §§ 441.474(c), 441.580(i), and 441.745(a)(1)(vii), respectively. Consistent with our proposal for section 1915(c) waivers, we propose these requirements based on our authority under section 1902(a)(6) of the Act, which requires State Medicaid agencies to make such reports, in such form and containing such information, as the Secretary may from time to time require, and to comply with such provisions as the Secretary may from time to time find necessary to assure the correctness and verification of such reports. We believe the same arguments for proposing these requirements for section 1915(c) waivers are equally applicable for these other HCBS authorities. We request comment on the application of these provisions across section 1915(i), (j), and (k) authorities. To accommodate the addition of new language at § 441.580(i), we are proposing to renumber existing § 441.580(i) as § 441.580(j).

We considered whether to also apply these reporting requirements to section 1905(a) ''medical assistance'' State plan personal care, home health, and case management services. However, we are not proposing that these requirements apply to any section 1905(a) State plan services based on State feedback that they do not have the same data collection and reporting capabilities in place for section 1905(a) services as they do for sections 1915(c), (i), (j), and (k) services and because the person-centered planning, service plan, and waiting list requirements that comprise a significant portion of these reporting requirements have little to no relevance for section 1905(a) services, in comparison to section 1915(c), (i), (j), and (k) services. Further, the vast majority of HCBS is delivered under section 1915(c), (i), (j), and (k) authorities, while only a small percentage of HCBS nationally is delivered under section 1905(a) State plan authority. We request comment on whether we should establish similar reporting requirements for section 1905(a) ''medical assistance'' State plan personal care, home health, and case management services.

We expect that, should we finalize these reporting requirements, we will establish new processes and forms for States to meet the reporting requirements, provide additional technical information on how States can meet the reporting requirements including related to sampling requirements (where States are

permitted to report on a sample of beneficiaries rather than on all individuals who meet the inclusion criteria for the reporting requirement), and amend existing templates and establish new templates under the Paperwork Reduction Act.

8. Home and Community-Based Services (HCBS) Quality Measure Set (§§ 441.312, 441.474(c), 441.585(d), and 441.745(b)(1)(v)

On July 21, 2022, we issued State Medicaid Director Letter # 22–003 [88] to release the first official version of the HCBS Quality Measure Set. The HCBS Quality Measure Set is a set of nationally standardized quality measures for Medicaid-covered HCBS. It is intended to promote more common and consistent use within and across States of nationally standardized quality measures in HCBS programs, create opportunities for CMS and States to have comparative quality data on HCBS programs, drive improvement in quality of care and outcomes for people receiving HCBS, and support States' efforts to promote equity in their HCBS programs. It is also intended to reduce some of the burden that States and other interested parties may experience in identifying and using HCBS quality measures. By providing States and other interested parties with a set of nationally standardized measures to assess HCBS quality and outcomes and by facilitating access to information on those measures, we believe that we can reduce the time and resources that States and other interested parties expend on identifying, assessing, and implementing measures for use in HCBS programs.

Section 1102(a) of the Act provides the Secretary of HHS with authority to make and publish rules and regulations that are necessary for the efficient administration of the Medicaid program. Section 1902(a)(6) of the Act requires State Medicaid agencies to make such reports, in such form and containing such information, as the Secretary may from time to time require, and to comply with such provisions as the Secretary may from time to time find necessary to assure the correctness and verification of such reports. Under our authority at sections 1102(a) and 1902(a)(6) of the Act, we are proposing to add a new section, at § 441.312, *Home and Community-Based Services Quality Measure Set,* to require use of the measure set in 1915(c) waiver programs and promote public transparency related to the administration of Medicaid-covered HCBS. We describe the basis and scope of this section in proposed paragraph (a).

We believe that quality is a critical component of efficiency, and as such, having a standardized set of measures that is used to assess the quality of Medicaid HCBS programs supports the efficient operation of the Medicaid program. Further, we believe that this proposal is necessary for the efficient administration of Medicaid-covered HCBS authorized under section 1915(c) of the Act, consistent with section 1902(a)(4) of the Act, as it would establish a process through which we would regularly update and maintain the required set of measures at § 441.311(c) in consultation with States and other interested parties (as described later in this section of the preamble). This process would ensure that the priorities of interested parties are reflected in the selection of the measures included in the HCBS Quality Measure Set. This process would also ensure that the required set of HCBS quality measures is updated to address gaps in the HCBS Quality Measure Set as new measures are developed and to remove measures that are less relevant or add less value than other available measures, and that it meets scientific and other standards for quality measures. Due to the constantly evolving field of HCBS quality measurement, we believe that the failure to establish such a process would result in ongoing reporting by States of measures that do not reflect the priorities of interested parties, measures that offer limited value compared to other measures, and measures that do not meet strong scientific and other standards. It would also result in a lack of reporting on key measurement priority areas, which could be addressed by updating the HCBS Quality Measure Set as new measures are developed. The failure to establish such a process would lead to inefficiency in States' HCBS quality measurement activities through the continued reporting on an outdated set of measures. In other words, we believe that such a process is necessary for the efficient administration of Medicaid-covered HCBS by ensuring that quality measure reporting requirements are focused on the most valuable, useful, and scientifically supported areas of quality measurement, and that quality measures with limited value are removed timely from quality measure reporting requirements.

We propose a definition at § 441.312(b)(1) for ''Attribution rules,'' to mean the process States use to assign beneficiaries to a specific health care program or delivery system for the purpose of calculating the measures on the ''HCBS Quality Measure Set'' as described in proposed § 441.312(d)(6), and at § 441.312(b)(2) for ''Home and Community-Based Services Quality Measure Set'' to mean the Home and Community-Based Measures for Medicaid established and updated at least every other year by the Secretary through a process that allows for public input and comments, including through the **Federal Register**.

At § 441.312(c), we describe the general process that the Secretary will follow to update and maintain the HCBS Quality Measure Set. Specifically, at § 441.312(c)(1), we propose that the Secretary will identify and update at least every other year, through a process that allows for public input and comment, the quality measures to be included in the HCBS Quality Measure Set. At § 441.312(c)(2), we propose that the Secretary will solicit comment at least every other year with States and other interested parties, which are identified later in this section of the preamble, to:

- Establish priorities for the development and advancement of the HCBS Quality Measure Set.
- Identify newly developed or other measures which should be added including to address gaps in the measures included in the HCBS Quality Measure Set.
- Identify measures which should be removed as they no longer strengthen the HCBS Quality Measure Set.
- Ensure that all measures included in the HCBS Quality Measure Set are evidence-based, are meaningful for States, and are feasible for State-level and program-level reporting as appropriate.

The proposed frequency for updating the quality measures included in the HCBS Quality Measure Set is aligned with the proposed frequency at § 441.311(c)(1)(i) for States' reporting of the measures in the HCBS Quality Measure Set. We have based other aspects of the process that the Secretary will follow to update and maintain the HCBS Quality Measure Set in part on the proposed processes for the Secretary to update and maintain the Child, Adult, and Health Home Core Sets as described in the Medicaid Program and CHIP; Mandatory Medicaid and

[88] CMS State Medicaid Director Letter. SMD# 22–003 Home and Community-Based Services Quality Measure Set. July 2022. Accessed at *https://www.medicaid.gov/federal-policy-guidance/downloads/smd22003.pdf.*

Children's Health Insurance Program (CHIP) Core Set Reporting proposed rule (87 FR 51303); (hereinafter the ''Mandatory Medicaid and CHIP Core Set Reporting proposed rule''). We believe that such alignment in processes will ensure consistency and promote efficiency for both CMS and States across Medicaid quality measurement and reporting activities.

At § 441.312(c)(3), we propose that the Secretary will, in consultation with States and other interested parties (as described later in this section of preamble), develop and update the measures in the HCBS Quality Measure Set, at least every other year, through a process that allows for public input and comment. We invite comments on whether the timeframes for updating the measures in the HCBS Quality Measure Set and conducting the process for developing and updating the HCBS Quality Measure Set is sufficient, whether we should conduct these activities more frequently (every year) or less frequently (every 3 years), and if an alternate timeframe is recommended, the rationale for that alternate timeframe.

At § 441.312(d), we describe the proposed process for developing and updating the HCBS Quality Measure Set. Specifically, we propose that the Secretary will address the following through the proposed process:

- Identify all measures in the HCBS Quality Measure Set, including newly added measures, measures that have been removed, mandatory measures, measures that the Secretary will report on States' behalf, measures that States can elect to have the Secretary report on their behalf, as well as the measures that the Secretary will provide States with additional time to report and the amount of additional time.
- Inform States how to collect and calculate data on the measures.
- Provide a standardized format and reporting schedule for reporting the measures.
- Provide procedures that States must follow in reporting the measure data.
- Identify specific populations for which States must report the measures, including people enrolled in a specific delivery system type, people who are dually eligible for Medicare and Medicaid, older adults, people with physical disabilities, people with intellectual or developmental disabilities, people who have serious mental illness, and people who have other health conditions; and provide attribution rules for determining how States must report on measures for beneficiaries who are included in more than one population.
- Identify the subset of measures that must be stratified by race, ethnicity, Tribal status, sex, age, rural/urban status, disability, language, or such other factors as may be specified by the Secretary.
- Describe how to establish State performance targets for each of the measures.

We anticipate that, for State reporting on the measures in the HCBS Quality Measure Set, as outlined in § 441.311, the technical information on attribution rules described at proposed § 441.312(d)(6), would call for inclusion in quality reporting based on a beneficiary's continuous enrollment in the Medicaid waiver. This would ensure the State has enough time to furnish services during the measurement period. In the technical information, we anticipate we would set attribution rules to address transitions in Medicaid eligibility, enrollment in Medicare, or transitions between different delivery systems or managed care plans, within a reporting year, for example, based on the length of time beneficiaries was enrolled in each. We invite comment on other considerations we should address in the attribution rules or other topics we should address in the technical information.

At § 441.312(e), we propose, in the process for developing and updating the Home and Community-Based Services Quality Measure Set described at proposed § 441.312(d), that the Secretary consider the complexity of State reporting and allow for the phase-in over a specified period of time of mandatory State reporting for some measures and of reporting for certain populations, such as older adults or people with intellectual and disabilities. At § 441.312(f), we propose that, in specifying the measures and the factors by which States must report stratified measures, the Secretary will consider whether such stratified sampling can be accomplished based on valid statistical methods, without risking a violation of beneficiary privacy, and, for measures obtained from surveys, whether the original survey instrument collects the variables or factors necessary to stratify the measures. This proposed stratification of data for the measures contained in the HCBS Quality Measure Set is consistent with our statutory authority under section 1902(a)(6) of the Act, which requires States to report information ''in such form and containing such information'' as the Secretary requires.

Stratified sampling is a method of sampling from a population, in which the sampling can be partitioned into sub-populations, such as by race, ethnicity, sex, age, rural/urban status, disability, language, or such other factors. Stratified data would enable us and States to identify the health and quality of life outcomes of underserved populations and potential differences in outcomes based on race, ethnicity, sex, age, rural/urban status, disability, language, or such factors on measures contained in the HCBS Quality Measure Set. Measuring health disparities, reporting these results, and driving improvements in quality are cornerstones of the CMS approach to advancing health equity. Advancing equity for underserved populations through data reporting and stratification aligns with E.O. 13985.[89] In line with the policy objective of E.O. 13985, CMS defines health equity as ''the attainment of the highest level of health for all people, where everyone has a fair and just opportunity to attain their optimal health regardless of race, ethnicity, disability, sexual orientation, gender identity, socioeconomic status, geography, preferred language, or other factors that affect access to care and health outcomes.'' [90] We are working to advance health equity by designing, implementing, and operationalizing policies and programs that support health for all the people served by our programs, eliminating avoidable differences in health and quality of life outcomes experienced by people who are disadvantaged or underserved, and providing the care and support that all individuals need to thrive.

We considered giving States the flexibility to choose which measures they would stratify and by what factors. However, as discussed in the Mandatory Medicaid and CHIP Core Set Reporting rule (87 FR 51313), consistent measurement of differences in health and quality of life outcomes between different groups of beneficiaries is essential to identifying areas for intervention and evaluation of those interventions.[91] This consistency could

[87] Exec. Order No. 13985 (2021), Accessed at *https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/20/executive-order-advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government/*.

[90] CMS definition of health equity. Accessed at *https://www.cms.gov/pillar/health-equity*.

[91] Schlotthauer AE, Badler A, Cook SC, Perez DJ, Chin MH. Evaluating Interventions to Reduce Health Care Disparities: An RWJF Program. Health Aff (Millwood). 2008;27(2):568–573.

not be achieved if each State made its own decisions about which data it would stratify and by what factors.[92] [93]

We recognize that States may be constrained in their ability to stratify measures in the HCBS Quality Measure Set and that data stratification would require additional State resources. There are several challenges to stratification of measure reporting. First, the validity of stratification is threatened when the demographic data are incomplete. Complete demographic information is often unavailable to us and to States due to several factors, including the fact that Medicaid applicants and beneficiaries are not required to provide race and ethnicity data. Second, when States with smaller populations and less diversity stratify data, it may be possible to identify individual data, raising privacy concerns. Therefore, if the sample sizes are too small, the data would be suppressed, in accordance with the CMS Cell Size Suppression Policy and the data suppression policies for associated measure stewards and therefore not publicly reported to avoid a potential violation of privacy.[94]

We also may face constraints in stratifying measures for which we are able to report on behalf of States, as our ability to stratify will be dependent on whether the original dataset or survey instrument: (1) collects the demographic information or other variables needed and (2) has a large enough sample size. The Transformed Medicaid Statistical Information System (T–MSIS), for example, currently has the capability to stratify some HCBS Quality Measure Set measures by sex and urban/rural status, but not by race, ethnicity, or disability status. This is because applicants provide information on sex and urban/rural address, which is reported to T–MSIS by States, whereas applicants are not required to provide information on their race and ethnicity or disability status, and often do not do so. However, we have developed the capacity to impute race and ethnicity using a version of the Bayesian Improved Surname Geocoding (BISG) method [95] that includes Medicaid-specific enhancements to optimize accuracy, and are able to stratify by race and ethnicity, urban/rural status, and sex.

The method proposed for this project utilizes State-submitted race/ethnicity data when it is complete and accurate as based on the Medicaid DQ Atlas assessment for a given year.[96] When State-submitted data is missing or inaccurate, imputed results are used to ensure statistical accuracy. Because imputations are only used when self-reported data is missing or States have systematic errors in reporting race and/or ethnicity, millions of self-reported datapoints are preserved and model accuracy is improved. This also reflects that, as the quality of State-submitted data improves, the imputations will be used less frequently. We will release detailed documentation about the methodology used to develop the imputations prior to the release of these results. While complete demographic information for beneficiaries would always be preferable to using imputed model values, reliable techniques to impute values is a substitute to enable identification and analysis of health disparities.

With these challenges in mind, we propose that stratification by States in reporting of HCBS Quality Measure Set data would be implemented through a phased-in approach in which the Secretary would specify which measures and by which factors States must stratify reported measures. In proposed § 441.312(f), States would be required to provide stratified data for 25 percent of the measures in the HCBS Quality Measure Set for which the Secretary has specified that reporting should be stratified by 3 years after the effective date of these regulations, 50 percent of such measures by 5 years after the effective date of these regulations, and 100 percent of measures by 7 years after the effective date of these regulations. We note that the percentages listed here align with the proposed phase-in of equity reporting in the Mandatory Medicaid and CHIP Core Set Reporting proposed rule, although the proposed deadlines for each compliance level would be longer here (87 FR 51314). However, the timeframe associated with each percentage is different from what was proposed in that rule. Specifically, that proposed rule would require States to provide stratified data for 25 percent of measures within 2 years after the effective date of the final rule, 50 percent of measures within 3 years after the effective date of the final rule, and 100 percent of measures within 5 years after the effective date of the final rule.

We propose a slower phase-in for stratification for the measures in the HCBS Quality Measure Set because the HCBS Quality Measure Set was only first released for voluntary use by States in July 2022, while Child, Adult, and Health Home Core Sets voluntary reporting has been in place for a number of years. Further, a substantial portion of the measures included in the HCBS Quality Measure Set, particularly compared to the Child, Adult, and Health Home Core Sets, are derived from beneficiary experience of care surveys, which are costlier to implement than other types of measures. In addition, the slower phase-in is also intended to take into consideration the overall burden of the reporting requirements in this proposed rule.

We have determined that this proposed phased-in approach to data stratification would be reasonable and minimally burdensome, and thus consistent with E.O. 13985 on Advancing Racial Equity and Support for Underserved Communities Through the Federal Government (January 20, 2021),[97] because we are balancing the importance of being able to identify differences in outcomes between populations under these measures with the potential operational challenges that States may face in implementing these proposed requirements.

We recognize that States may need to make enhancements to their data and information systems or incur other costs in implementing the HCBS Quality Measure Set. We remind States that enhanced FFP is available at a 90 percent match rate for the design, development, or installation of improvements of mechanized claims

[92] Centers for Medicare & Medicaid Services (CMS) Office of Minority Health (OMH). Stratified Reporting. 2022; *https://www.cms.gov/About-CMS/Agency-Information/OMH/research-and-data/statistics-and-data/stratified-reporting.*

[93] National Quality Forum. A Roadmap for Promoting Health Equity and Eliminating Disparities. Sep 2017. Accessed at *https://www.qualityforum.org/Publications/2017/09/A_Roadmap_for_Promoting_Health_Equity_and_Eliminating_Disparities__The_Four_I_s_for_Health_Equity.aspx.*

[94] CMS Cell Size Suppression Policy, Issued 2020: *https://www.hhs.gov/guidance/document/cms-cell-suppression-policy* or the cell suppression standards of the associated measure stewards.

[95] Elliott, Marc N., et al. ''Using the Census Bureau's surname list to improve estimates of race/ethnicity and associated disparities.'' *Health Services and Outcomes Research Methodology* 9.2 (2009): 69–83.

[96] Medicaid DQ Atlas. ''Race and Ethnicity.'' *https://www.medicaid.gov/dq-atlas/landing/topics/single/map?topic=g3m16&tafVersionId=32.*

[97] Exec. Order No. 13985 (2021), Accessed at *https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/20/executive-order-advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government/.*

processing and information retrieval systems, in accordance with applicable Federal requirements.[98] Enhanced FFP at a 75 percent match rate is also available for operations of such systems, in accordance with applicable Federal requirements.[99] Receipt of these enhanced funds is conditioned upon States meeting a series of standards and conditions to ensure investments are efficient and effective.[100] States are also encouraged to advance the interoperable exchange of HCBS data and support quality improvement activities by adopting standards in 45 CFR part 170 and other relevant standards identified in the ISA.[101]

We solicit comments on the proposed schedule for phasing in reporting of HCBS Quality Measure Set data. We also seek comment on whether we should phase-in reporting on all of the measures in the HCBS Quality Measure Set.

At § 441.312(g), we propose the list of interested parties with whom the Secretary must consult to specify and update the quality measures established in the HCBS Quality Measure Set. The proposed list of interested parties includes: State Medicaid Agencies and agencies that administer Medicaid-covered HCBS; health care and HCBS professionals who specialize in the care and treatment of older adults, children and adults with disabilities, and individuals with complex medical needs; health care and HCBS professionals, providers, and direct care workers who provide services to older adults, children and adults with disabilities and complex medical and behavioral health care needs who live in urban and rural areas or who are members of groups at increased risk for poor outcomes; HCBS providers; direct care workers and organizations representing direct care workers; consumers and national organizations representing consumers; organizations and individuals with expertise in HCBS quality measurement; voluntary consensus standards setting organizations and other organizations involved in the advancement of evidence-based measures of health care; measure development experts; and other interested parties the Secretary may determine appropriate.

Because these quality measurement requirements are relevant to other HCBS authorities, we are proposing to incorporate these requirements within the applicable regulatory sections for other HCBS authorities. Specifically, we propose to apply the proposed requirements at § 441.312 to section 1915(j), (k), and (i) State plan services by cross-referencing at §§ 441.474(c), 441.585(d), and 441.745(b)(1)(v), respectively. Consistent with our proposal for section 1915(c) waivers, we propose these requirements based on our authority under section 1902(a)(6) of the Act, which requires State Medicaid agencies to make such reports, in such form and containing such information, as the Secretary may from time to time require, and to comply with such provisions as the Secretary may from time to time find necessary to assure the correctness and verification of such reports. We believe the same arguments for proposing these requirements for section 1915(c) waivers are equally applicable for these other HCBS authorities. We request comment on the application of these provisions across sections 1915(i), (j), and (k) authorities.

9. Website Transparency (§§ 441.313, 441.486, 441.595, and 441.750)

Section 1102(a) of the Act provides the Secretary of HHS with authority to make and publish rules and regulations that are necessary for the efficient administration of the Medicaid program. Under our authority at section 1102(a) of the Act, we are proposing to add a new section, at § 441.313, titled *Website transparency,* to promote public transparency related to the administration of Medicaid-covered HCBS. As noted earlier in section II.B.8. of this preamble, we believe that quality is a critical component of efficiency, as payments for services that are low quality do not produce their desired effects and, as such, are more wasteful than payments for services that are high quality. However, feedback from interested parties during various public engagement activities over the past several years have indicated that it is difficult to find information on HCBS access, quality, and outcomes in many States. As a result, it is not possible for beneficiaries, consumer advocates, oversight entities, or other interested parties to hold States accountable for ensuring that services are accessible and high quality for people who need Medicaid HCBS. As a result, we believe that the proposal described immediately below supports the efficient administration of Medicaid-covered HCBS authorized under section 1915(c) of the Act by promoting public transparency and accountability of the quality and performance of Medicaid HCBS systems, as the availability of such information will improve the ability of interested parties to hold States accountable for the quality and performance of their HCBS systems.

Specifically, at § 441.313(a), we propose to require States to operate a website that meets the availability and accessibility requirements at § 435.905(b) of this chapter and that provides the results of the reporting requirements under newly proposed § 441.311 (specifically, incident management, critical incident, person centered planning, and service provision compliance data; data on the HCBS Quality Measure Set; access data; and payment adequacy data). We request comment on whether the requirements at § 435.905(b) are sufficient to ensure the availability and the accessibility of the information for people receiving HCBS and other HCBS interested parties and for specific requirements to ensure the availability and accessibility of the information.

At § 441.313(a)(1), we propose to require that the data and information that States are required to report under § 441.311 be provided on one web page, either directly or by linking to the web pages of the managed care organization, prepaid ambulatory health plan, prepaid inpatient health plan, or primary care case management entity that is authorized to provide services. We request comment on whether States should be permitted to link to web pages of these managed care entities and whether we should limit the number of separate web pages that a State could link to, in place of directly reporting the information on its own web page.

At § 441.313(a)(2), we propose to require that the web page include clear and easy to understand labels on documents and links. We request comment on whether these requirements are sufficient to ensure the accessibility of the information for people receiving HCBS and other HCBS interested parties and for specific requirements to ensure the accessibility of the information.

At § 441.313(a)(3), we propose to require that States verify the accurate function of the website and the timeliness of the information and links

[98] See section 1903(a)(3)(A)(i) of the Act and § 433.15(b)(3), 80 FR 75817 through 75843; *https://www.medicaid.gov/state-resourcecenter/faq-medicaid-and-chip-affordable-care-act-implementation/downloads/affordable-care-act-faq-enhancedfunding-for-medicaid.pdf; https://www.medicaid.gov/federal-policy-guidance/downloads/SMD16004.pdf.*

[99] See section 1903(a)(3)(B) and § 433.15(b)(4).

[100] See § 433.112 (b, 80 FR 75841; *https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-C/part-433/subpart-C.*

[101] Relevant standards adopted by HHS and identified in the ISA include the USCDI (*https://www.healthit.gov/isa/united-states-core-data-interoperability-uscdi*), eLTSS (*https://www.healthit.gov/isa/documenting-care-plans-person-centered-services), and Functional Assessment Standardized Items (https://www.healthit.gov/isa/representing-patient-functional-status-andor-disability*).

at least quarterly. We request comment on whether this timeframe is sufficient or if we should require a shorter timeframe (monthly) or a longer timeframe (semi-annually or annually).

At § 441.313(a)(4), we propose to require that States include prominent language on the website explaining that assistance in accessing the required information on the website is available at no cost and include information on the availability of oral interpretation in all languages and written translation available in each non-English language, how to request auxiliary aids and services, and a toll-free and TTY/TDY telephone number.

We are also proposing at § 441.313(b) that CMS must report on its CMS website the information reported by States to us under § 441.311. For example, we envision that we will update CMS's website to provide HCBS comparative information reported by States that can be compared to HCBS information shared by other States. We also envision using data from State reporting in future iterations of the CMS Medicaid and CHIP Scorecard.[102]

We are proposing at § 441.313(c), to provide States with 3 years to implement these requirements in FFS delivery systems following effective date of the final rule. For States with managed care delivery systems under the authority of sections 1915(a), 1915(b), 1932(a), or section 1115(a) of the Act and that include HCBS in the MCO's, PIHP's, or PAHP's contract, we are proposing to provide States until the first managed care plan contract rating period that begins on or after 3 years after the effective date of the final rule to implement these requirements. This time period is based primarily on the effective date for State reporting at § 441.311. We also have considered all of the HCBS proposals outlined in the proposed rule as whole. We invite comments on whether this timeframe is sufficient, whether we should require a longer timeframe (4 years) to implement these provisions, and if a longer timeframe is recommended, the rationale for that longer timeframe.

As discussed earlier in section II.B.1. of this preamble, section 2402(a)(3)(A) of the Affordable Care Act requires States to improve coordination among, and the regulation of, all providers of Federally and State-funded HCBS programs to achieve a more consistent administration of policies and procedures across HCBS programs. In the context of Medicaid coverage of HCBS, it should not matter whether the services are covered directly on a FFS basis or by a managed care entity to its enrollees. The requirement for ''consistent administration'' should require consistency between these two modes of service delivery. We accordingly are proposing to specify that a State must ensure compliance with the requirements in § 441.313, with respect to HCBS delivered both under FFS and managed care delivery systems.

Similarly, because we are proposing to apply the reporting requirements at § 441.311 to other HCBS State plan options, we are proposing to incorporate these website transparency requirements within the applicable regulatory sections. Specifically, we propose to apply the proposed requirements of § 441.313 to section 1915(j), (k), and (i) State plan services by cross-referencing at §§ 441.486, 441.595, and 441.750, respectively. Consistent with our proposal for section 1915(c) waivers, we propose these requirements based on our authority under section 1102(a) of the Act to make and publish rules and regulations that are necessary for the efficient administration of the Medicaid program. We believe the same arguments for proposing these requirements for section 1915(c) waivers are equally applicable for these other HCBS authorities. We request comment on the application of these provisions across section 1915(i), (j), and (k) authorities.

10. Applicability of Proposed Requirements to Managed Care Delivery Systems

As discussed earlier in sections II.B.1., II.B.4., II.B.5., II.B.7., and II.J. of this rule, we are proposing to apply the requirements at §§ 441.301(c)(3), 441.302(a)(6), 441.302(k), 441.311, and 441.313 to both FFS and managed care delivery systems. Although the proposed provisions at §§ 441.301(c)(3), 441.302(a)(6) and (k), 441.311, and 441.313 would apply to LTSS programs that use a managed care delivery system to deliver services authorized under section 1915(c) waivers and section 1915(i), (j), and (k) State plan authorities, we believe incorporating a reference in 42 CFR part 438 would be helpful to States and managed care plans. Therefore, we propose to add a cross reference to the requirements in proposed § 438.72 to be explicit that States that include HCBS in their MCO, PIHP, or PAHP contracts would have to comply with the requirements at §§ 441.301(c)(1) through (3), 441.302(a)(6) and (k), 441.311, and 441.313. We believe this would make the obligations of States that implement LTSS programs through a managed care delivery system clear, consistent, and easy to locate. While we believe the list proposed in § 438.72 would help States easily identify the provisions related to LTSS, we identify that a provision specified in any other section of 42 CFR part 438 or any other Federal regulation but omitted from § 438.72, is still in full force and effect. We also note that § 438.208(c)(3)(ii) currently includes a cross-reference to § 441.301(c)(1) and (2). We are not proposing any changes to the regulatory language at § 441.301(c)(1) or (2) or to § 438.208(c)(3)(ii) through this rule. We have included § 441.301(c)(1) and (2) in the proposed regulatory language at § 438.72 so that it is clear that the requirements at § 441.301(c)(1) and (2) continue to apply when States include HCBS in their MCO, PIHP, or PAHP contracts.

C. Documentation of Access to Care and Service Payment Rates (§ 447.203)

Section 1902(a)(30)(A) of the Act requires that State plans ''assure that payments are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area.'' Through the proposed provisions in § 447.203, we seek to establish an updated process through which States would be required to document, and we would ensure, compliance with the requirements of section 1902(a)(30)(A) of the Act.

In the 2015 final rule with comment period, we codified a process that requires States to complete and make public AMRPs that analyze and inform determinations of the sufficiency of access to care (which may vary by geographic location in the State) and are used to inform State policies affecting access to Medicaid services, including provider payment rates. The AMRP must specify data elements that support the State's analysis of whether beneficiaries have sufficient access to care, based on data, trends, and factors that measure beneficiary needs, availability of care through enrolled providers, and utilization of services. States are required to update their AMRPs at regular intervals and whenever the State proposes to reduce FFS provider payment rates or restructure them in circumstances when the changes could result in diminished access. Specifically, the current AMRP process at § 447.203 requires States to consider the extent to which beneficiary needs are fully met; the availability of

[102] CMS's Medicaid and CHIP Scorecard. Accessed at *https://www.medicaid.gov/state-overviews/scorecard/index.html.*

care through enrolled providers to beneficiaries in each geographic area, by provider type and site of service; changes in beneficiary utilization of covered services in each geographic area; the characteristics of the beneficiary population (including considerations for care, service and payment variations for pediatric and adult populations and for individuals with disabilities); and actual or estimated levels of provider payment available from other payers, including other public and private payers, by provider type and site of service. The analysis further requires consideration of beneficiary and provider input, and an analysis of the percentage comparison of Medicaid payment rates to other public and private health insurer payment rates within geographic areas of the State, for each of the services reviewed, by the provider types and sites of service. While the current regulations do include broad requirements for what an acceptable analysis methodology must include, States retain discretion in establishing their processes, including but not limited to the specification of data sources and analytical methodologies to be used. The result is a large analytical burden on States without a standardization that would allow us and other interested parties to compare data between States to understand whether the Federal access standards are successfully achieving robust access consistent with section 1902(a)(30)(A) of the Act for beneficiaries nationwide.

Through AMRPs, we aimed to create a transparent and data-driven process through which to ensure State compliance with section 1902(a)(30)(A) of the Act. Following publication of the 2011 proposed rule and as discussed in both the 2015 final rule with comment period and the 2016 final rule, as we worked with States to implement the AMRP requirements, many States expressed numerous concerns about the rule.[103] [104] [105] States were concerned about the administrative burden of completing the AMRPs and questioned whether the AMRP process is the most effective way to establish that access to care in a State's Medicaid program meets statutory requirements. States with high managed care enrollment penetration were also concerned about the AMRP process because the remaining FFS populations in their State often reside in long-term care facilities or require only specialized care that is carved out from managed care, but long-term care and specialized care services were not required to be analyzed under the AMRP process. We have also heard concerns from other interested parties, including medical associations and non-profit organizations, that the 2015 final rule with comment period afforded States too much discretion in developing access measures which could lead to ineffective monitoring and enforcement as well as challenges comparing access across States. One commenter was concerned that States had too much discretion in ''. . . setting standards and access measures . . .'' and ''. . .whether they have met their chosen standards'' as this process relies on self-regulation rather than ''an independent, objective third party as the primary arbiter of a State's compliance . . .'' [106] Another commenter stated that ''CMS should designate a limited and standardized set of data measures that would be collected rather than leaving the decision of which data measures to use to State discretion'' as this would ''enable the development of key, valid, and uniform measures; more effective monitoring and enforcement; and will ensure comparability of objective measures across the States.'' [107] At the time of publication of the 2011 proposed rule and 2015 final rule with comment period, we believed that a uniform approach to meeting the statutory requirement under section 1902(a)(30)(A) of the Act, including setting standardized access to care data measures, could prove difficult given then-current limitations on data, local variations in service delivery, beneficiary needs, and provider practice roles.[108] [109]

Separately, the Supreme Court, in *Armstrong* v. *Exceptional Child Center, Inc.,* 135 S. Ct. 1378 (2015), ruled that Medicaid providers and beneficiaries do not have a private right of action to challenge Medicaid payment rates in Federal courts. This decision means provider and beneficiary legal challenges are unavailable in Federal court to supplement our oversight as a means of ensuring compliance with section 1902(a)(30)(A) of the Act. The Armstrong decision also underscored HHS' and CMS' unique responsibility for resolving issues concerning the interpretation and implementation of section 1902(a)(30)(A) of the Act. By concluding that the responsible Federal administrative agency is better suited than Federal courts to make determinations regarding the sufficiency of Medicaid payment rates, the Supreme Court's Armstrong decision placed added importance on CMS' administrative review of SPAs proposing to reduce or restructure FFS payment rates. Accordingly, the 2015 final rule with comment period was an effort to establish a more robust oversight and enforcement strategy with respect to section 1902(a)(30)(A) of the Act.

In consideration of State agencies' and other interested parties' feedback on the AMRP process, as well as CMS' obligation to ensure continued compliance with section 1902(a)(30)(A) of the Act, we propose to update the requirements in § 447.203. We propose to rescind and replace the AMRP requirements currently in § 447.203(b)(1) through (8) with a streamlined and standardized process, described in proposed § 447.203(b) and (c). This proposed change is informed by a center-wide review of our policy and processes regarding access to care for all facets of the Medicaid program. The 2015 final rule with comment period acknowledged our need to better understand FFS rate actions and their potential impact on State programs, and the requirements we finalized require a considerable amount of data from States. To ensure States were meeting the statutory requirement under section 1902(a)(30)(A) of the Act, the AMRP process was originally intended to establish a transparent data-driven process for States to measure the current status of access to services within the State and utilize this process for monitoring access when proposing rate reductions and restructurings.[110] As the rule took effect and as we reviewed State's AMRPs, we found that some rate reductions and restructurings had much smaller impacts than others. The 2017 SMDL reflected the experience that certain payment rate changes would not likely result in diminished access to care and do not require the substantial review of access data that generally is required under the 2015 final rule with comment period. Since publication of the 2019 CMCS Informational Bulletin stating the agency's intention to establish a new access strategy, we have developed this proposal for a new process that considers the lessons learned under the AMRP process, and emphasizes transparency and data

[103] 76 FR 26341.

[104] 80 FR 67576 at 67583–67584.

[105] 81 FR 21479 at 21479.

[106] American Medical Association, Comment Letter on 2015 Final Rule with Comment Period (January 4, 2016), *https://www.regulations.gov/comment/CMS-2011-0062-0328.*

[107] American Association of Retired Persons, Comment Letter on 2011 Propose Rule (July 5, 2011), *https://www.regulations.gov/comment/CMS-2011-0062-0121.*

[108] 76 FR 26341 at 26349.

[109] 80 FR 67576 at 67577, 67579, 67590.

[110] 80 FR 67576 at 67577.

analysis, with specific proposed requirements varying depending on the State's current payment levels relative to Medicare, the magnitude of the proposed rate reduction or restructuring, and any access to care concerns raised to State Medicaid agency by interested parties. With these proposed provisions, we aim to balance Federal and State administrative burden with our shared obligation to ensure compliance with section 1902(a)(30)(A) of the Act (and our obligation to oversee State compliance with the same).

1. Fully Fee-For-Service States

We are seeking comment on whether additional access standards for States with a fully FFS delivery system may be appropriate. Because the timeliness standards of the proposed Medicaid and Children's Health Insurance Program Managed Care Access, Finance, and Quality proposed rule (Managed Care proposed rule) at § 438.68 would not apply to any care delivery in such States, we are considering whether a narrow application of timeliness standards to fully FFS States that closely mirrors the proposed appointment wait time standards, secret shopper survey requirements, and publication requirements (as applied to outpatient mental health and substance use disorder, adult and pediatric; primary care, adult and pediatric; obstetrics and gynecology; and an additional type of service determined by the State) in that rule might be appropriate. Given that timeliness standards would apply directly to States, we also seek comment on a potentially appropriate method for CMS to collect data demonstrating that States meet the established standards at least 90 percent of the time.

2. Payment Rate Transparency (§ 447.203(b))

We propose to rescind § 447.203(b) in its entirety and replace it with new requirements to ensure FFS Medicaid payment rate adequacy, including a new process to promote payment rate transparency. This new proposed process would require States to publish their FFS Medicaid payment rates in a clearly accessible, public location on the State's website, as described later in this section. Then, for certain services, States would be required to conduct a comparative payment rate analysis between the States' Medicaid payment rates and Medicare rates, or provide a payment rate disclosure for certain HCBS that would permit CMS to develop and publish HCBS payment benchmark data.

In paragraph (b)(1), we propose to require the State agency to publish all Medicaid FFS payment rates on a website developed and maintained by the single State agency that is accessible to the general public. We propose that published Medicaid FFS payment rates would include fee schedule payment rates made to providers delivering Medicaid services to Medicaid beneficiaries through a FFS delivery system. We also propose to require that the website be easily reached from a hyperlink easily reached from a hyperlink on the State Medicaid agency's website.

Within this payment rate publication, we propose that FFS Medicaid payment rates must be organized in such a way that a member of the public can readily determine the amount that Medicaid would pay for the service and, in the case of a bundled or similar payment methodology, identify each constituent service included within the rate and how much of the bundled payment is allocated to each constituent service under the State's methodology. We also propose that, if the rates vary, the State must separately identify the Medicaid FFS payment rates by population (pediatric and adult), provider type, and geographical location, as applicable.

Longstanding legal requirements to provide effective communication with individuals with disabilities and the obligation to take reasonable steps to provide meaningful access to individuals with limited English proficiency also apply to the State's website containing Medicaid FFS payment rate information. Under Title II of the Americans with Disabilities Act of 1990, section 504 of the Rehabilitation Act, section 1557 of the Affordable Care Act, and implementing regulations, qualified individuals with disabilities may not be excluded from participation in, or denied the benefits of any programs or activities of the covered entity, or otherwise be subjected to discrimination by any covered entity, on the basis of disability, and programs must be accessible to people with disabilities.[111] Individuals with disabilities are entitled to communication that is as effective as communication for people without disabilities, including through the provision of auxiliary aids and services.[112] Section 1557 of the Affordable Care Act requires recipients of Federal financial assistance, including State Medicaid programs, to take reasonable steps to provide meaningful access to their programs or activities for individuals with limited English proficiency, and requires the provision of interpreting services and translations when it is a reasonable step to provide meaningful access.[113]

We propose that for States that pay varying Medicaid FFS payment rates by population (pediatric and adult), provider type, and geographical location, as applicable, those States would need to separately identify their Medicaid FFS payment rates in the payment rate transparency publication by each grouping or multiple groupings, when applicable to a State's program. In the event rates vary according to these factors, as later discussed in this proposed rule, our intent is that a member of the public be readily able to determine the payment amount that would be made, accounting for all relevant circumstances. For example, a State that varies their Medicaid FFS payment rates by population may pay for a service identified by code 99202 when provided to a child at a rate of $110.00 and when provided to an adult at a rate of $80.00. Because the Medicaid FFS payment rates vary based on population, both of these Medicaid FFS payment rates would need to be included separately as Medicaid FFS payment rates for 99202 in the State's payment rate transparency publication. As another example, a State that varies their Medicaid FFS payment rates by provider type may pay for 99202 when delivered by a physician at a rate of $50.00, and when delivered by a nurse practitioner or physician assistant at a rate of $45.00.

We are aware that some State plans include language that non-physician practitioners (NPPs), such as a nurse practitioner or physician assistant, are paid a percentage of the State's fee schedule rate. Because the Medicaid FFS payment rates vary by provider type, both of the Medicaid FFS payment rates in both situations (fee schedule rates of $50.00 and $45.00) would need to be separately identified as Medicaid FFS payment rates for 99202 in the State's payment rate transparency publication, regardless of whether the State has individually specified each amount certain in its approved payment schedule or has State plan language specifying the nurse practitioner or physician assistant rate as a percentage of the physician rate. Additionally, for

[111] 29 U.S.C. 794; 42 U.S.C. 18116(a); 42 U.S.C. 12132; 28 CFR. 35.130(a); 45 CFR 84.4(a); 45 CFR 92.2(b).

[112] 28 CFR 35.160; 45 CFR 92.102; *see also* 45 CFR 84.52(d).

[113] 45 CFR 92.101; *see also https://www.hhs.gov/civil-rights/for-providers/laws-regulations-guidance/guidance-federal-financial-assistance-title-vi/index.html.*

example, a State that varies their Medicaid FFS payment rates by geographical location may pay for 99202 delivered in a rural area at a rate of $70, in an urban or non-rural area as a rate of $60, and in a major metropolitan area as a rate of $50. We are also aware that States may vary their Medicaid FFS payment rates by geographical location by zip code, by metropolitan or micropolitan areas, or other geographical location breakdowns determined by the State. Because the Medicaid FFS payment rates vary based on geographical location, all Medicaid FFS payment rates based on geographical location would need to be included separately as Medicaid FFS payment rates for 99202 in the State's payment rate transparency publication.

For a State that varies its Medicaid FFS payment rates by any combination of these groupings, then the payment rate transparency publication would be required to reflect these multiple groupings. For example, the State would be required to separately identify the rate for a physician billing 99202 provided to a child in a rural area, the rate for a nurse practitioner billing 99202 provided to a child in a rural area, the rate for a physician billing 99202 provided to an adult in a rural area, the rate for a nurse practitioner billing 99202 provided to an adult in a rural area, the rate for a physician billing 99202 provided to a child in an urban area, the rate for a nurse practitioner billing 99202 provided to a child in an urban area, and so on. This information would be required to be presented clearly so that a member of the public can readily determine the payment rate for a service that would be paid for each grouping or combination of groupings (population (pediatric and adult), provider type, and geographical location), as applicable. We acknowledge that States may also pay a single Statewide rate regardless of population (pediatric and adult), provider type, and geographical location, and as such would only need to list the single Statewide rate in their payment rate transparency publication.

We acknowledge that there may be additional burden associated with our proposal that the payment rate transparency publication include a payment rate breakdown by population (pediatric and adult), provider type, and geographical location, as applicable, when States' Medicaid FFS payment rates vary based on these groupings. Despite the additional burden, we believe that the additional level of granularity in the payment rate transparency publication is important for ensuring compliance with section 1902(a)(30)(A) of the Act, given State Medicaid programs rely on multiple provider types to deliver similar services to Medicaid beneficiaries of all ages, across multiple Medicaid benefit categories, throughout each area of each State.

We further propose that Medicaid FFS payment rates published under the proposed payment rate transparency requirement would only include fee schedule payment rates made to providers delivering Medicaid services to Medicaid beneficiaries through a FFS delivery system. To ensure maximum transparency in the case of a bundled fee schedule payment rate or rate determined by a similar payment methodology where a single payment rate is used to pay for multiple services, we propose that the State must identify each constituent service included in the bundled fee schedule payment rate or rate determined by a similar payment methodology. We also propose that the State must identify how much of the bundled fee schedule payment rate or rate determined by a similar payment methodology is allocated to each constituent service under the State's payment methodology. For example, if a State's fee schedule lists a bundled fee schedule rate that pays for day treatment under the rehabilitation benefit and the following services are included in the day treatment bundle: community based psychiatric rehabilitation and support services, individual therapy, and group therapy, then the State would need to identify services community based psychiatric rehabilitation and support services, individual therapy, and group therapy separately and each portion of the bundled fee schedule payment rate for day treatment that is allocated to community based psychiatric rehabilitation and support services, individual therapy, and group therapy. Proposing to require States identify the portion of the bundled fee is allocable to each constituent service included in the bundled fee schedule payment rate would add an additional level of granularity to the payment rate transparency publication that continues to enable a member of the public to readily be able to determine the payment amount that would be made for a service, accounting for all relevant circumstances, including the payment rates for each constituent service within a bundle and as a standalone service. We also propose to require that the website be easily reached from a hyperlink to ensure transparency of payment rate information is available to beneficiaries, providers, CMS, and other interested parties.

We propose the initial publication of Medicaid FFS payment rates would occur no later than January 1, 2026, and include approved Medicaid FFS payment rates in effect as of that date, January 1, 2026. We propose this timeframe to provide States with at least 2 years from the possible effective date of the final rule, if this proposal is finalized, to comply with the payment rate transparency requirement. The proposed timeframe would initially set a consistent baseline for all States to first publish their payment rate transparency information and then set a clear schedule for States to update their payment rates based on the cadence of the individual States' payment rate changes.

The same initial publication due date for all States to publish their payment rates as of January 1, 2026, would promote comparability between States' payment rate transparency publications. Once States would begin making updates to their payment rate transparency publication, there would be a clear distinction between State payment rates that have recently updated their payment rates and State payment rates that have long maintained the same payment rates. For example, two States initially publish their payment rates for 99202 at $50; however, one State annually increases their payment rate by 5 percent over the next 2 years and would update their payment rate transparency publication in 2027 with a payment rate of $52.50, then in 2028 with a payment rate of $55.13, while the other States' payment rate for the same service remains at $50 in 2027 and 2028. The transparency of a State's recent payment rates including the date the payment rates were last updated on the State Medicaid agency's website, as discussed later, as well as the ability to compare payment rates between States on accessible and easily reachable State-maintained websites, highlights how the proposed payment rate transparency would help to ensure that Medicaid payment rate information is available to beneficiaries, providers, CMS, and other interested parties for the purposes of assessing access to care issues to better ensure compliance with section 1902(a)(30)(A) of the Act.

We also propose that the initial publication include approved Medicaid FFS payment rates in effect as of January 1, 2026. We propose this language to narrow the scope of the publication to CMS-approved payment rates and methodologies, thereby excluding any rate changes for which a SPA or similar amendment request is

pending CMS review or approval. SPAs are submitted throughout the year, can include retroactive effective dates, and are subject to a CMS review period that varies in duration.[114] [115]

As discussed later in this proposed rule regarding paragraph (b)(2) and(b)(3), States are encouraged to use the proposed payment rate transparency publication as a source of Medicaid payment rate data for compliance with the paragraph (b)(3)(i)(B) proposed comparative payment rate analysis and paragraph (b)(3)(ii)(B) proposed payment rate disclosure requirements. However, we note that the comparative payment rate analysis and payment rate disclosure requirements impose a one-year lag on the date when rates are effective. We include a more in-depth discussion of the timeframes for publication of the comparative payment rate analysis and payment rate disclosure in paragraph (b)(4) later in this proposed rule, where we note that the 1-year shift in timeframe is necessitated by the timing of when Medicare publishes their payment rates in November and the rates taking effect on January 1, leaving insufficient time for CMS to publish the code list for States to use for the comparative payment rate analysis and for States develop and publish their comparative payment rate analysis and payment rate disclosure by January 1. We note that the ongoing payment transparency publication requirements will allow the public to view readily available, current Medicaid payment rates at all times, even if slightly older Medicaid payment rate information must be used for comparative payment rate analyses due to the cadence of Medicare payment rate changes as well as the payment rate disclosure. We are cognizant that the payment rate disclosure does not depend on the availability of Medicare payment rates, however, we are proposing to provide States with the same amount of time to comply with both of the proposed comparative payment rate analysis and payment rate disclosure requirements.

If this proposal is finalized at a time that does not allow for States to have a period of at least 2 years between the effective date of the final rule and the proposed January 1, 2026, due date for the initial publication of Medicaid FFS payment rates, then we would propose an alternative date of July 1, 2026, for the initial publication of Medicaid FFS payment rates and for the initial publication to include approved Medicaid FFS payment rates as of that date, July 1, 2026. This shift would allow more time for States to comply with the payment rate transparency requirements. We acknowledge that the date of the initial payment rate transparency publication is subject to change based on the final rule publication schedule and effective date, if this rule is finalized. If further adjustment is necessary beyond the July 1, 2026, timeframe to allow adequate time for States to comply with the payment rate transparency requirements, then we would adjust date of the initial payment rate transparency publication in 6-month intervals, as appropriate, to allow for approximately 2 years between the effective date of the final rule and the initial required payment rate transparency publication.

We propose to require the that the single State agency include the date the payment rates were last updated on the State Medicaid agency's website. We also propose to require that the single State agency ensure that Medicaid FFS payment rates are kept current where any necessary updates to the State fee schedules made no later than 1 month following the date of CMS approval of the SPA, section 1915(c) HCBS waiver, or similar amendment revising the provider payment rate or methodology. Finally, in paragraph (b)(1), we propose that, in the event of a payment rate change that occurs in accordance with a previously approved rate methodology, the State would be required to update its payment rate transparency publication no later than 1 month after the effective date of the most recent update to the payment rate. This provision is intended to capture Medicaid FFS payment rate changes that occur because of previously approved SPAs containing payment rate methodologies. For example, if a State sets their Medicaid payment rates for Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) at a percentage of the most recent Medicare fee schedule rate, then the State's payment rate would change when Medicare adopts a new fee schedule rate through the quarterly publications of the Medicare DMEPOS fee schedule, unless otherwise specified in the approved State plan methodology that the State implements a specific quarterly publication, for example, the most recent April Medicare DMEPOS fee schedule. Therefore, the State's Medicaid FFS payment rate automatically updates when Medicare publishes a new fee schedule, without the submission of a SPA because the State's methodology pays a percentage of the most recent State plan specified Medicare fee schedule rate. In this example, the State would need to update its Medicaid FFS payment rates in the payment rate transparency publication no later than 1 month after the effective date of the most recent update to the Medicare fee schedule payment rate made applicable under the approved State plan payment methodology.

While there is no current Federal requirement for States to consistently publish their rates in a publicly accessible manner, we are aware that most States already publish at least some of their payments through FFS rate schedules on State agency websites. Currently, rate information may not be easily obtained from each State's website in its current publication form, making it difficult to understand the amounts that States pay providers for items and services furnished to Medicaid beneficiaries and to compare Medicaid payment rates to other health care payer rates or across States. However, through this proposal we seek to ensure all States do so in a format that is publicly accessible and where all Medicaid FFS payment rates can be easily located and understood. The new transparency requirements under this proposed rule would help to ensure that interested parties have access to updated payment rate schedules and could conduct analyses that would provide insights into how State Medicaid payment rates compare to, for example, Medicare payment rates and other State Medicaid payment rates. The proposal intends to help ensure that payments are transparent and clearly understandable to beneficiaries, providers, CMS, and other interested parties. We are seeking public comment on the proposed requirement for States to publish their Medicaid FFS payment rates for all services, the proposed structure for Medicaid FFS payment rate transparency publication on the State's website, and the timing of the publication of and updates to the State's Medicaid FFS payment rates for the

[114] In accordance with 42 CFR 430.20, an approved SPA can be effective no earlier than the first day of the calendar quarter in which an approvable amendment is submitted. For example, a SPA submitted on September 30th can be retroactively effective to July 1st.

[115] In accordance with 42 CFR 430.16, a SPA will be considered approved unless CMS, within 90 days after submission, requests additional information or disapproves the SPA. When additional information is requested by CMS and the State has respond to the request, CMS will then have another 90 days to either approve, disapprove, and request the State withdraw the SPA or the State's response to the request for additional information. This review period includes two 90-day review periods plus additional time when CMS has requested additional information which can result is a wide variety of approval timeframes.

proposed payment rate transparency requirements in § 447.203(b)(1).

In paragraph (b)(2), we propose to require States to develop and publish a comparative payment rate analysis of Medicaid payment rates for certain specified services, and a payment rate disclosure for certain HCBS. In paragraph (b)(2) we specify the categories of services that States would be required to include in a comparative payment rate analysis and payment rate disclosure of Medicaid payment rates. Specifically, we are proposing that for each of the categories of services in paragraphs (b)(2)(i) through (iii), each State agency would be required to develop and publish a comparative payment rate analysis of Medicaid payment rates as specified in proposed § 447.203(b)(3). We also propose that for each of the categories of services in paragraph (b)(2)(iv), each State agency would be required to develop and publish a payment rate disclosure of Medicaid payment rates as specified in proposed § 447.203(b)(3). We propose for both the comparative payment rate analysis and payment rate disclosure that, if the rates vary, the State must separately identify the payment rates by population (pediatric and adult), provider type, and geographical location, as applicable. The categories of services listed in paragraph (b)(2) include: primary care services; obstetrical and gynecological services; outpatient behavioral health services; and personal care, home health aide, and homemaker services, as specified in § 440.180(b)(2) through (4), provided by individual providers and providers employed by an agency.

In paragraph (b)(2), we propose to require States separately identify the payment rates in the comparative payment rate analysis and payment rate disclosure, if the rates vary, by population (pediatric and adult), provider type, and geographical location, as applicable. These proposed breakdowns of the Medicaid payment rates, similar to how we propose payment rates would be broken down in the payment rate transparency disclosures under proposed § 447.203(b)(1), would apply to all proposed categories of services listed in paragraph (b)(2): primary care services, obstetrical and gynecological services, outpatient behavioral health services, and personal care, home health aide, and homemaker services provided by individual providers and providers employed by an agency.

We acknowledge that not all States pay varied payment rates by population (pediatric and adult), provider type, and geographical location, which is why we have included language ''if the rates vary'' and ''as applicable'' in the proposed regulatory text. This language is included in the proposed regulatory text to ensure the comparative payment rate analysis and payment rate disclosure captures all Medicaid payment rates, including when States pay varied payment rates by population (pediatric and adult), provider type, and geographical location. We also included proposed regulatory text for the payment rate disclosure that ensures the average hourly payment rates for *COM007*personal care, home health aide, and homemaker services provided by individual providers and providers employed by an agency are separately identified for payments made to individual providers and to providers employed by an agency, if the rates vary, as later discussed in connection with proposed § 447.203(b)(3)(ii). For States that do not pay varied payment rates by population (pediatric and adult), provider type, and geographical location and pay a single Statewide payment rate for a single service, then the comparative payment rate analysis and payment rate disclosure would only need to include the State's single Statewide payment rate.

We propose to include a breakdown of Medicaid payment rates by population (pediatric and adult), provider type, and geographical location, as applicable, on the Medicaid side of the comparative payment rate analysis in paragraph (b)(2) to align with the proposed payment rate transparency provision, to account for State Medicaid programs that pay variable Medicaid payment rates by population (pediatric and adult), provider type, and geographical location, and to help ensure the State's comparative payment rate analyses accurately align with Medicare. Following the initial year that the provisions proposed in this rule would be in effect, these proposed provisions would align with and build on the payment rate transparency requirements described in § 447.203(b)(1), because States could source the codes and their corresponding Medicaid payment rates that the State already would publish to meet the payment rate transparency requirements.

These proposed provisions are also intended to help ensure that the State's comparative payment rate analysis contains the highest level of granularity in each proposed aspect by considering and accounting for any variation in Medicaid payment rates by population (pediatric and adult), provider type, and geographical location, as currently required in the AMRP process under current § 447.203(b)(1)(iv) and (v), and (b)(3). Additionally, Medicare varies payment rates for certain NPPs (nurse practitioners, physician assistants, and clinical nurse specialists) by paying them 85 percent of the full Medicare physician fee schedule amount and varies their payment rates by geographical location through calculated adjustments to the pricing amounts to reflect the variation in practice costs from one geographical location to another; therefore, the comparative payment rate analysis accounting for these payment rate variations is crucial to ensuring the Medicaid FFS payment rates accurately align with FFS Medicare Physician Fee Schedule (PFS) rates.[116] As discussed later in this proposed rule, Medicare payment variations for provider type and geographical location would be directly compared with State Medicaid payment rates that also apply the same payment variations, in addition to payment variation by population (pediatric and adult) which is unique to Medicaid, yet an important payment variation to take into consideration when striving for transparency of Medicaid payment rates. For States that do not pay varied payment rates by population (pediatric and adult), provider type, or geographical location and pay a single Statewide payment rate for a single service, Medicare payment variations for provider type and geographical location would be considered by calculating a Statewide average of Medicare PFS rates which is later discussed in this proposed rule.

Similar to the payment rate transparency publication, we acknowledge that there may be additional burden associated with our proposal that the payment rate transparency publication and the comparative payment rate analysis include a payment rate breakdown by population (pediatric and adult), provider type, and geographical location, as applicable, when States' payment rates vary based on these groupings. However, we believe that any approach to requiring a comparative payment rate analysis would involve some level of burden that is greater for States that choose to employ these payment rate differentials, since any comparison methodology would need to take account—through a separate comparison, weighted average, or other mathematically reasonable approach—of all rates paid under the Medicaid program for a given service. In all

[116] *https://www.medpac.gov/wp-content/uploads/2021/11/MedPAC_Payment_Basics_22_Physician_FINAL_SEC.pdf.*

events, we believe this proposal would create an additional level granularity in the analysis that is important for ensuring compliance with section 1902(a)(30)(A) of the Act. Multiple types of providers, for example, physicians, physician assistants, and nurse practitioners, are delivering similar services to Medicaid beneficiaries of all ages, across multiple Medicaid benefit categories, throughout each State. Section 1902(a)(30)(A) states ''. . . that payments are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area,'' and we believe that having sufficient access to a variety of provider types is important to ensuring access for Medicaid beneficiaries meets this statutory standard. For example, a targeted payment rate reduction to nurse practitioners, who are often paid less than 100 percent of the State's physician fee schedule rate, could have a negative impact on access to care for services provided by nurse practitioners, but this reduction would not directly impact physicians or their willingness to participate in Medicaid and furnish services to beneficiaries. By proposing that the comparative payment rate analysis include a breakdown by provider type, where States distinguish payment rates for a service by provider type, the analysis would capture this payment rate variation among providers of the same services and provide us with a granular level of information to aid in determining if access to care is sufficient, particularly in cases where beneficiaries depend to a large extent on the particular provider type(s) that would be affected by the proposed rate change for the covered service(s).

We identified payment rate variation by population (pediatric and adult), provider type, and geographical location as the most commonly applied adjustments to payment rates that overlap between FFS Medicaid and Medicare and could be readily broken down into separately identified payment rates for comparison in the comparative payment rate analysis. For transparency purposes and to help to ensure the comparative payment rate analysis is conducted at a granular level of analysis, we believe it is important for the State to separately identify their rates, if the rates vary, by population (pediatric and adult), provider type, and geographical location, as applicable. We are seeking public comments on the proposal to require the comparative payment rate analysis includes, if the rates vary, separate identification of payment rates by population (pediatric and adult), provider type, and geographical location, as applicable, in the comparative payment rate analysis in proposed § 447.203(b)(2).

We acknowledge that States may apply additional payment adjustments or factors, for example, the Consumer Price Index, Medicare Economic Index, or State-determined inflationary factors or budget neutrality factors, to their Medicaid payment rates other than population (pediatric and adult), provider type, and geographical location identified in this proposed rule. We would expect any other additional payment adjustments and factors to already be included in the State's published Medicaid fee schedule rate or calculable from the State plan because § 430.10 requires the State plan to be a ''comprehensive written statement . . . contain[ing] all information necessary for CMS to determine whether the plan can be approved to serve as a basis for . . . FFP . . .'' Therefore, for States paying for services with a fee schedule payment rate, the Medicaid fee schedule is the sole source of information for providers to locate their final payment rate for Medicaid services provide to Medicaid beneficiaries under a FFS delivery system. For States with a rate-setting methodology where the approved State plan describes how rates are set based upon a fee schedule (for example, payment for NPPs are set a percentage of a certain published Medicaid fee schedule), the Medicaid fee schedule would again be the source of information for providers to identify the relevant starting payment rate and apply the rate-setting methodology described in the State plan to ascertain their Medicaid payment.[117] We are also seeking public comment on any additional types of payment adjustments or factors States make to their Medicaid payment rates as listed on their State fee schedules that should be identified in the comparative payment rate analysis that we have not already discussed in § 447.203(b)(i)(B) of this proposed rule, and how the inclusion of any such additional adjustments or factors should be considered in the development of the Medicare PFS rate to compare Medicaid payment rates to, as later described in § 447.203(b)(3)(i)(C), of this proposed rule.

In paragraphs (b)(2)(i) through (iv), we propose that primary care services, obstetrical and gynecological services, and outpatient behavioral health services would be subject to a comparative payment rate analysis of Medicaid payment rates and personal care, home health aide, and homemaker services provided by individual providers and providers employed by an agency would be subject to a payment rate disclosure of Medicaid payment rates. We begin with a discussion about the importance of primary care services, obstetrical and gynecological services, and outpatient behavioral health services as proposed in § 447.203(b)(2)(i) through (iii), and the reason for their inclusion in this proposed requirement. Then, we will discuss the importance and justification for including personal care, home health aide, and homemaker services provided by individual providers and providers employed by an agency as proposed in § 447.203(b)(2)(iv).

In § 447.203(b)(2)(i) through (iii), we propose to require primary care services, obstetrical and gynecological services, and outpatient behavioral health services be included in the comparative payment rate analysis, because we believe that these categories of services are critical preventive, routine, and acute medical services in and of themselves, and that they often serve as gateways to access to other needed medical services, including specialist services, laboratory and x-ray services, prescription drugs, and other mandatory and optional Medicaid benefits that States cover. Including these categories of services in the comparative payment rate analysis would require States to closely examine their Medicaid FFS payment rates to comply with section 1902(a)(30)(A) of the Act. As described in the recent key findings from public comments on the February 2022 RFI that we published, payment rates are a key driver of provider participation in the Medicaid program.[118] By proposing that States compare their Medicaid payment rates for primary care services, obstetrical and gynecological services, and outpatient behavioral health services to Medicare payment rates, States would be required to analyze if and how their payments are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and

[117] *https://www.medicaid.gov/state-resource-center/downloads/spa-and-1915-waiver-processing/fed-req-pymt-methodologies.docx.*

[118] Summary of Public Comments in response to the CMS 2022 Request for Information: Access to Coverage and Care in Medicaid & CHIP. December 2022. For the report, see *https://www.medicaid.gov/medicaid/access-care/downloads/access-rfi-2022-report.pdf.*

services are available to the general population in the geographic area.

As discussed later in this section, we believe that Medicare payment rates for these services are likely to serve as a reliable benchmark for a level of payment sufficient to enlist providers to furnish the relevant services to a beneficiary because Medicare delivers services through a FFS delivery system across all geographical regions of the US and historically, the vast majority of physicians accept new Medicare patients, with extremely low rates of physicians opting out of the Medicare program, suggesting that Medicare's payment rates are generally consistent with a high level of physician willingness to accept new Medicare patients.[119] Additionally, Medicare payment rates are publicly published in an accessible and consistent format by CMS making Medicare payment rates an available and reliable comparison point for States, rather than private payer data which typically is considered proprietary information and not generally available to the public. Therefore, the proposed requirement that States develop and publish a comparative payment rate analysis would enable States, CMS, and other interested parties to closely examine the relationship between State Medicaid FFS payment rates and those paid by Medicare. This analysis would continually help States to ensure that their Medicaid payment rates are set at a level that is likely sufficient to meet the statutory access standard under 1902(a)(30)(A) of the Act that payments by enlisting enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area. We believe that the comparative payment rate analysis would provide States, CMS, and other interested parties with clear and concise information for identifying when there is a potential access to care issue, such as Medicaid payment rates not keeping pace with changes in corresponding Medicare rates and decreases in claims volume and beneficiary utilization of services. As discussed later in this section, numerous studies have found a relationship between Medicaid payment rates and provider participation in the Medicaid program and, given the statutory standard of ensuring access for Medicaid beneficiaries, a comparison of Medicaid payment rates to other payer rates, particularly Medicare payment rates as justified later in this rule, is an important barometer of whether State payment rates and policies are sufficient for meeting the statutory access standard under section 1902(a)(30)(A) of the Act.

We propose to focus on these particular services because they are critical medical services and of great importance to overall beneficiary health. Beginning with primary care, these services provide access to preventative services and facilitate the development of crucial doctor-patient relationships. Primary care providers often deliver preventative health care services, including immunizations, screenings for common chronic and infectious diseases and cancers, clinical and behavioral interventions to manage chronic disease and reduce associated risks, and counseling to support healthy living and self-management of chronic diseases; Medicaid coverage of preventative health care services promotes disease prevention which is critical to helping people live longer, healthier lives.[120] Accessing primary care services can often result in beneficiaries receiving referrals or recommendations to schedule an appointment with physician specialists, such as gastroenterologists or neurologists, that they would not be able to obtain without the referral or recommendation by the primary care physician. Additionally, primary care physicians provide beneficiaries with orders for laboratory and x-ray services as well as prescriptions for necessary medications that a beneficiary would not be able to access without the primary care physician. Research over the last century has shown that the impact of the doctor-patient relationship on patient's health care experience, health outcomes, and health care costs exists [121] and more recent studies have shown that the quality of the physician-patient relationship is positively associated with functional health among patients.[122] Another study found that higher primary care payment rates reduced mental illness and substance use disorders among non-elderly adult Medicaid enrollees, suggesting that positive spillover from increasing primary care rates also positively impacted behavioral health outcomes.[123] Lastly, research has shown that a reduction in barriers to accessing primary care services has been associated with helping reduce health disparities and the risk of poor health outcomes. [124] [125] These examples illustrate how crucial access to primary care services is for overall beneficiary health and to enable access to other medical services. We are seeking public comment on primary care services as one of the proposed categories of services subject to the comparative payment rate analysis requirements in proposed § 447.203(b)(2)(i).

Similar to primary care services, both obstetrical and gynecological services and outpatient behavioral health services provide access to preventative and screening services unique to each respective field. A well-woman visit to an obstetrician–gynecologist often provides access to screenings for cervical and breast cancer; screenings for Rh(D) incompatibility, syphilis infection, and hepatitis B virus infection in pregnant persons; monitoring for healthy weight and weight gain in pregnancy; immunization against the human papillomavirus infection; and perinatal depression screenings among other recommended preventive services.[126] [127] Behavioral health care

[119] Physicians and practitioners who do not wish to enroll in the Medicare program may ''opt-out'' of Medicare. This means that neither the physician, nor the beneficiary submits the bill to Medicare for services rendered. Instead, the beneficiary pays the physician out-of-pocket and neither party is reimbursed by Medicare. A private contract is signed between the physician and the beneficiary that states, that neither one can receive payment from Medicare for the services that were performed. See *https://data.cms.gov/provider-characteristics/medicare-provider-supplier-enrollment/opt-out-affidavits.*

[120] *https://www.medicaid.gov/medicaid/benefits/prevention/index.html.*

[121] Cockerham, W.C. (2021). *The Wiley Blackwell Companion to Medical Sociology* (1st ed.). John Wiley & Sons.

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[123] Maclean, Johanna Catherine, McCleallan, Chandler, Pesko, Michael F., and Polsky, Daniel. (2023). Medicaid reimbursement rates for primary care services and behavioral health outcomes. Health economics, 1–37. *https://doi.org/10.1002/hec.4646.*

[124] Starfield, B., Shi, L., & Macinko, J. (2005). Contribution of primary care to health systems and health. The Milbank quarterly, 83(3), 457–502. *https://doi.org/10.1111/j.1468-0009.2005.00409.x.*

[125] *https://health.gov/healthypeople/priority-areas/social-determinants-health/literature-summaries/access-primary-care.*

[126] Rh(D) incompatibility is a preventable pregnancy compilation where a woman who is Rh negative is carrying a fetus that is Rh positive (Rh factor is a protein that can be found on the surface of red blood cells). When the blood of an Rh-positive fetus gets into the bloodstream of an Rh-negative woman, her body will recognize that the Rh-positive blood is not hers. Her body will try to destroy it by making anti-Rh antibodies. These antibodies can cross the placenta and attack the fetus's blood cells. This can lead to serious health problems, even death, for a fetus or a newborn. Prevention of Rh(D) incompatibility screening for Rh negative early in pregnancy (or before pregnancy) and, if needed, giving you a medication to prevent antibodies from forming.

Continued

promotes mental health, resilience, and wellbeing; the treatment of mental and substance use disorders; and the support of those who experience and/or are in recovery from these conditions, along with their families and communities. Outpatient behavioral health services can overlap with preventative primary care and obstetrical and gynecological services, for example screening for depression in adults and perinatal depression screenings, but also provide unique preventative and screening services such as screenings for unhealthy alcohol use in adolescents and adults, anxiety in children and adolescents, and eating disorders in adolescents and adults, among other recommended preventive services.[128]

The U.S. is simultaneously experiencing a maternal health crisis and mental health crisis, putting providers of obstetrical and gynecological and outpatient behavioral health services, respectively, at the forefront.[129] [130] According to MACPAC, ''Medicaid plays a key role in providing maternity-related services for pregnant women, paying for slightly less than half of all births nationally in 2018.'' [131] Given Medicaid's significant role in maternal health during a time when maternal mortality rates in the United States continue to worsen and the racial disparities among mothers continues to widen,[132] [133] accessing obstetrical and gynecological care, including care before, during, and after pregnancy is crucial to positive maternal and infant outcomes.[134] We are seeking public comment on obstetrical and gynecological services as one of the proposed categories of services subject to the comparative payment rate analysis requirements in proposed § 447.203(b)(2)(ii).

Improving access to behavioral health services is a critical, national issue facing all payors, particularly for Medicaid which plays a crucial role in mental health care access as the single largest payer of services and has a growing role in payment for substance use disorder services, in part due to Medicaid expansion and various efforts by Congress to improve access to mental health and substance use disorder services.[135] [136] Several studies have found an association between reducing the uninsured rate through increased Medicaid enrollment and improved and expanded access to critically needed behavioral health services.[137] Numerous studies have found positive outcomes associated with Medicaid expansion: increases in the insured rate and access to care and medications for adults with depression, increases in coverage rates and a greater likelihood of being diagnosed with a mental health condition as well as the use of prescription medications for a mental health condition for college students from disadvantaged backgrounds,[138] and a decrease in delayed or forgone necessary care in a nationally representative sample of non-elderly adults with serious psychological distress.[139] While individuals who are covered by Medicaid have better access to behavioral health services compared to people who are uninsured, some coverage gaps remain in access to behavioral health care for many people, including those with Medicaid.

Some of the barriers to accessing behavioral health treatment in Medicaid reflect larger system-wide access problems: overall shortage of behavioral health providers in the United States and relatively small number of psychiatrists who accept any form of insurance or participate in health coverage programs.[140] Particularly for outpatient behavioral health services for Medicaid beneficiaries, one reason physicians are unwilling to accept Medicaid patients is because of low Medicaid payment rates.[141] One study found evidence of low Medicaid payment rates by examining outpatient Medicaid claims data from 2014 in 11 States with a primary behavioral health diagnosis and an evaluation and management (E/M) procedure code of 99213 (Established patient office visit, 20–29 minutes) or 99214 (Established patient office visit, 30–39 minutes) and found that psychiatrists in nine States were paid less, on average, than primary care physicians.[142] These pieces of research and data about the importance of outpatient behavioral health services and the existing challenges beneficiaries face in trying to access outpatient behavioral health services underscore how crucial access to outpatient behavioral health services is, and that adequate Medicaid payment rates for these services is likely to be an important driver of access for beneficiaries. We are seeking public comment on outpatient behavioral health services as one of the proposed categories of services subject to the comparative payment rate analysis requirements in proposed § 447.203(b)(2)(iii).

In § 447.203(b)(2)(iv), we propose to require personal care, home health aide, and homemaker services provided by individual providers and providers employed by an agency in the payment rate disclosure requirements proposed in § 447.203(b)(3)(ii). We are cognizant that many HCBS providers nationwide are facing workforce shortages and high staff turnover that have been exacerbated by the COVID–19 pandemic, and these issues and related difficulty accessing HCBS can lead to higher rates of costly, institutional stays for beneficiaries.[143] As with any covered service, the supply of HCBS providers has a direct and immediate impact on beneficiaries' ability to access high quality HCBS, therefore, we included special considerations for LTSS, specifically HCBS, through two proposed provisions in § 447.203. The first provision in proposed paragraph

[127] *https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2018/10/well-woman-visit.*

[128] *https://www.uspreventiveservicestaskforce.org/uspstf/topic_search_results?topic_status=P.*

[129] *https://www.whitehouse.gov/wp-content/uploads/2022/06/Maternal-Health-Blueprint.pdf.*

[130] *https://www.whitehouse.gov/briefing-room/statements-releases/2022/05/31/fact-sheet-biden-harris-administration-highlights-strategy-to-address-the-national-mental-health-crisis/.*

[131] *https://www.macpac.gov/wp-content/uploads/2020/01/Medicaid%E2%80%99s-Role-in-Financing-Maternity-Care.pdf.*

[132] *https://www.cdc.gov/nchs/data/hestat/maternal-mortality/2020/maternal-mortality-rates-2020.htm.*

[133] *https://www.nytimes.com/2022/02/23/health/maternal-deaths-pandemic.html?smid=url-share.*

[134] *https://www.cms.gov/About-CMS/Agency-Information/OMH/equity-initiatives/rural-health/09032019-Maternal-Health-Care-in-Rural-Communities.pdf.*

[135] *https://www.medicaid.gov/medicaid/access-care/downloads/coverage-and-behavioral-health-data-spotlight.pdf.*

[136] *https://www.medicaid.gov/medicaid/benefits/behavioral-health-services/index.html.*

[137] *https://www.cbpp.org/research/health/to-improve-behavioral-health-start-by-closing-the-medicaid-coverage-gap.*

[138] Cowan, Benjamin W. & Hao, Zhuang. (2021). Medicaid expansion and the mental health of college students. Health economics, 30(6), 1306–1327. *https://www.nber.org/system/files/working_papers/w27306/w27306.pdf.*

[139] Novak, P., Anderson, A. C., & Chen, J. (2018). Changes in Health Insurance Coverage and Barriers to Health Care Access Among Individuals with Serious Psychological Distress Following the Affordable Care Act. Administration and policy in mental health, 45(6), 924–932. *https://doi.org/10.1007/s10488-018-0875-9.*

[140] *https://www.kff.org/medicaid/issue-brief/medicaids-role-in-financing-behavioral-health-services-for-low-income-individuals/.*

[141] *https://www.healthaffairs.org/do/10.1377/forefront.20190401.678690/full/.*

[142] Mark, Tami L., Parish, William, Zarkin, Gary A., and Weber, Ellen. (2020). Comparison of Medicaid Reimbursements for Psychiatrists and Primary Care Physicians. Psychiatry services 71(9), 947–950. *https://doi.org/10.1176/appi.ps.202000062.*

[143] *https://www.kff.org/coronavirus-covid-19/event/march-30-web-event-unsung-heroes-the-crucial-role-and-tenuous-circumstances-of-home-health-aides-during-the-pandemic/; https://www.macpac.gov/wp-content/uploads/2022/03/MACPAC-brief-on-HCBS-workforce.pdf.*

(b)(2)(iv) would require States to include personal care, home health aide, and homemaker services provided by individual providers and providers employed by an agency to be included in the payment rate disclosure in proposed paragraph (b)(3)(ii). The second provision in paragraph (b)(6), discussed in the next section, would require States to establish an interested parties' advisory committee to advise and consult on rates paid to certain HCBS providers. This provision is intended to help contextualize lived experience of direct care workers and beneficiaries who receive the services they deliver by providing direct care workers, beneficiaries and their authorized representatives, and other interested parties with the ability to make to recommendations to the Medicaid agency regarding the sufficiency of Medicaid payment rates for these specified services to help ensure sufficient provider participation so that these HCBS are accessible to beneficiaries consistent with section 1902(a)(30)(A) of the Act.

The proposed payment rate disclosure would require States to publish the average hourly payment rates made to individual providers and to providers employed by an agency, separately, if the rates vary, for each category of services specified in paragraph (b)(2)(iv) of this section. No comparison to Medicare payment rates would be required in recognition that Medicare generally does not cover and pay for these services, and when these services are covered and paid for by Medicare, the services are very limited and provided on a short-term basis, rather than long-term basis as with Medicaid HCBS. While Medicare covers part-time or intermittent home health aide services (only if a Medicare beneficiary is also getting other skilled services like nursing and/or therapy at the same time) under Medicare Part A (Hospital Insurance) or Medicare Part B (Medical Insurance), Medicare does not cover personal care or homemaker services.[144]

We propose to require these services be subject to a payment rate disclosure because this proposed rule aims to standardize data and monitoring across service delivery systems with the goal of improving access to care. To remain consistent with the proposed HCBS provisions at § 441.311(d)(2) and (e), where we propose to require annual State reporting on access and payment adequacy metrics for homemaker, home health aide, and personal care services, we are proposing to include these services, provided by individual providers and providers employed by an agency in the FFS payment rate disclosure proposed in § 447.203(b)(2). As described earlier in the HCBS provisions of this rule, these specific services were chosen because we expect them to be most commonly conducted in individuals' homes and general community settings and, therefore, constitute the vast majority of FFS payments for direct care workers delivering services under FFS. We acknowledge that the proposed analyses required of States in the HCBS provisions at § 441.311(d)(2) and (e) and in the FFS provisions at § 447.203(b)(2) are different, although, unique to assessing access in each program and delivery system. We are proposing to include personal care, home health aide, and homemaker services for consistency with HCBS access and payment adequacy provisions in this proposed rule, and also to include these services in the proposed provisions of § 447.203(b)(2) to require States to conduct and publish a payment rate disclosure. We believe the latter proposal is important because the payment rate disclosure of personal care, home health aide, and homemaker services would provide CMS with sufficient information, including average hourly payment rates, claims volume, and number of Medicaid enrolled beneficiaries who received a service as specified in proposed § 447.203(b)(3)(ii), from States for ensuring compliance with section 1902(a)(30)(A) of the Act, which requires that payments be consistent with efficiency, economy, and quality of care and sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area. Additionally, this proposal to include personal care, home health aide, and homemaker services provided by individual providers and providers employed by an agency is supported by the statutory mandate at section 2402(a) of the Affordable Care Act. Among other things, section 2402(a) of the Affordable Care Act directs the Secretary to promulgate regulations ensuring that all States develop service systems that ensure that there is an adequate number of qualified direct care workers to provide self-directed services. We are seeking public comment on personal care, home health aide, and homemaker services provided by individual providers and providers employed by an agency as the proposed categories of services subject to the payment rate disclosure requirements in proposed § 447.203(b)(2)(iv).

After discussing our proposed categories of services for the comparative payment rate analysis and payment rate disclosure requirements, we discuss the similarities and differences between the proposed rule and services currently included in the existing AMRP requirements. While this proposed rule would eliminate the triennial AMRP process, there are some similarities between the service categories for which we are proposing to require a comparative payment rate analysis or payment rate disclosure in § 447.203(b)(2) and those subject to the current AMRP requirements under § 447.203(b)(5)(ii). Specifically, § 447.203(b)(5)(ii)(A) currently requires the State agency to use data collected through the AMRP to provide a separate analysis for each provider type and site of service for primary care services (including those provided by a physician, FQHC, clinic, or dental care). We are proposing the comparative payment rate analysis include primary care services, without any parenthetical description. We believe this is appropriate because the proposed rule includes a comparative payment rate analysis that is at the Current Procedural Terminology (CPT) or Healthcare Common Procedure Coding System (HCPCS) code level, as applicable, the specifics for which are discussed later in this section. This approach requires States to perform less sub-categorization of the data analysis, and as discussed later the analysis, would exclude FQHCs and clinics.

The current AMRP process also includes in § 447.203(b)(5)(ii)(C) behavioral health services (including mental health and substance use disorder); however, this proposed rule specifies that the comparative payment rate analysis only would include outpatient behavioral health services to narrow the scope of the analysis by excluding inpatient behavioral health services (including inpatient behavioral health services furnished in psychiatric residential treatment facilities, institutions for mental diseases, and psychiatric hospitals). While we acknowledge that behavioral health services encompass a broad range of services provided in a wide variety of settings, from outpatient screenings in a physician's office to inpatient hospital treatment, we are proposing to narrow the scope of behavioral health services to just outpatient services to focus the comparative payment rate analysis on ambulatory care provided by practitioners in an office-based setting without duplicating existing

[144] *https://www.medicare.gov/coverage/home-health-services.*

requirements, or analysis that must be completed to satisfy existing requirements, for upper payment limits (UPL) and the supplemental payment reporting requirements under section 1903(bb) of the Act, as established by Division CC, Title II, Section 202 (section 202) of the Consolidated Appropriations Act, 2021 (CAA) (Public Law 116–260).

The proposed categories of services in this rule are delivered as ambulatory care where the patient does not need to be hospitalized to receive the service being delivered. Particularly for behavioral health services, we propose to narrow the scope to outpatient behavioral health services to maintain consistency within the categories of service included in the proposed comparative payment rate analysis and payment rate disclosure all being classified as ambulatory care. Additionally, as discussed further in this section of the proposed rule, we proposed that the comparative payment rate analysis would be conducted on a CPT/HCPCS code level, focusing on E/M codes. By narrowing the comparative payment rate analysis to E/M CPT/HCPCS codes, we are proposing States' analyses includes a broad range of core services which would cover a variety of commonly provided services that fall into the categories of service proposed in paragraphs (b)(2)(i) through (iii). To balance State administrative burden with our oversight of State compliance with the access requirement in section 1902(a)(30)(A) of the Act, we are also proposing to limit the services to those delivered primarily by physicians and NPPs in an office-based setting for primary care, obstetrical and gynecological, and outpatient behavioral health services. By excluding facility-based services, particularly inpatient behavioral health services, we intend to ensure the same E/M CPT/HCPCS code-level methodology could be used for all categories of services included in the proposed comparative payment rate analysis, including the use of E/M CPT/HCPCS codes used for outpatient behavioral health services. Rather than fee schedule rates, States often pay for inpatient behavioral health services using prospective payment rate methodologies, such as Diagnosis Related Groups (DRGs), or interim payment methodologies that are reconciled to actual cost.[145] These methodologies pay for a variety of services delivered by multiple providers that a patient receives during an inpatient hospital stay, rather than a single ambulatory service billed by a single provider using a single CPT/HCPCS code. Variations in these payment methodologies and what is included in the rate could complicate the proposed comparison to FFS Medicare rates for the services identified in paragraphs (b)(2)(i) through (iii) and could frustrate comparisons between States and sometimes even within a single State. Therefore, we do not believe the E/M CPT/HCPCS code level methodology proposed for the comparative payment rate analysis would be feasible for inpatient behavioral health services or other inpatient and facility-based services in general.

While we considered including inpatient behavioral health services as one of the proposed categories of services in the comparative payment rate analysis, we ultimately did not because we already collect and review Medicaid and Medicare payment rate data for inpatient behavioral health services through annual upper payment limits demonstrations (UPL) and supplemental payment reporting requirements under section 1903(bb) of the Act. SMDL 13–003 discusses the annual submission of State UPL demonstrations for inpatient hospital services, among other services, including a complete data set of payments to Medicaid providers and a reasonable estimate of what Medicare would have paid for the same services.[146] [147] UPL requirements go beyond the proposed requirements in this rule by requiring States to annually submit the following data for all inpatient hospital services, depending on the State's UPL methodology, on a provider level basis: Medicaid charges, Medicaid base payments, Medicaid supplemental payments, Medicaid discharges, Medicaid case mix index, Medicaid inflation factors, other adjustments to Medicaid payments, Medicaid days, Medicare costs, Medicare payments, Medicare discharges, Medicare case mix index, Medicare days, UPL inflation factors, Medicaid provider tax cost, and other adjustments to the UPL amount. If we proposed inpatient behavioral health services as one of the categories of services subject to the comparative payment rate analysis, then this proposed rule would require States to biennially submit the following data for only inpatient behavioral health services on a CPT/HCPCS code level basis: Medicaid base payment rates for select E/M CPT/HCPCS codes (accounting for rate variation based on population (pediatric and adult), provider type, and geographical location, as applicable), the corresponding Medicare payment rates, Medicaid base payment rate as a percentage of Medicare payment rate, and the number of Medicaid-paid claims. While the UPL requires aggregated total payment and cost data at the provider level and the comparative payment rate analysis would require more granular base payment data at the CPT/HCPCS code level, the UPL overall requires aggregate Medicaid provider payment data for both base and supplemental payments as well as more detailed data for calculating what Medicare would have paid as the upper payment amount. Therefore, proposing to require States include Medicaid and Medicare payment rate data for inpatient behavioral health services in the comparative payment rate analysis would be duplicative of existing UPL requirements that are inclusive of and more comprehensive than the payment information proposed in the comparative payment rate analysis.

Additionally, section 1903(bb) of the Act requires us to establish a Medicaid supplemental payment reporting system that collects detailed information on State Medicaid supplemental payments, including total quarterly supplemental payment expenditures per provider; information on base payments made to providers that have received a supplemental payment; and narrative information describing the methodology used to calculate a provider's payment, criteria used to determine which providers qualifies to receive a payment, and explanation describing how the supplemental payments comply with section 1902(a)(30)(A) of the Act. Section 1903(bb)(1)(C) of the Act requires us to make State-reported supplemental payment information publicly available. For States making or wishing to make supplemental payments, including for inpatient behavioral health services, States must report supplemental payment information to us and we must make that information public and, therefore, transparent. Though this proposed rule seeks to increase transparency, with the

[145] *https://www.cms.gov/icd10m/version37-fullcode-cms/fullcode_cms/Design_and_development_of_the_Diagnosis_Related_Group_(DRGs).pdf.*

[146] *https://www.medicaid.gov/sites/default/files/Federal-Policy-Guidance/Downloads/SMD-13-003-02.pdf.*

[147] If a State's payment methodology describes payment at no more than 100 percent of the Medicare rate for the period covered by the UPL, then the State does not need to submit a demonstration. See FAQ ID: 92201. *https://www.medicaid.gov/faq/index.html?search_api_fulltext=ID%3A92201&sort_by=field_faq_date&sort_order=DESC.*

proposed provisions under § 447.203(b)(1) through (5) focusing on transparency of FFS Medicaid base payment rates, including inpatient behavioral health services as a category of service in § 447.203(b)(2) subject to the comparative payment rate analysis would be duplicative of the existing upper payment limit and supplemental payment reporting requirements, which capture and make transparent base and supplemental payment information for inpatient behavioral health services. However, we are seeking public comment regarding our decision not to include inpatient behavioral health services as one of the categories of services subject to the comparative payment rate analysis requirements in proposed § 447.203(b)(2) in the final rule, should we finalize the comparative payment rate analysis proposal.

The AMRP process also currently includes in § 447.203(b)(5)(ii)(D) pre- and post-natal obstetric services including labor and delivery; we are proposing to include these services in the comparative payment rate analysis requirements under proposed § 447.203(b)(2)(ii), but intend to broaden the scope of this category of services to include both obstetrical and gynecological services. This expanded proposed provision would capture a wider array of services, both obstetrical and gynecological services, for States and CMS to assess and ensure access to care in Medicaid FFS is at least as great for beneficiaries as is generally available to the general population in the geographic area, as required by with section 1902(a)(30)(A) of the Act. Lastly, similar to current § 447.203(b)(5)(ii)(E), which specifies that Home health services are included in the AMRP process, we are proposing to include personal care, home health aide, and homemaker services, provided by individual providers and providers employed by an agency. This refined proposed provision would help ensure a more standardized effort to monitor access across Medicaid delivery systems, including for Medicaid-covered LTSS. We believe this proposal also addresses public comments received in response to the February 2022 RFI.[148] Many commenters highlighted the workforce crisis among direct care workers and the impact on HCBS. Specifically, commenters indicated that direct care workers receive low payment rates, and for agency-employed direct care workers, home health agencies often cite low Medicaid payment as a barrier to raising wages for workers. Commenters suggested that States should be collecting and reporting to CMS the average of direct care worker wages while emphasizing the importance of data transparency and timeliness. We are responding to these public comments through this proposed rule by proposing to require States to transparently publish a payment rate disclosure that collects and reports the average hourly rate paid to individual providers and providers employed by an agency for services provided by certain direct care workers (personal care, home health aide, and homemaker services).

In public comments that we received during the public comment period for the 2015 final rule with comment period, many commenters requested that we require States to publish access to care analyses for pediatric services, including pediatric primary care, behavioral health, and dental care. At the time, we responded that pediatric services did not need to be specified in the required service categories because States were already required through § 447.203(b)(1)(iv) to consider the characteristics of the beneficiary population, ''including . . . payment variations for pediatric and adult populations,'' within the AMRPs.[149] Although we are proposing to eliminate the AMRP requirements, our proposed rule continues to include special considerations for pediatric populations that are addressed in the discussion of proposed paragraph (b)(2).

We are proposing to eliminate the following from the current AMRP process without replacement in the proposed comparative payment rate analysis requirement, § 447.203(b)(5)(ii)(F): Any additional types of services for which a review is required under current § 447.203(b)(6); § 447.203(b)(5)(ii)(G): Additional types of services for which the State or CMS has received a significantly higher than usual volume of beneficiary, provider or other interested party access complaints for a geographic area, including complaints received through the mechanisms for beneficiary input consistent with current § 447.203(b)(7); and § 447.203(b)(5)(ii)(H): Additional types of services selected by the State.

We propose to eliminate § 447.203(b)(5)(ii)(F) and (G) without a direct replacement because the proposed State Analysis Procedures for Rate Reduction or Restructuring described in § 447.203(c) are inclusive of and more refined than the current AMRP requirements for additional types of services for which a review is required under current § 447.203(b)(6). Specifically, as discussed later in this section, we are proposing in § 447.203(c)(1) that States seeking to reduce provider payment rates or restructure provider payments would be required to provide written assurance and relevant supporting documentation that three conditions are met to qualify for a streamlined SPA review process, including that required public processes yielded no significant access to care concerns for beneficiaries, providers, or other interested parties, or if such processes did yield concerns, that the State can reasonably respond to or mitigate them, as appropriate. If the State is unable to meet all three of the proposed conditions for streamlined SPA review, including the absence of or ability to appropriately address any access concern raised through public processes, then the State would be required to submit additional information to support that its SPA is consistent with the access requirement in section 1902(a)(30)(A) of the Act, as proposed in § 447.203(c)(2). We are proposing to modify this aspect of the current AMRP process, because our implementation experience since the 2017 SMDL has shown that States typically have been able to work directly with the public (including beneficiaries and beneficiary advocacy groups, and providers) to resolve access concerns, which emphasizes that public feedback continues to be a valuable source of knowledge regarding access in Medicaid. We believe this experience demonstrates that public processes that occur before the submission of a payment SPA to CMS often resolve initial access concerns, and where concerns persist, they will be addressed through the SPA submission and our review process, as provided in proposed § 447.203(c). Rather than services affected by proposed provider rate reductions or restructurings (current § 447.203(b)(5)(ii)(F)) and services for which the State or CMS received significantly higher than usual volume of complaints (current § 447.203(b)(5)(ii)(G)) being addressed through an AMRP, these services subject to rate reductions or restructurings and services where a high volume of complaints have been expressed would now be addressed by the State analysis procedures in proposed § 447.203(c). We believe this approach would ensure public feedback is fully considered in the context of a payment SPA, without the need to specifically require a

[148] Summary of Public Comments in response to the CMS 2022 Request for Information: Access to Coverage and Care in Medicaid & CHIP. December 2022. For the report, see *https://www.medicaid.gov/medicaid/access-care/downloads/access-rfi-2022-report.pdf.*

[149] 80 CFR 67576 at 67592.

comparative payment rate analysis for the service(s) subject to payment rate reduction or restructuring under proposed § 447.203(b)(2).

Lastly, we propose to eliminate current § 447.203(b)(5)(ii)(H), requiring the AMRP include analysis regarding ''Additional types of services selected by the State,'' without a direct replacement because our implementation experience has shown that the majority of States did not select additional types of service to include in their AMRPs beyond the required services § 447.203(b)(5)(ii)(A) through (G). When assessing which services to include in this proposed rule, we determined that the absence of an open-ended type of service option, similar to § 447.203(b)(5)(ii)(H) is unlikely to affect the quality of the analysis proposed in this rule and therefore, we are not including it in the proposed set of services required for the comparative payment rate analysis. These shifts in policy were informed by our implementation experience and our consideration of State concerns about the burden and value of the AMRP process.

In paragraph (b)(3), we propose that the State agency would be required to develop and publish, consistent with the publication requirements described in paragraph (b)(1) of this section for payment rate transparency data, a comparative payment rate analysis and payment rate disclosure. This comparative payment rate analysis is divided into two sections based on the categories of services and the organization of each analysis or disclosure. Paragraph (b)(3)(i) describes the comparative payment rate analysis for the categories of service described in paragraphs (b)(2)(i) through (iii): primary care services, obstetrical and gynecological services, and outpatient behavioral health services. Paragraph (b)(3)(ii) describes the payment rate disclosure for the categories of service described in paragraphs (b)(2)(iv): personal care, home health aide, and homemaker services provided by individual providers and providers employed by an agency.

Specifically, in paragraph (b)(3)(i), we propose that for the categories of service described in paragraphs (b)(2)(i) through (iii), the State's analysis would compare the State's Medicaid FFS payment rates to the most recently published Medicare payment rates effective for the same time period for the E/M CPT/HCPCS codes applicable to the category of service. The proposed comparative payment rate analysis of FFS Medicaid payment rates to FFS Medicare payment rates would be conducted on a code-by-code basis at the CPT/HCPCS code level using the most current set of codes published by us. It is intended to provide an understanding of how Medicaid payment rates compare to the payment rates established and updated under the FFS Medicare program.

We would expect to publish the E/M CPT/HCPCS codes to be used for the comparative payment rate analysis in subregulatory guidance along with the final rule, if this proposal is finalized. We propose that we would identify E/M CPT/HCPCS codes to be included in the comparative payment rate analysis based on the following criteria: the code is effective for the same time period of the comparative payment rate analysis; the code is classified as an E/M CPT/HCPCS code by the American Medical Association (AMA) CPT Editorial Panel; the code is included on the Berenson-Eggers Type of Service (BETOS) code list effective for the same time period as the comparative payment rate analysis and falls into the E/M family grouping and families and subfamilies for primary care services, obstetrics and gynecological services, and outpatient behavioral services; and the code has an A (Active), N (Non-Covered), R (Restricted), or T (Injections) code status on the Medicare PFS with a Medicare established relative value unit (RVU) and payment amount for the same time period of the comparative payment rate analysis.[150] [151] [152]

The CMS published list of E/M CPT/HCPCS codes subject to the comparative payment rate analysis would classify each E/M CPT/HCPCS code into a corresponding category of service as described in proposed § 447.203(b)(2)(i) through (iii). As previously discussed, by narrowing the comparative payment rate analysis to CMS-specified E/M CPT/HCPCS codes, we are proposing States' analyses include a broad range of core services which would cover a variety of commonly provided services that fall into the categories of service proposed in paragraphs (b)(2)(i) through (iii), while also limiting the services to those delivered primarily by physicians and NPPs in an office-based setting. Based on the categories of services specified in proposed § 447.203(b)(2)(i) through (iii), we expect the selected E/M CPT/HCPCS codes to fall under mandatory Medicaid benefit categories, and therefore, we expect that all States would cover and pay for the selected E/M CPT/HCPCS codes. To clarify, we did not narrow the list of E/M CPT/HCPCS codes to those with an A (Active), N (Non-Covered), R (Restricted), or T code status on the Medicare PFS with a Medicare established relative value unit (RVU) and payment amount on the basis of Medicare coverage of a particular code. We are cognizant that codes with N (Non-Covered), R (Restricted), or T code statuses have limited or no Medicare coverage, however, Medicare may establish RVUs and payment amounts for these codes. Therefore, when Medicare does establish RVUs and payment amounts for codes with N (Non-Covered), R (Restricted), or T (Injections) code statuses on the Medicare PFS, we are proposing to include these codes in the comparative payment rate analysis in order to ensure the analysis includes a comprehensive set of codes, for example pediatric services, including well child visits (for example, 99381 through 99384), that are commonly provided services that fall into the categories of service proposed in paragraphs (b)(2)(i) through (iii) and delivered primarily by physicians and NPPs in an office-based setting, as previously described.

As discussed later in this rule, we propose that the comparative payment rate analysis would be updated no less than every 2 years. Therefore, prior to the start of the calendar year in which States would be required to update their comparative payment rate analysis, we would intend to publish an updated list of E/M CPT/HCPCS codes for States to use for their comparative payment rate analysis updates through subregulatory guidance. The updated list of E/M CPT/HCPCS codes would incorporate changes made by to the AMA CPT Editorial Panel (such as additions, removals, or amendments to a code definition where there is a change in the set of codes classified as an E/M CPT/HCPCS code billable for primary care services, obstetrics and gynecological services, or outpatient behavioral services) and changes to the Medicare PFS based on the most recent Medicare PFS final rule (such as changes in code status or creation of Medicare-specific codes).[153]

We intend to publish the initial and subsequent updates of the list of E/M CPT/HCPCS codes subject to the comparative payment rate analysis in a timely manner that allows States approximately one full calendar year between the publication of the CMS-

[150] *https://www.ama-assn.org/practice-management/cpt/cpt-evaluation-and-management.*

[151] *https://data.cms.gov/provider-summary-by-type-of-service/provider-service-classifications/restructured-betos-classification-system.*

[152] *https://www.cms.gov/medicare/medicare-fee-for-service-payment/physicianfeesched.*

[153] *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.*

published list of E/M CPT/HCPCS codes and the due date of the comparative payment rate analysis, if this proposal is finalized. We are aware that Medicare may issue a correction to the Medicare PFS after the final rule is in effect, and this correction may impact our published list of E/M CPT/HCPCS codes. In this instance, for codes included on our published list of E/M CPT/HCPCS codes that are affected by a correction to the most recent Medicaid PFS final rule, we may add or remove an E/M CPT/HCPCS code from the published list, as appropriate, depending on the change to the Medicare PFS. Alternatively, depending on the nature of the change, we would expect States to accurately identify which code(s) are used in the Medicaid program during the relevant period that best correspond to the CMS-identified E/M CPT/HCPCS code(s) affected by the Medicare PFS correction. We would expect States to rely on the CMS published list of E/M CPT/HCPCS codes subject to the comparative payment rate analysis for complying with the proposed requirements in paragraphs (b)(2) through (4).

We acknowledge that there are limitations to relying on E/M CPT/HCPCS codes to select payment rates for comparative payment rate analysis to aid States, CMS, and other interested parties in assessing if payments are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area. Providers across the country and within each State deliver a variety of services to patients, including individuals with public and private sources of coverage, and then bill them under a narrow subset of CPT/HCPCS codes that fit into the E/M classification as determined by the AMA CPT Editorial Panel. The actual services delivered can require a wide array of time, skills, and experience of the provider which must be represented by a single five digit code for billing to receive payment for the services delivered. While there are general principles that guide providers in billing the most representative E/M CPT/HCPCS code for the service they delivered, two providers might perform substantially similar activities when delivering services and yet bill different E/M CPT/HCPCS codes for those activities, or bill the same E/M CPT/HCPCS code for furnishing two very different services. The E/M CPT/HCPCS code itself is not a tool for capturing the exact service that was delivered, but medical documentation helps support the billing of a particular E/M CPT/HCPCS code.

Although they do not encompass all Medicaid services covered and paid for in the Medicaid program which are subject to the requirements in section 1902(a)(30)(A) of the Act, E/M CPT/HCPCS codes are some of the most commonly billed codes and including them in the comparative payment rate analysis would allow us to uniformly compare Medicaid payment rates for these codes to Medicare PFS rates. As such, to balance administrative burden on States and our enforcement responsibilities, we are proposing to use E/M CPT/HCPCS codes in the comparative payment rate analysis to define the parameters of our analysis to how much Medicaid and the FFS Medicare program would pay for services that can be classified into a particular E/M CPT/HCPCS code. We are seeking public comment on the proposed comparative payment rate analysis requirement in § 447.203(b)(3)(i), including the proposed requirement to conduct the analysis at the CPT/HCPCS code level, the proposed criteria that we would apply in selecting E/M CPT/HCPCS codes for inclusion in the required analysis, and the proposed requirement for States to compare Medicaid payment rates for the selected E/M CPT/HCPCS codes to the most recently published Medicare non-facility payment rate as listed on the Medicare PFS effective for the same time period which is discussed in more detail later in this rule when describing the proposed provisions of § 447.203(b)(3)(i)(C).

In paragraph (b)(3)(i), we further propose that the State's comparative payment rate analysis would be required to meet the following requirements: (A) the analysis must be organized by category of service as described in § 447.203(b)(2)(i) through (iii); (B) the analysis must clearly identify the Medicaid base payment rates for each E/M CPT/HCPCS code identified by us under the applicable category of service, including, if the rates vary, separate identification of the payment rates by population (pediatric and adult), provider type, and geographical location, as applicable; (C) the analysis must clearly identify the Medicare PFS non-facility payment rates effective for the same time period for the same set of E/M CPT/HCPCS codes, and for the same geographical location as the Medicaid base payment rates, that correspond to the Medicaid payment rates identified under paragraph (b)(3)(i)(B); (D) the analysis must specify the Medicaid payment rate identified under paragraph (b)(3)(i)(B) as a percentage of the Medicare payment rate identified under paragraph (b)(3)(i)(C) for each of the services for which the Medicaid payment rate is published under paragraph (b)(3)(i)(B); and (E) the analysis must specify the number of Medicaid-paid claims within a calendar year for each of the services for which the Medicaid payment rate is published under paragraph (b)(3)(i)(B). We are seeking public comment on the proposed requirements and content of the items in proposed § 447.203(b)(3)(i)(A) through (E).

In paragraph (b)(3)(i)(A), we propose to require States to organize their comparative payment rate analysis by the service categories described in paragraphs (b)(2)(i) through (iii) of this section. This proposed requirement is included to ensure the analysis breaks out the payment rates for primary care services, obstetrical and gynecological services, and outpatient behavioral health services separately for individual analyses of the payment rates for each CMS-selected E/M CPT/HCPCS code, grouped by category of service. We are seeking public comment on the proposed requirement for States to break out their payment rates at the CPT/HCPCS code level for primary care services, obstetrical and gynecological services, and outpatient behavioral health services, separately, in the comparative payment rate analysis as specified in proposed § 447.203(b)(3)(i)(A).

In paragraph (b)(3)(i)(B), after organizing the analysis by § 447.203(b)(2)(i) through (iii) categories of service and CMS-specified E/M CPT/HCPCS code, we propose to require States to clearly identify the Medicaid base payment rate for each code, including, if the rates vary, separate identification of the payment rates by population (pediatric and adult), provider type, and geographical location, as applicable. We propose that the Medicaid base payment rate in the comparative payment rate analysis would only include the State's Medicaid fee schedule rate, that is, the State's Medicaid base rate for each E/M CPT/HCPCS code. By specifying the services included in the comparative payment rate analysis by E/M CPT/HCPCS code, we expect the Medicaid base payment rate in the comparative payment rate analysis would only include the State's Medicaid fee schedule rate for that particular E/M CPT/HCPCS code as published on the State's Medicaid fee schedule effective for the same time period covered by the comparative payment rate analysis. As an example,

the State's Medicaid fee schedule rate as published on the Medicaid fee schedule effective for the time period of the comparative payment rate analysis for 99202 is listed as $50.00. This rate would be the Medicaid base payment rate in the State's comparative payment rate analysis for comparison to the Medicare non-facility rate which is discussed later in this section.

Medicaid base payment rates are typically determined through one of three methods: the resource-based relative value scale (RBRVS), a percentage of Medicare's fee, or a State-developed fee schedule using local factors.[154] The RBRVS system, initially developed for the Medicare program, assigns a relative value to every physician procedure based on the complexity of the procedure, practice expense, and malpractice expense. States may also adopt the Medicare fee schedule rate, which is also based on RBRVS, but select a fixed percentage of the Medicare amount to pay for Medicaid services. States can develop their own PFSs, typically determined based on market value or an internal process, and often do this in situations where there is no Medicare or private payer equivalent or when an alternate payment methodology is necessary for programmatic reasons. States often adjust their payment rates based on provider type, geography, site of services, patient age, and in-State or out-of-State provider status. Additionally, Medicaid base payment rates can be paid to physicians in a variety of settings, including clinics, community health centers, and private offices.

We acknowledge that only including Medicaid base payments in the analysis does not necessarily represent all of a provider's revenues that may be related to furnishing services to Medicaid beneficiaries, and that other revenues not included in the proposed comparative analysis may be relevant to a provider's willingness to participate in Medicaid (such as beneficiary cost sharing payments, disproportionate share hospital payments for qualifying hospitals, supplemental payments, etc.). Public comments we received on the 2011 proposed rule and responded to in the 2015 final rule with comment period regarding the AMRPs expressed differing views regarding which provider ''revenues'' should be included within comparisons of Medicaid to Medicare payment rates. One commenter ''noted that the preamble of the 2011 proposed rule refers to 'payments' and 'rates' interchangeably but that courts have defined payments to include all Medicaid provider revenues rather than only Medicaid FFS rates.'' The commenter stated that if the final rule consider[ed] all Medicaid revenues received by providers, States may be challenged to make any change to the Medicaid program that might reduce provider revenues.'' [155] This proposed rule narrows the Medicaid base payment rates to the amount listed on the State's fee schedule in order for the comparative payment rate analysis to accurately and analogously compare Medicaid fee schedule rates to Medicare fee schedule rates as listed on the Medicare PFS.

We believe this proposal represents the best way to create a consistent metric across States against which to evaluate access. To be specific, we are not proposing to include supplemental payments in the comparative payment rate analysis. Requiring supplemental payment data be collected and included under this rule would be duplicative of existing requirements. State supplemental payment and DSH payment data are already subject to our review in various forms, such as through DSH audits for DSH payments, and through annual upper payment limits demonstrations, and through supplemental payment reporting under section 1903(bb) of the Act.[156] [157] As such, we do not see a need to add additional reporting requirements concerning supplemental payments as part of the proposals in this rulemaking to allow us the opportunity to review the data. Also, supplemental payments are often made for specific Medicaid-covered services and targeted to a subset of Medicaid-participating providers; not all Medicaid-participating providers, and not all providers of a given Medicaid-covered service, may receive supplemental payments in a State. Therefore, including supplemental payments in the comparative payment rate analysis would create additional burden for States without then also providing an accurate benchmark of how payments may affect beneficiary access due to the potentially varied and uneven distribution of supplemental payments. Accordingly, we are proposing to require that States conduct the comparative payment rate analysis for only Medicaid base payment rates for selected E/M CPT/HCPCS codes. For each proposed category of service listed in paragraphs (b)(2)(i) through (iii), this would result in a transparent and parallel comparison of Medicaid base payment rates that all Medicaid-participating providers of the service would receive to the payment rates that Medicare would pay for the same E/M CPT/HCPCS codes.

Additionally, in paragraph (b)(3)(i)(B), we propose that, if the States' payment rates vary, the Medicaid base payment rates must include a breakdown by payment rates paid to providers delivering services to pediatric and adult populations, by provider type, and geographical location, as applicable, to capture this potential variation in the State's payment rates. This proposed provision to breakdown the Medicaid payment rate is first stated in proposed paragraph (b)(2) and carried through in proposed paragraph (b)(3)(i)(B) to provide clarity to States about how the Medicaid payment rate should be reported in the comparative payment rate analysis.

In paragraph (b)(3)(i)(C), we propose to require States' comparative payment rate analysis clearly identify the Medicare non-facility payment rates effective for the same time period for the same set of E/M CPT/HCPCS codes, and for the same geographical location, that correspond to the Medicaid payment rates identified under paragraph (b)(3)(i)(B), including, separate identification of the payment rates by provider type. We are not proposing to establish a threshold percentage of Medicare non-facility payment rates that States would be required to meet when setting their Medicaid payment rates. Rather, we are proposing to use Medicare non-facility payment rates as listed on the Medicare PFS as a benchmark to which States would compare their Medicaid payment rates to inform their and our assessment of whether the State's payment rates are compliant with section 1902(a)(30)(A) of the Act. Benchmarking against FFS Medicare, another of the nation's large public health coverage programs, serves as an important data point in determining whether payment rates are likely to be sufficient to ensure access for Medicaid beneficiaries at least as great as for the general population in the geographic area, and whether any identified access concerns may be related to payment sufficiency. Similar to Medicaid, Medicare provides health coverage for a significant number of

[154] *https://www.macpac.gov/wp-content/uploads/2017/02/Medicaid-Physician-Fee-for-Service-Payment-Policy.pdf.*

[155] 80 FR 67576 at 67581.

[156] CMS State Medicaid Director Letter: SMDL 13–003. March 2013. Federal and State Oversight of Medicaid Expenditures. Available at *https://www.medicaid.gov/sites/default/files/Federal-Policy-Guidance/Downloads/SMD-13-003-02.pdf.*

[157] CMS State Medicaid Director Letter: SMDL 21–006. December 2021. New Supplemental Payment Reporting and Medicaid Disproportionate Share Hospital Requirements under the Consolidated Appropriations Act, 2021. Available at *https://www.medicaid.gov/federal-policy-guidance/downloads/smd21006.pdf.*

Americans across the country. In December 2022, total Medicaid enrollment was at 85.2 million individuals [158] while total Medicare enrollment was at 65.4 million individuals.[159] [160] Both the Medicare and Medicaid programs cover and pay for services provided to beneficiaries residing in every State and territory of the United States. As previously described, Medicare non-facility payment rates as listed on the Medicare PFS for covered, non-covered, and limited coverage services generally are determined on a national level as well as adjusted to reflect the variation in practice costs from one geographical location to another. Medicare also ensures that their payment rate data are publicly available in a format that can be analyzed. The accessibility and consistency of the Medicare non-facility payment rates as listed on the Medicare PFS, compared to negotiated private health insurance payment rates that typically are considered proprietary information and, therefore, not generally available to the public, makes Medicare non-facility payment rates as listed on the Medicare PFS an available and reliable comparison point for States to use in the comparative payment rate analysis.

Additionally, Medicare is widely accepted nationwide according to recent findings from the National Electronic Health Records Survey. In 2019, 95 percent of physicians accepting new patients overall, and 89 percent of office-based physicians, were accepting new Medicare patients, and the percentage of office-based physicians accepting new Medicare patients has remained stable since 2011 when the value was 88 percent, with modest fluctuations in the years in between.[161] In regards to physician specialties that align with the proposed categories of services in this rule, 81 percent of general practice/family medicine physicians and 81 percent of physicians specializing in internal medicine were accepting new Medicare patients, 93 percent of physicians specializing obstetrics and gynecology were accepting new Medicare patients, and 60 percent of psychiatrists were accepting new Medicare patients in 2019. Although the percentage of psychiatrists who accept Medicare is lower than other types physicians providing services included in the comparative payment rate analysis, this circumstance is not unique to Medicare amongst payers. For example, 60 percent of psychiatrists were also accepting new privately insured patients in 2019. Therefore, the decreased rate of acceptance by psychiatrists relative to certain other physician specialists does not make Medicare an inappropriate benchmark when evaluated against other options for comparison.[162]

Historically, Medicare has low rates of physicians formally opting out of the Medicare program with 1 percent of physicians consistently opting out between 2013 and 2019 and of that 1 percent of physicians opting out of Medicare, 42 percent were psychiatrists.[163] This information suggests that Medicare's payment rates generally are consistent with a high level of physician willingness to accept new Medicare patients, with the vast majority of physicians willing to accept Medicare's payment rates. For the reasons previously described, we are proposing to use Medicare non-facility payment rates as listed on the Medicare PFS as a national benchmark for States to compare their Medicaid payment rates in the comparative payment rate analysis because we believe that the Medicare payment rates for these services are likely to serve as a reliable benchmark for a level of payment sufficient to enlist providers to furnish the relevant services to an individual. We are seeking public comment on the proposed used of Medicare non-facility payment rates as listed on the Medicare PFS as a benchmark for States to compare their Medicaid payment rates to in the comparative payment rate analysis requirements in proposed § 447.203(b)(3)(i) to help assess if Medicaid payments are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area.

Specifically, in paragraph (b)(3)(i)(C), we propose to require States to compare their Medicaid payment rates to the Medicare non-facility payment rates effective for the same time period as the same set of E/M CPT/HCPCS codes paid under Medicaid as specified under paragraph (b)(3)(i)(B) of this section, including, separate identification of the payment rates by provider type. We propose to require States to compare their payment rates to the corresponding Medicare PFS non-facility rates because we are seeking a payment analysis that compares Medicaid payment rates to Medicare payment rates at comparable location of service delivery (that is, in a non-clinic, non-hospital, ambulatory setting such as a physician's office). States often pay physicians operating in an office based on their Medicaid fee schedule whereas they may pay physicians operating in hospitals or clinics using an encounter rate. The Medicaid fee schedule rate typically reflects payment for an individual service that was rendered, for example, an office visit that is billed as a single CPT/HCPCS code. An encounter rate often reflects reimbursement for total facility specific costs divided by the number of encounters to calculate a per visit or per encounter rate that is paid to the facility for all services received during an encounter, regardless of which specific services are provided during a particular encounter. For example, the same encounter rate may be paid for a beneficiary who has an office visit with a physician, a dental examination and cleaning from a dentist, and laboratory tests and for a beneficiary who receives an office visit with a physician and x-rays. Encounter rates are typically paid to facilities, such as hospitals, FQHCs, RHCs, or clinics, many of which function as safety net providers that offer a wide variety of medical services. Within the Medicaid program, encounter rates can vary

[158] *https://www.medicaid.gov/medicaid/national-medicaid-chip-program-information/downloads/December-2022-medicaid-chip-enrollment-trend-snapshot.pdf.*

[159] Total Medicare enrollment equals the Tot_Benes variable in the Medicare Monthly Enrollment Data for December (Month) 2022 (Year) at the national level (Bene_Geo_Lvl). Tot_Benes is a count of all Medicare beneficiaries, including beneficiaries with Original Medicare and beneficiaries with Medicare Advantage and Other Health Plans. We utilized the count of all Medicare beneficiaries because Original Medicare, Medicare Advantage, and other Health Plans offer fee-for-service payments to providers. See the Medicare Monthly Enrollment Data Dictionary for more information about the variables in the Medicare Monthly Enrollment Data: *https://data.cms.gov/sites/default/files/2023-02/1ec24f76-9964-4d00-9e9a-78bd556b7223/Medicare%20Monthly%20Enrollment_Data_Dictionary%2020230131_508.pdf.*

[160] *https://data.cms.gov/summary-statistics-on-beneficiary-enrollment/medicare-and-medicaid-reports/medicare-monthly-enrollment.*

[161] *https://www.kff.org/medicare/issue-brief/most-office-based-physicians-accept-new-patients-including-patients-with-medicare-and-private-insurance/.*

[162] *https://www.kff.org/medicare/issue-brief/faqs-on-mental-health-and-substance-use-disorder-coverage-in-medicare/.*

[163] Physicians and practitioners who do not wish to enroll in the Medicare program may ''opt-out'' of Medicare. This means that neither the physician, nor the beneficiary submits the bill to Medicare for services rendered. Instead, the beneficiary pays the physician out-of-pocket and neither party is reimbursed by Medicare. A private contract is signed between the physician and the beneficiary that states, that neither one can receive payment from Medicare for the services that were performed. See 2022 opt-out affidavit data published by the Centers for Medicare & Medicaid services: *https://data.cms.gov/provider-characteristics/medicare-provider-supplier-enrollment/opt-out-affidavits.*

widely in the rate itself and services paid for through the encounter rate. Proposing States demonstrate the economy and efficiency of their encounter rates would be an entirely different exercise to the fee schedule rate comparison proposed in this rule because encounter rates are often based on costs unique to the provider, and States often require providers to submit cost reports to States for review to support payment of the encounter rate. Comparing cost between the Medicaid and Medicare program would require a different methodology, policies, and oversight than what is proposed in this rule due to the differences within and between each program. While the Medicare program has a broad, national policy for calculating encounter rates for providers, including prospective payment systems for hospitals, FQHCs, and other types of facilities, Medicare calculates these encounter rates differently than States may calculate analogous rates in Medicaid. Therefore, proposing States disaggregate each of their encounter rates and services covered in each encounter rate to compare to Medicare's encounter rates would be challenging for States.

From that logic, we likewise determined that the Medicare non-facility payment rates as listed on the Medicare PFS rate afforded the best point of comparison because it is the most accurate and most analogous comparison of a service-based access analysis using Medicare non-facility payment rates as listed on the Medicare PFS as a benchmark to compare Medicaid fee schedule rates on a CPT/HCPCS code level basis, as opposed to an encounter rate which could include any number of services or specialties. The Medicare non-facility payment rate as listed on the Medicare PFS is described as ''. . . the fee schedule amount when a physician performs a procedure in a non-facility setting such as the office'' and ''[g]enerally, Medicare gives higher payments to physicians and other health care professionals for procedures performed in their offices [compared to those performed elsewhere] because they must supply clinical staff, supplies, and equipment.'' [164] As such, we believe the Medicaid fee schedule best represents the payment intended to pay physicians and non-physician practitioners for delivery of individual services in an office (non-facility) setting, and the Medicare non-facility payment rate as listed on the Medicare PFS represents the best equivalent to that amount and consideration.

For the purposes of the comparative payment rate analysis, we would expect States to source the Medicare non-facility payment rate from the published Medicare fee schedule amounts on the Medicare PFS through one or both of the following sources: the Physician Fee Schedule Look-Up Tool [165] on *cms.gov* or Excel file downloads of the Medicare PFS Relative Value Files [166] for the relevant calendar year from *cms.gov.* We encourage States to begin sourcing Medicare non-facility payment rates from the Physician Fee Schedule Look-Up Tool and utilize the Physician Fee Schedule Guide for instructions on using the Look-Up Tool. When codes are not available in the Look-Up Tool, we would direct States to the Excel file downloads of the Medicare PFS Relative Value Files where States can find necessary information for calculating Medicare non-facility payment rates.

As described in the Medicare Claims Processing Manual, most physician services are paid according to the Medicare PFS and the fee schedule amounts for a particular procedure code (including HCPCS, CPT, and CDT) are computed using a resource-based formula made up of three components of a procedure's RVU: physician work, practice expense, and malpractice as well as geographical differences in each locality area of the country.[167] The resource-based formula also includes adjustments to reflect the variation in practice costs from one geographical location to another. Medicare establishes a geographic practice cost index (GPCI) for every Medicare payment locality for each of the three components of a procedure's RVU for physician work, practice expense, and malpractice and applies the GPCIs in the calculation of a fee schedule payment amount by multiplying the RVU for each component times the GPCI for that component.[168]

Medicare also includes adjustments to the fee schedule amounts, for example, based on site of service (non-facility versus facility setting), where the rate, facility or non-facility, that a physician service is paid under the PFS is determined by the place of service (POS) code that is used to identify the setting where the beneficiary received the face-to-face encounter with the billing practitioner. We are proposing States use the Medicare non-facility payment rate as listed on the Medicare PFS in the comparative payment rate analysis. For codes that are not available in the Look-Up Tool, we would direct States to the Excel file downloads of the Medicare PFS Relative Value Files which include the RVUs, GPCI, and the ''National Physician Fee Schedule Relative Value File Calendar Year 2023'' file which contains the associated relative value units (RVUs), a fee schedule status indicator, and various payment policy indicators needed for payment adjustment (*i.e.,* payment of assistant at surgery, team surgery, bilateral surgery, etc.). We expect States to utilize the formula for the Non-Facility Pricing Amount in ''National Physician Fee Schedule Relative Value File Calendar Year 2023'' file to calculate the ''Non-Facility Price'' using the RVUs, GPCIs, and conversion factors for codes not available in the Look-Up Tool. For codes available in the Look-Up Tool, we expect States to specifically use the Medicare payment rates listed under the ''Non-Facility Price'' header as described on the Medicare PFS. The Non-Facility Price is the established Medicare payment rate as listed on the Medicare PFS which includes the amount that Medicare pays for the claim and any applicable co-insurance and deductible amounts owed by the patient.

Medicaid fee-schedule rates should be representative of the total computable payment amount a provider would expect to receive as payment-in-full for the provision of Medicaid services to individual beneficiaries. 42 CFR 447.15 defines payment-in-full as ''the amounts paid by the agency plus any deductible, coinsurance or copayment required by the plan to be paid by the individual.'' Therefore, the State's Medicaid base payment rate used for comparison should be inclusive of total base payment from the Medicaid agency plus any applicable coinsurance and deductibles to the extent that a beneficiary is expected to be liable for those payments. If a State Medicaid fee schedule does not include these additional beneficiary cost-sharing payment amounts, then the Medicaid fee schedule amounts would need to be modified to align with the inclusion of expected beneficiary cost sharing in Medicare's non-facility payment rates as listed on the Medicare PFS.[169]

[164] *https://www.cms.gov/files/document/physician-fee-schedule-guide.pdf.*

[165] *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PFSlookup.*

[166] *https://www.cms.gov/medicare/medicare-fee-for-service-payment/physicianfeesched/pfs-relative-value-files.*

[167] *https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c12.pdf.*

[168] *https://www.cms.gov/medicare/physician-fee-schedule/search/overview.*

[169] *According to the Medicare Physician Fee Schedule Guide, for most codes, Medicare pays*

In paragraph (b)(3)(i)(C), we propose that the Medicare non-facility payment rates must be effective for the same time period for the same set of E/M CPT/HCPCS codes that correspond to the Medicaid base payment rates identified under paragraph (b)(3)(i)(B) of this section. We included this language to ensure the comparative payment rate analysis is as accurate and analogous as possible by proposing that the Medicaid and Medicare payment rates that are effective during the same time period for the same set of E/M CPT/HCPCS codes. As later described in this rule, in paragraph (b)(4), we propose the initial comparative payment rate analysis and payment rate disclosure of its Medicaid payment rates would be a retroactive analysis of payment rates that are in effect as of January 1, 2025, with the analysis and disclosure published no later than January 1, 2026. For example, the first comparative payment rate analysis a State develops and publishes would compare Medicaid base payment rates in effect as of January 1, 2025, to the Medicare non-facility payment rates effective January 1, 2025, to ensure the Medicare non-facility payment rates are effective for the same time period for the same set of E/M CPT/HCPCS codes that correspond to the Medicaid base payment rates identified under paragraph (b)(3)(i)(B) of this section.

Additionally, in paragraph (b)(3)(i)(C), we propose that the Medicare non-facility payment rates as listed on the Medicare PFS used for the comparison must be for the same geographical location as the Medicaid base payment rates. For States that pay Medicaid payment rates based on geographical location (for example, payment rates that vary by rural or non-rural location, by zip code, or by metropolitan statistical area), we propose that States comparative payment rate analysis would need to utilize the Medicare non-facility payment rates as listed on the Medicare PFS for the same geographical location as the Medicaid base payment rates to achieve an equivalent comparison. We would expect States to review Medicare's published listing of the current PFS locality structure organized by State, locality area, and when applicable, counties assigned to each locality area and identify the comparable Medicare locality area for the same geographical area as the Medicaid base payment rates.[170]

We recognize that States that make Medicaid payment based on geographical location may not use the same locality areas as Medicare. For example, a State may use its own State-determined geographical designations, resulting in 5 geographical areas in the State for purposes of Medicaid payment while Medicare recognizes 3 locality areas for the State based on Metropolitan Statistical Area (MSA) delineations determined by the US Office of Management and Budget (OMB) and are the result of the application of published standards to Census Bureau data.[171] In this instance, we would expect the State to determine an appropriate method to accomplish the comparative payment rate analysis that aligns the geographic area covered by each payer's rate as closely as reasonably feasible. For example, if the State identifies two geographic areas for Medicaid payment purposes that are contained almost entirely within one Medicare geographic area, then the State reasonably could determine to use the same Medicare non-facility payment rate as listed on the Medicare PFS in the comparative payment rate analysis for each Medicaid geographic area. As another example, if the State defined a single geographic area for Medicaid payment purposes that contained two Medicare geographic areas, then the State might determine a reasonable method to weight the two Medicare payment rates applicable within the Medicaid geographic area, and then compare the Medicaid payment rate for the Medicaid-defined geographic area to this weighted average of Medicare payment rates. Alternatively, as discussed in the next paragraph, the State could determine to use the unweighted arithmetic mean of the two Medicare payment rates applicable within the Medicaid-defined geographic area. We are seeking public comment on the proposed use of Medicare non-facility payment rates as listed on the Medicare PFS as a benchmark for States to compare their Medicaid payment rates to in the comparative payment rate analysis requirements in proposed § 447.203(b)(3)(i) to help assess if Medicaid payments are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area.

We are aware that States may not determine their payment rates by geographical location. For States that do not pay Medicaid payment rates based on geographical location, we propose that States compare their Medicaid payment rates (separately identified by population, pediatric and adult, and provider type, as applicable) to the Statewide average of Medicare non-facility payment rates as listed on the Medicare PFS for a particular CPT/HCPCS code. The Statewide average of the Medicare non-facility payment rates as listed on the Medicare PFS for a particular CPT/HCPCS code would be calculated as a simple average or arithmetic mean where all Medicare non-facility payment rates as listed on the Medicare PFS for a particular CPT/HCPCS code for a particular State would be summed and divided by the number of all Medicare non-facility payment rates as listed on the Medicare PFS for a particular CPT/HCPCS code for a particular State. This calculated Statewide average of the Medicare non-facility payment rates as listed on the Medicare PFS would be calculated for each CPT/HCPCS code subject to the comparative payment rate analysis using the Non-Facility Price for each locality in the State rates as listed on the Medicare PFS. As previously mentioned, Medicare has published a listing of the current PFS locality structure organized by State, locality area, and when applicable, counties assigned to each locality area and we would expect States to utilize this listing to identify the Medicare locality areas in their State. For example, the Specific Medicare Administrative Contractor (MAC) for Maryland is 12302 and there are two Specific Locality codes, 1230201 for BALTIMORE/SURR. CNTYS and 1230299 for REST OF STATE. When using the Medicare Physician Fee Schedule Look Up Tool to identify the Medicare Non-Facility Price(s) for CY 2023 for 99202 in the Specific MAC locality code for Maryland (12302 MARYLAND), the following search results are populated: Medicare Non-Facility Price of $77.82 for BALTIMORE/SURR. CNTYS and $74.31 for REST OF STATE.[172] These two Medicare Non-Facility Price(s) would be averaged to obtain a calculated Statewide average for Maryland of $76.07.

For States that do not determine their payment rates by geographical location, we propose that States would use the Statewide average of the Medicare Non-Facility Price(s) as listed on the PFS, as previously described, because it ensures consistency across all States' comparative payment rate analysis,

80% of the amount listed and the beneficiary is responsible for 20 percent.

[170] *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Locality.*

[171] *https://www.census.gov/programs-surveys/metro-micro/about/delineation-files.html.*

[172] *https://www.cms.gov/medicare/physician-fee-schedule/search?Y=0&T=4&HT=0&CT=1&H1=99202&C=43&M=5.*

aligns with the geographic area requirement of section 1902(a)(30)(A) of the Act, and ensures the Medicare non-facility payment rates as listed on the Medicare PFS that States use in their comparative payment rate analysis accurately reflect how Medicare pays for services. This proposal ensures that all States' comparative payment rate analyses consistently incorporate Medicare geographical payment rate adjustments as proposed in paragraph (b)(3)(i)(C). As previously discussed, we propose that States that do pay varying rates by geographical location would need to identify the comparable Medicare locality area for the same geographical area as their Medicaid base payment rates. However, for States that do not pay varying rates by geographical location, at the operational level, the State is effectively paying a Statewide Medicaid payment rate, regardless of geographical location, that cannot be matched to a Medicare non-facility payment rate in a comparable Medicare locality area for the same geographical area as the Medicaid base payment rates. Therefore, in order consistently apply the proposed provision that the Medicare non-facility payment rate must be for the same geographical location as the Medicaid base payment rates, States that do not pay varying rates by geographical location would be required to calculate a Statewide average of the Medicare non-facility payment rate to compare the State's Statewide Medicaid payment rate.

Additionally, we propose that States that do not determine their payment rates by geographical location should use the Statewide average of the Medicare non-facility payment rates as listed on the Medicare PFS to align the implementing regulatory text with the statute's geographic area requirement in section 1902(a)(30)(A) of the Act. Section 1902(a)(30)(A) of the Act requires that Medicaid payments are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area. Therefore, the proposed provisions of this rule, which are implementing section 1902(a)(30)(A) of the Act, must include a method of ensuring we have sufficient information for determining sufficiency of access to care as compared to the general population in the geographic area. As we have proposed to use Medicare non-facility payment rates as a benchmark for comparing Medicaid base payment rates, we believe that utilizing a Statewide average of Medicare non-facility payment rates as listed on the Medicare PFS for States that do not pay varying rates by geographical location would align the geographic area requirement of section 1902(a)(30)(A) of the Act, treating the entire State (throughout which the Medicaid base payment rate applies uniformly) as the relevant geographic area.

We considered requiring States weight the Statewide average of the Medicare non-facility payment rates by the proportion of the Medicare beneficiary population covered by each rate, but we did not propose this due to the additional administrative burden this would create for States complying with the proposed comparative payment rate analysis as well as limited availability of Medicare beneficiary and claims data necessary to weight the Statewide average of the Medicare non-facility payment rates as described above. As proposed, States that do not determine their payment rates by geographical location would be required to consider Medicare's geographically determined payment rates by Statewide average of the Medicare non-facility payment rates. We believe that proposing an additional step to weight the Statewide average by the proportion of the Medicare beneficiary population covered by each rate would create would not result in a practical version of the Medicare non-facility payment rate for purposes of the comparative payment rate analysis. Additionally, proposing only States that do not determine their payment rates by geographical location would result in additional administrative burden that is not imposed on States who do determine their payment rates by geographical location. Additionally, in order to accurately weight the Statewide average of the Medicare non-facility payment rates by the proportion of the Medicare beneficiary population covered by each rate, States would likely require Medicare-paid claims data for each code subject to the comparative payment rate analysis, broken down by each of the comparable Medicare locality areas for the same geographical area as the Medicaid base payment rates that are included in the Statewide average of Medicare non-facility payment rates. While total Medicare beneficiary enrollment data broke down by State and county level is publicly available on *data.cms.gov,* Medicare-paid claims data broken down by the Medicare locality areas used in the Medicare PFS and by code level is not published by CMS and would be inaccessible for the State to utilize in weighting the Statewide average of the Medicare non-facility payment rates by the proportion of the Medicare beneficiary population covered by each rate. As proposed, we believe that States that do not determine their payment rates by geographical location calculating simple Statewide average of the Medicare non-facility rates in their State ensures consistency across all States' comparative payment rate analysis, aligns with the geographic area requirement of section 1902(a)(30)(A) of the Act, and ensures the Medicare non facility payment rates as listed on the Medicare PFS that States use in their comparative payment rate analysis accurately reflect how Medicare pays for services. We are seeking public comment regarding our decision not to propose requiring States that do not pay varying Medicaid rates by geographical location weight the Statewide average of the Medicare non-facility payment rates by the distribution of Medicare beneficiaries in the State.

Furthermore, in paragraph (b)(3)(i)(C), we propose that the Medicare non-facility payment rate must separately identify the payment rates by provider type. We previously discussed that some States and Medicare pay a percentage less than 100 percent of their fee schedule payment rates to NPPs, including, for example, nurse practitioners, physician assistants, and clinical nurse specialists. To ensure a State's comparative payment rate analysis is as accurate as possible when comparing their Medicaid payment rates to Medicare, we are proposing that States include a breakdown of Medicare's non-facility payment rates by provider type. The proposed breakdown of Medicare's payment rates by provider type would be required for all States, regardless of whether or how the State's Medicaid payment rates vary by provider type, because it ensures the comparative payment rate analysis accurately reflects this existing Medicare payment policy on the Medicare side of the analysis. Therefore, every comparative payment rate analysis would include the following Medicare non-facility payment rates for the same set of E/M CPT/HCPCS codes paid under Medicaid as described in § 447.203(b)(3)(i)(B): the non-facility payment rate as listed on Medicare PFS rate as the Medicare payment rate for physicians and the non-facility payment rate as listed on Medicare PFS rate multiplied by 0.85 as the Medicare payment rate for NPPs.

As previously mentioned in this proposed rule, Medicare pays nurse practitioners, physician assistants, and clinical nurse specialists at 85 percent of the Medicare PFS rate. Medicare

implements a payment policy where the fee schedule amounts, including the Medicare non facility payment rates, as listed on the Medicare PFS are reduced to 85 percent when billed by NPPs, including nurse practitioners, physician assistants, and clinical nurse specialists, whereas physicians are paid 100 percent of the fee schedule amounts as listed on the Medicare PFS.[173] As proposed, States' comparative payment rate analysis would need to match their Medicaid payment rates for each provider type to the corresponding Medicare non-facility payment rates for each provider type, regardless of the State paying varying or the same payment rates to their providers for the same service. As an example of a State that pays varying rates based on provider type, if a State's Medicaid fee schedule lists a rate of $100.00 when a physician delivers and bills for 99202, then the $100.00 Medicaid base payment rate would be compared to 100 percent of the Medicare non-facility payment rate as listed on the Medicare PFS. If the same State's Medicaid fee schedule lists a rate of $75 when a nurse practitioner delivers and bills for 99202 (or the State's current approved State plan language states that a nurse practitioner is paid 75 percent of the State's Medicaid fee schedule rate), then the $75 Medicaid base payment rate would be compared to the Medicare non-facility payment rate as listed on the Medicare PFS multiplied by 0.85. Both Medicare non-facility payments rates would need to account for any applicable geographical variation, including the Non-Facility Price as listed on the Medicare PFS for each relevant locality area or the calculated Statewide average of the Non-Facility Price as listed on the Medicare PFS for all relevant areas of a State, as previously discussed in this section, for an accurate comparison to the corresponding Medicaid payment rate. Alternatively, if a State pays the same $80 Medicaid base payment rate for the service when delivered by physicians and by nurse practitioners, then the $80 would be listed separately for physicians and nurse practitioners as the Medicaid base payment rate and compared to the Medicare non-facility payment rate as listed on the Medicare PFS for physicians and the Medicare non-facility payment rate as listed on the Medicare PFS multiplied by 0.85 for nurse practitioners.

This granular level of comparison provides States with the opportunity to benchmark their Medicaid payment rates against Medicare as part of the State's and our process for ensuring compliance with section 1902(a)(30)(A) of the Act. For example, a State's comparative payment rate analysis may show that the State's Medicaid base payment rate for physicians is 80 percent of the Medicare non-facility payment rate and their Medicaid base payment rate for nurse practitioners is 71 percent of the Medicare non-facility payment rate for NPPs, because the State pays a reduced rate to nurse practitioners. Although Medicare also pays a reduced rate to nurse practitioners, the reduced rate the State pays to nurse practitioners compared to Medicare's reduced rate is still a lower percentage than the physician rate. However, another State's comparative payment rate analysis may show that the State's Medicaid base payment rate for physicians is 95 percent of the Medicare non-facility payment rate and their Medicaid base payment rate for nurse practitioners is 110 percent of the Medicare non-facility payment rate because the State pays all providers the same Medicaid base payment rate while Medicare pays a reduced rate of 85 percent of the Medicare non-facility payment rate as listed on the Medicare PFS when the service is furnished by an NPP. By conducting this level of analysis through the comparative payment rate analysis, States would be able to pinpoint where there may be existing or potential future access to care concerns rooted in payment rates. We are seeking public comment on the proposed requirement for States to compare their Medicaid payment rates to the Medicare non-facility payment rate as listed on the Medicare PFS, effective for the same time period for the same set of E/M CPT/HCPCS codes, and for the same geographical location as the Medicaid base payment rates, that correspond to the Medicaid base payment rates identified under paragraph (b)(3)(i)(B) of this section, including, separate identification of the payment rates by provider type, as proposed in § 447.203(b)(3)(i)(C).

In paragraph (b)(3)(i)(D), we propose to require States specify the Medicaid base payment rate identified under proposed § 447.203(b)(3)(i)(B) as a percentage of the Medicare non-facility payment rate identified under proposed § 447.203(b)(3)(i)(C) for each of the services for which the Medicaid base payment rate is published under proposed § 447.203(b)(3)(i)(B). For each E/M CPT/HCPCS code that we select, we propose that States would calculate each Medicaid base payment rate as specified in paragraph (b)(3)(i)(B) as a percentage of the corresponding Medicare non-facility payment rate specified in paragraph (b)(3)(i)(C). Both rates would be required to be effective for the same time period of the comparative payment rate analysis. As previous components of the proposed comparative payment rate analysis have considered variance in payment rates based on population the service is delivered to (adult or pediatric), provider type, and geographical location to extract the most granular and accurate Medicaid and Medicare payment rate data, we propose that States would calculate the Medicaid base payment rate as a percentage of the Medicare non-facility payment rate in the comparative payment rate analysis to obtain an informative metric that can be used in the State's and our assessment of whether the State's payment rates are compliant with section 1902(a)(30)(A) of the Act. As previously discussed, benchmarking against Medicare serves as an important data point in determining whether payment rates are likely to be sufficient to ensure access for Medicaid beneficiaries at least as great as for the general population in the geographic area, and whether any identified access concerns may be related to payment sufficiency. We propose that States would calculate their Medicaid payment rates as a percentage of the Medicare non-facility payment rate because it is a common, simple, and informative statistic that can provide us with a gauge of how Medicaid payment rates compare to Medicare non-facility payment rates in the same geographic area. Initially and over time, States, CMS, and other interested parties would be able to compare the State's Medicaid payment rates as a percentage of Medicare's non-facility payment rates to identify how the percentage changes over time, in view of changes that may take place to the Medicaid and/or the Medicare payment rate. Being able to track and analyze the change in percentage over time would help States and CMS identify possible access concerns that may be related to payment insufficiency.

The organization and content of the comparative payment rate analysis, including the expression of the Medicaid base payment rate as a percentage of the Medicare payment rate, can provide us with a great deal of information about access in the State. For example, we would be able to identify when and how the Medicaid base payment rate as a percentage of the Medicare non-facility payment rate for E/M CPT/HCPCS codes for primary care

[173] *https://www.cms.gov/files/document/physician-fee-schedule-guide.pdf.*

services may decrease over time if Medicare adjusts its rates and a State does not, and use this information to more closely examine for possible access concerns. This type of analysis would provide us with actionable information to help ensure consistency with section 1902(a)(30)(A) of the Act by using Medicare non-facility payment rates paid across the same geographical areas of the State as a point of comparison for payment rate sufficiency as a critical element of beneficiary access to care. When explaining the rationale for proposing to use Medicare non-facility payment rates for comparison earlier in this rule, we emphasized the ability to demonstrate to States that certain Medicaid payment rates have not kept pace with changes to Medicare non-facility payment rates and how the comparative payment rate analysis would help them identify areas where they also might want to consider rate increases that address market changes. We are seeking public comment on the proposed requirement for States to calculate their Medicaid payment rates as a percentage of the Medicare non-facility payment rate for each of the services for which the Medicaid base payment rate is published under proposed paragraph (b)(3)(i)(B), as described in proposed § 447.203(b)(3)(i)(D). We are also seeking public comment on any challenges States might encounter when comparing their Medicaid payment rates to Medicare non-facility payment rates under proposed § 447.203(b)(3)(i)(D), particularly for any of the proposed categories of service in paragraphs (b)(2)(i) through (iii), as well as suggestions for an alternative comparative analysis that might be more helpful, or less burdensome and equally helpful, for States, CMS, and other interested parties to assess whether a State's Medicaid payment rates are consistent with the access standard in section 1902(a)(30)(A) of the Act.

We are aware that provider payment rates are an important factor influencing beneficiary access; as expressly indicated in section 1902(a)(30)(A) of the Act, insufficient provider payment rates are not likely to enlist enough providers willing to serve Medicaid beneficiaries to ensure broad access to care; however, there may be situations where access issues are principally due to other causes. For example, even if Medicaid payment rates are generally consistent with amounts paid by Medicare (and those amounts have been sufficient to ensure broad access to services for Medicare beneficiaries), Medicaid beneficiaries may have difficulty scheduling behavioral health care appointments because the overall number of behavioral health providers within a State is not sufficient to meet the demands of the general population. Therefore, a State's rates may be consistent with the requirements of section 1902(a)(30)(A) of the Act even when access concerns exist, and States and CMS may need to examine other strategies to improve access to care beyond payment rate increases. By contrast, comparing a State's Medicaid behavioral health payment rates to Medicare may demonstrate that the State's rates fall far below Medicare non-facility payment rates, which would likely impede beneficiaries from accessing needed care when the demand already exceeds the supply of providers within a State. In that case, States may need to evaluate budget priorities and take steps to ensure behavioral health rates are consistent with section 1902(a)(30)(A) of the Act.

Lastly, in paragraph (b)(3)(i)(E), we propose to require States to specify in their comparative payment rate analyses the number of Medicaid-paid claims and the number of Medicaid enrolled beneficiaries who received a service within a calendar year for each of the services for which the Medicaid base payment rate is published under paragraph (b)(3)(i)(B). The previous components of the comparative payment rate analysis focus on the State's payment rate for the E/M CPT/HCPCS code and comparing the Medicaid base payment rate to the Medicare non-facility payment rate for the same code (separately, for each Medicaid base payment rate by population (adult or pediatric), provider type, and geographic area, as applicable). This component examines the Medicaid-paid claims volume of each E/M CPT/HCPCS code included in the comparative payment rate analysis relative to the number of Medicaid enrolled beneficiaries receiving each service within a calendar year. We propose to limit the claims volume data to Medicaid-paid claims, and the number of beneficiaries would be limited to Medicaid-enrolled beneficiaries who received a service in the calendar year of the comparative payment rate analysis, where the service would fall into the list of CMS-identified E/M CPT/HCPCS code(s). In other words, a beneficiary would be counted in the comparative payment rate analysis for a particular calendar year when the beneficiary received a service that is included in one of the categories of services described in paragraphs (b)(2)(i) through (iii) for which the State has a Medicaid-based payment rate (the number of Medicaid-enrolled beneficiaries who received a service). A claim would be counted in the comparative payment rate analysis for a particular calendar year when that beneficiary had a claim submitted on their behalf by a provider who billed one of the codes from the list of CMS-identified E/M CPT/HCPCS code(s) to the State and the State paid the claim (number of Medicaid-paid claims). With this proposal, we are seeking to ensure the comparative payment rate analysis reflects actual services received by beneficiaries and paid for by the State, or realized access.[174]

We considered but did not propose States identify the number of unique Medicaid-paid claims and the number of unique Medicaid-enrolled beneficiaries who received a service within a calendar year for each of the services for which the Medicaid base payment rate is published pursuant to paragraph (b)(3)(i)(B). We considered this detail in order to identify the unique, or deduplicated, number of beneficiaries who received a service that falls into one of the categories of services described in in paragraph (b)(2)(i) through (iii) in a calendar year. For example, if a beneficiary has 6 visits to their primary care provider in a calendar year and the provider bills 6 claims with 99202 for the same beneficiary, then the beneficiary and claims for 99202 would only be counted as one claim and one beneficiary. Therefore, we chose not to propose this aspect because we intend for the comparative payment rate analysis to capture the total amount of actual services received by beneficiaries and paid for by the State. We are seeking public comment regarding our decision not to propose States identify the number of unique Medicaid-paid claims and the number of unique Medicaid enrolled beneficiaries who received a service within a calendar year for each of the services for which the Medicaid base payment rate is published pursuant to paragraph (b)(3)(i)(B) in comparative payment rate analysis as proposed § 447.203(b)(3)(i)(E).

We also considered but did not propose States identify the total Medicaid-enrolled population who could potentially receive a service within a calendar year for each of the services for which the Medicaid base

[174] Andersen, R.M., and P.L. Davidson. 2007. Improving access to care in America: Individual and contextual indicators. In Changing the U.S. health care system: Key issues in health services policy and management, 3rd edition, Andersen, R.M., T.H. Rice, and G.F. Kominski, eds. San Francisco, CA: John Wiley & Sons.

payment rate is published pursuant to paragraph (b)(3)(i)(B), in addition to the proposing States identify the number of Medicaid-enrolled beneficiaries who received a service. This additional data element in the comparative payment rate analysis would reflect the number of Medicaid-enrolled beneficiaries who could have received a service, or potential access, in comparison to the number of Medicaid-enrolled beneficiaries who actually received a service. We did not propose this aspect because this could result in additional administrative burden on the State, as we already collect and publish similar data through Medicaid and CHIP Enrollment Trends Snapshots published on *Medicaid.gov.* We are also seeking public comment regarding our decision not to propose States identify the total Medicaid-enrolled population who could receive a service within a calendar year for each of the services for each of the services for each of the services for which the Medicaid base payment rate is published pursuant to paragraph (b)(3)(i)(B) in the comparative payment rate analysis as proposed § 447.203(b)(3)(i)(E).

We propose to include beneficiary and claims information in the comparative payment rate analysis to contextualize the payment rates in the analysis, and to be able to identify longitudinal changes in Medicaid service volume in the context of the Medicaid beneficiary population receiving services, since utilization changes could be an indication of an access to care issue. For example, a decrease in the number of Medicaid-paid claims for primary care services furnished to Medicaid beneficiaries in an area (when the number of Medicaid-enrolled beneficiaries who received primary care services in the area is constant or increasing) could be an indication of an access to care issue. Without additional context provided by the number of Medicaid enrolled beneficiaries who received a service, changes in claims volume could be attributed to a variety of changes in the beneficiary population, such as a temporary loss of coverage when enrollees disenroll and then re-enroll within a short period of time.

Further, if the Medicaid base payment rate for the services with decreasing Medicaid service volume has failed to keep pace with the corresponding Medicare non-facility payment rate over the period of decrease in utilization (as reflected in changes in the Medicaid base payment rate expressed as a percentage of the Medicare non-facility payment rate as required under proposed § 447.203(b)(3)(i)(D)), then we would be concerned and would further scrutinize whether any access to care issue might be caused by insufficient Medicaid payment rates for the relevant services. With each biennial publication of the State's comparative payment rate analysis, as proposed in § 447.203(b)(4), discussed later in this section, States and CMS would be able to compare the number of paid claims in the context of the number of Medicaid enrolled beneficiaries receiving services within a calendar year for the services subject to the comparative payment rate analysis with previous years' comparative payment rate analyses. Collecting and comparing the number of paid claims data in the context of the number of Medicaid enrolled beneficiaries receiving services alongside Medicaid base payment rate data may reveal trends where an increase in the Medicaid base payment rate is correlated with an increase in service volume and utilization, or vice versa with a decrease in the Medicaid base payment rate is correlated with a decrease in service volume and utilization. As claims utilization and number of Medicaid enrolled beneficiaries receiving services are only correlating trends, we acknowledge that there may be other contextualizing factors outside of the comparative payment rate analysis that affect changes in service volume and utilization and we would (and would expect States and other interested parties to) take such additional factors into account in analyzing and ascribing significance to changes in service volume and utilization. We are seeking public comment on the proposed requirement for States to include the number of Medicaid-paid claims and the number of Medicaid enrolled beneficiaries who received a service within a calendar year for which the Medicaid base payment rate is published under proposed paragraph (b)(3)(i)(B), as specified in proposed § 447.203(b)(3)(i)(E).

We believe the comparative payment rate analysis proposed in paragraph (b)(3) is needed to best enable us to ensure State compliance with the requirement in section 1902(a)(30)(A) of the Act that payments are sufficient to enlist enough providers so that care and services are available to Medicaid beneficiaries at least to the extent they are available to the general population in the geographic area. As demonstrated by the findings of Sloan, et al.,[175] which have since been supported and expanded upon by numerous researchers, multiple studies examining the relationship between Medicaid payment and physician participation,[176] [177] at the State level,[178] and among specific provider types,[179] [180] have found a direct, positive association between Medicaid payment rates and provider participation in the Medicaid program. While multiple factors may influence provider enrollment (such as administrative burden), section 1902(a)(30)(A) of the Act specifically concerns the sufficiency of provider payment rates. Given this statutory requirement, a comparison of Medicaid payment rates to other payer rates is an important barometer of whether State payment policies are likely to support the statutory standard of ensuring access for Medicaid beneficiaries such that covered care and services are available to them at least to the extent that the same care and services are available to the general population in the geographic area.

The AMRP requirements currently address this standard under section 1902(a)(30)(A) of the Act by requiring States to compare Medicaid payment rates to the payment rates of other

[175] Sloan, F. et al. ''Physician Participation in State Medicaid Programs.'' *The Journal of Human Resources,* Volume 13, Supplement: National Bureau of Economic Research Conference on the Economics of Physician and Patient Behavior, 1978, p. 211–245. *https://www.jstor.org/stable/145253?seq=1#metadata_info_tab_contents.* Accessed August 16, 2022.

[176] Chen, A. ''Do the Poor Benefit from More Generous Medicaid Policies'' SSRN Electronic Journal, January 2014., p. 1–46. *https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2444286.* Accessed June 16, 2022.

[177] Holgash, K. and Martha Heberlein, ''Physician Acceptance of New Medicaid Patients: What Matters and What Doesn't'' *Health Affairs,* April 10, 2019. *https://www.healthaffairs.org/do/10.1377/forefront.20190401.678690/#:~:text=Physicians%E2%80%99%20acceptance%20of%20new%20Medicaid%20patients%20is%20only,of%20Medicaid%20patients%20already%20in%20the%20physician%E2%80%99s%20care.* Accessed June 16, 2022.

[178] Fakhraei, H. ''Payments for Physician Services: An analysis of Maryland Medicaid Reimbursement Rates'' *International Journal of Healthcare Technology and Management, Volume 7,* Numbers 1–2, January 2005, p. 129–142. *https://www.researchgate.net/publication/228637758_Payments_for_physician_services_An_analysis_of_Maryland_Medicaid_reimbursement_rates.* Accessed June 16, 2022.

[179] Berman, S., et al. ''Factors that Influence the Willingness of Private Primary Care Pediatricians to Accept More Medicaid Patients,'' *Pediatrics,* Volume 110, Issue 2, August 2002, p. 239–248. *https://publications.aap.org/pediatrics/article-abstract/110/2/239/64380/Factors-That-Influence-the-Willingness-of-Private?redirectedFrom=fulltext?autologincheck=redirected.* Accessed June 16, 2022.

[180] Suk-fong S., Tang, et al. ''Increased Medicaid Payment and Participation by Office-Based Primary Care Pediatricians,'' *Pediatrics,* Volume 141, number 1, January 2018, p. 1–9. *https://publications.aap.org/pediatrics/article/141/1/e20172570/37705/Increased-Medicaid-Payment-and-Participation-by.* Accessed June 16, 2022.

public and private payers in current § 447.203(b)(1)(v) and (b)(3). While we are proposing to eliminate the AMRP requirements with this proposed rule, we believe that our proposal to require States to compare their Medicaid payment rates for services under specified E/M CPT/HCPCS codes against Medicare non-facility payment rates for the same codes, as described in § 447.203(b)(3), would well position States and CMS to continue to meet the statutory access requirement. Some studies examining the relationship between provider payments and various access measures have quantified the relationship between the Medicaid-Medicare payment ratio and access measures. Two studies observed that increases in the Medicaid-Medicare payment ratio is associated with higher physician acceptance rates of new Medicaid patients and with an increased probability of a beneficiary having an office-based physician as the patient's usual source of care.[181] [182] These studies led us to conclude that Medicare non-facility payment rates are likely to be a sufficient benchmark for evaluating access to care, particularly ambulatory physician services, based on provider payment rates.

By comparing FFS Medicaid payment rates to corresponding FFS Medicare non-facility payment rates, where Medicare is a public payer with large populations of beneficiaries and participating providers whose payment rates are readily available, we aim to establish a uniform benchmarking approach that allows for more meaningful oversight and transparency and reduces the burden on States and CMS relative to the current AMRP requirements that do not impose specific methodological standards for comparing payment rates and that contemplate the availability of private payer rate information that has proven difficult for States to obtain due to its often proprietary nature. This aspect of the proposal specifically responds to States' expressed concerns that the AMRP requirement to include ''actual or estimated levels of provider payment available from other payers, including other public and private payers'' was challenging to accomplish based on the general unavailability of this information, as discussed elsewhere in this proposed rule.

Following the 2011 proposed rule, and as addressed by us through public comment response in the 2015 final rule with comment period, States expressed concerns that private payer payment rates were proprietary information and not available to them and that large private plans did not exist within some States so there were no private payer rates to compare to, therefore, the State would need to rely on State employee health plans or non-profit insurer rates.[183] States also expressed that other payer data, including public and private payers, in general may be unsound for comparisons because of a lack of transparency about the payment data States would have compared their Medicaid payment rates to. Since 2016, we have learned a great deal from our implementation experience of the AMRP process. We have learned that very few States were able to include even limited private payer data in their AMRPs. States that were able include private payer data were only able to do so because the State had existing Statewide all payer claiming or rate-setting systems, which gave them access to private payer data in their State, or the State previously based their State plan payment rates off of information about other payers (such as the American Dental Association's Survey of Dental Fees) that gave them access to private payer data.[184] Based on our implementation experience and concerns from States about the current requirement in § 447.203(b)(1)(v) to obtain private payer data, we are proposing to require States only compare their Medicaid payment rates to Medicare's, for which payment data are readily and publicly available.

Next, in paragraph (b)(3)(ii), we propose that for each category of services described in proposed paragraph (b)(2)(iv), the State agency would be required to publish a payment rate disclosure that expresses the State's payment rates as the average hourly payment rates, separately identified for payments made to individual providers and to providers employed by an agency, if the rates differ. The payment rate disclosure would be required to meet specified requirements. The reason for including this proposal builds on our justification for including personal care, home health aide, and homemaker services provided by individual providers and providers employed by an agency in this proposed rule, which is to remain consistent with the proposed HCBS provisions at § 441.311(d)(2) and (e) and take specific action regarding direct care workers per Section 2402(a) of the Affordable Care Act. HCBS and direct care workers that deliver these services are unique to Medicaid and often not covered by other payers, which is why we are proposing a different analysis of payment rates for providers of these services that does not involve a comparison to Medicare. As previously stated, Medicare covers part-time or intermittent home health aide services (only if a Medicare beneficiary is also getting other skilled services like nursing and/or therapy at the same time) under Medicare Part A (Hospital Insurance) or Medicare Part B (Medical Insurance); however, Medicare does not cover personal care or homemaker services. Therefore, comparing personal care and homemaker services to Medicare, as we proposed in paragraph (b)(3)(i) for other specified categories of services, would not be feasible for States, and a comparison of Medicaid home health aide average hourly payment rates to analogous rates for Medicare would be of limited utility given the differences in circumstances when Medicaid and Medicare may pay for such services.

As previously discussed, private payer data are often considered proprietary and not available to States, thereby eliminating private payers as feasible point of comparison. Even if private payer payment rate data were more readily available, like Medicare, many private payers do not cover HCBS as HCBS is unique to the Medicaid program, leaving Medicaid as the largest or the only payer for personal care, home health aide, and homemaker services. Given Medicaid's status as the most important payer for HCBS, we believe that scrutiny of Medicaid HCBS payment rates themselves, rather than a comparison to other payer rates that frequently do not exist, is most important in ascertaining whether such Medicaid payment rates are sufficient to enlist adequate providers so that the specified services are available to Medicaid beneficiaries at least to the same extent as to the general population in the geographic area. We acknowledge that individuals without insurance may self-pay for medical services provided in their home or community; however, similar to private payer data, self-pay data is unlikely to be available to States. Because HCBS coverage is unique to Medicaid, Medicaid beneficiaries are generally the only individuals in a given geographic area with access to HCBS. Through the proposed payment rate disclosure, Medicaid payments rates

[181] Holgash, K. and Martha Heberlein, *Health Affairs,* April 10, 2019.

[182] Cohen, J.W., *Inquiry,* Fall 1993.

[183] Alaska Department of Health and Social Services, Comment Letter on 2011 Proposed Rule (July 7, 2011), *https://www.regulations.gov/comment/CMS-2011-0062-0102.*

[184] *https://www.medicaid.gov/sites/default/files/2019-12/co-amrp-2016.pdf, https://www.medicaid.gov/sites/default/files/2019-12/md-amrp-16.pdf, https://www.medicaid.gov/sites/default/files/2019-12/sd-amrp-16.pdf.*

would be transparent and comparable among States and would assist States to analyze if and how their payment rates are compliant with section 1902(a)(30)(A) of the Act.

As noted previously in this section, we propose to require States to express their rates separately as the average hourly payments made to individual providers and providers employed by an agency, if the rates differ, as applicable for each category of service specified in proposed § 447.203(b)(2)(iv). We believe expressing the data in this manner would best account for variations in types and levels of payment that may occur in different settings and employment arrangements. Individual providers are often self-employed or contract directly with the State to deliver services as a Medicaid provider while providers employed by an agency are employed by the agency which works directly with the Medicaid agency to provide Medicaid services. These differences in employment arrangements often include differences in the hourly rate a provider would receive for services delivered, for example, providers employed by an agency typically receive benefits, such as health insurance, and the cost of those benefits are factored into the hourly rate that the State pays for the services delivered by providers employed by an agency (even though the employed provider does not retain the entire amount as direct monetary compensation). However, these benefits are not always available for individual providers who may need to separately purchase a marketplace health plan or be able to opt into the State-employee health plan, for example. Therefore, the provider employed by an agency potentially could receive a higher hourly rate because benefits are factored into the hourly rate they receive for delivering services, whereas the individual provider might be paid a rate that does not reflect employment benefits.

With States expressing their payment rates separately as the average hourly payment rate made to individual and agency employed providers for personal care, home health aide, and homemaker services, States, CMS, and other interested parties would be able to compare payment rates among State Medicaid programs. Such comparisons may be particularly relevant for States in close geographical proximity to each other or that otherwise may compete to attract providers of the services specified in proposed paragraph (b)(2)(iv) or where such providers may experience similar costs or other incentives to provide such services. For example, from reviewing all States' payment rate analyses for personal care, home health aide, and homemaker services, we would be able to learn that two neighboring States have similar hourly rates for providers of these services, but a third neighboring State has much lower hourly rates than both of its neighbors. This information could highlight a potential access issue, since providers in the third State might have an economic incentive to move to one of the two neighboring States where they could receive higher payments for furnishing the same services. Such movement could result in beneficiaries in the third State having difficulty accessing covered services, compared to the general population in the tri-State geographic area.

Additionally in paragraph (b)(3)(ii), we propose that the State's payment rate disclosure must meet the following requirements: (A) the State must organize the payment rate disclosure by category of service as specified in proposed paragraph (b)(2)(iv); (B) the disclosure must identify the average hourly payment rates, including, if the rates vary, separate identification of the average hourly payment rates for payments made to individual providers and to providers employed by an agency by population (pediatric and adult), provider type, and geographical location, as applicable; and (C) the disclosure must identify the number of Medicaid-paid claims and the number of Medicaid enrolled beneficiaries who received a service within a calendar year for each of the services for which the Medicaid base payment rate is published under proposed paragraph (b)(3)(ii)(B). We are seeking public comment on the proposed requirements and content of the items in proposed § 447.203(b)(3)(ii)(A) through (C).

In paragraph (b)(3)(ii)(A), we propose to require States to organize their payment rate disclosures by each of the categories of services specified in proposed paragraph (b)(2)(iv), that is, to break out the payment rates for personal care, home health aide, and homemaker services provided by individual providers and providers employed by an agency, separately for individual analyses of the payment rates for each category of service and type of employment structure. We are seeking public comment on the proposed requirement for States to break out their payment rates for personal care, home health aide, and homemaker services separately for individual analyses of the payment rates for each category of service in the comparative payment rate analysis, as described in proposed § 447.203(b)(3)(ii)(A).

In paragraph (b)(3)(ii)(B), we propose to require States identify in their disclosure the Medicaid average hourly payment rates by applicable category of service, including, if the rates vary, separate identification of the average hourly payment rates for payments made to individual providers and to providers employed by an agency, as well as by population (pediatric and adult), provider type, and geographical location, as applicable. Given that direct care workers deliver unique services in Medicaid that are often not covered by other payers, we are proposing to require a payment rate disclosure, instead of comparative payment rate analysis. To be clear, we are not proposing to require a State's payment rate disclosure for personal care, home health aide, and homemaker services be broken down and organized by E/M CPT/HCPCS codes, nor are we proposing States compare their Medicaid payment rates to Medicare for these services.

We propose to require States calculate their Medicaid average hourly payment rates made to providers of personal care, home health aide, and homemaker services, separately, for each of these categories of services, by provider employment structures (individual providers and agency employed providers). For each of the categories of services in paragraph (b)(3)(ii)(A), one Medicaid average hourly payment rate would be calculated as a simple average or arithmetic mean where all payment rates would be adjusted to an hourly figure, summed, then divided by the number of all hourly payment rates. As an example, the State's Medicaid average hourly payment rate for personal care providers may be $10.50 while the average hourly payment rate for a home health aide is $15.00. A more granular analysis may show that within personal care providers receiving a payment rate of $10.50, an individual personal care provider is paid an average hourly payment rate of $9.00, while a personal care provider employed by an agency is paid an average hourly payment rate of $12.00 for the same type of service. Similarly for home health aides, a more granular analysis may show that within home health aides receiving a payment rate of $15.00, an individual home health aide is paid an average hourly payment rate of $13.00, while a home health aide employed by an agency is paid an average hourly payment rate of $17.00.

We understand that States may set payment rates for personal care, home health aide, and homemaker services based on a particular unit of time for delivering the service, and that time

may not be in hourly increments. For example, different States might pay for personal care services using 15-minute increments, on an hourly basis, through a daily rate, or based on a 24-hour period. By proposing to require States to represent their rates as an hourly payment rate, we would be able to standardize the unit (hourly) and payment rate for comparison across States, rather than comparing to Medicare. To the extent a State pays for personal care, home health aide, or homemaker services on an hourly basis, the State would simply use that hourly rate in its Medicaid average hourly payment rate calculation of each respective category of service. However, if for example a State pays for personal care, home health aide, or homemaker services on a daily basis, we would expect the State to divide that rate by the number of hours covered by the rate.

Additionally, and similar to proposed paragraph (b)(3)(i)(E), we propose in paragraph (b)(3)(ii)(B), that, if the States' Medicaid average hourly payment rates vary, the rates must separately identify the average hourly payment rates for payments made to individual providers and to providers employed by an agency, by population (pediatric and adult), provider type, and geographical location, as applicable. We include this proposed provision with the intent of ensuring the payment rate disclosure contains the highest level of granularity in each element. As previously discussed, States may pay providers different payment rates for billing the same service based on the population being served, provider type, and geographical location of where the service is delivered. We are seeking public comments on the proposed requirement for States to calculate the Medicaid average hourly payment rate made separately to individual providers and to agency employed providers, which accounts for variation in payment rates by population (pediatric and adult), provider type, and geographical location, as applicable, in the payment rate disclosure as discussed in this section about proposed § 447.203(b)(3)(ii)(B).

In paragraph (b)(3)(ii)(C), we propose to require that the State disclosure must identify the number of Medicaid-paid claims and the number of Medicaid enrolled beneficiaries who received a service within a calendar year for each of the services for which the Medicaid payment rate is published under proposed paragraph (b)(3)(ii)(B), so that States, CMS, and other interested parties would be able to contextualize the previously described payment rate information with information about the volume of paid claims and number of beneficiaries receiving personal care, home health aide, and homemaker services.

We propose that the number of Medicaid-paid claims and number of Medicaid enrolled beneficiaries who received a service be reported under the same breakdown as paragraph (b)(3)(ii), where the State provides the number of paid claims and number of beneficiaries receiving services from individual providers versus agency-employed providers of personal care, home health aide services, and homemaker services. As with the comparative payment rate analysis, we are proposing the claims volume data would be limited to Medicaid-paid claims and the number of beneficiaries would be limited to Medicaid enrolled beneficiaries who received a service in the calendar year of the payment rate disclosure, where the services would fall into the categories of service for which the average hourly payment rates are published pursuant to paragraph (b)(3)(ii)(B). In other words, beneficiary would be counted in the payment rate disclosure for a particular calendar year when the beneficiary received a service that is included in one of the categories of services described in paragraph (b)(2)(iv) that the State has calculated average hourly payment rates for (the number of Medicaid enrolled beneficiaries who received a service). A claim would be counted when that beneficiary had a claim submitted on their behalf by a provider who billed for one of the categories of services described in paragraph (b)(2)(iv) and the State paid the claim (number of Medicaid-paid claims). We are seeking to ensure the payment rate disclosure reflects actual services received by beneficiaries and paid for by the State, or realized access.[185]

Similar to the comparative payment rate analysis, we considered but did not propose States identify the number of unique Medicaid-paid claims and the number of unique Medicaid enrolled beneficiaries who received a service within a calendar year for each of the services for which the average hourly payment rates are published pursuant to paragraph (b)(3)(ii)(B). We also considered but did not propose States identify the total Medicaid enrolled population who could receive a service within a calendar year for each of the services for which the average hourly payment rates are published pursuant to paragraph (b)(3)(ii)(B) in addition to the proposing States identify the number of Medicaid enrolled beneficiaries who received a service. As discussed in the comparative payment rate discussion, we are requesting public comment on our decision not to require these levels of detail for the payment rate disclosure. Also similar to the comparative payment rate analysis requirement under proposed paragraph (b)(3)(i)(E), this disclosure element would help States, CMS, and other interested parties identify longitudinal changes in Medicaid service volume and beneficiary utilization changes that may be an indication of an access to care issue. Again, with each biennial publication of the State's comparative payment rate analysis and payment rate disclosure, States and CMS would be able to compare the number of Medicaid-paid claims and number of Medicaid enrolled beneficiaries who received a service within a calendar year for services subject to the payment rate disclosure with previous years' disclosures. Collecting and comparing data on the number of paid claims and number of Medicaid enrolled beneficiaries alongside Medicaid average hourly payment rate data may reveal trends, such as where a provider type that previously delivered a low volume of services to beneficiaries has increased their volume of services delivered after receiving an increase in their payment rate.

We acknowledge that one limitation of using the average hourly payment rate is that the statistic is sensitive to highs and lows so one provider receiving an increase in their average hourly payment rate would bring up the average overall while other providers may not see an improvement. As these are only correlating trends, we also acknowledge that there may be other contextualizing factors outside of the payment rate disclosure that may affect changes in service volume and utilization. We are seeking public comments on the proposed requirement for States to include the number of Medicaid-paid claims and number of Medicaid enrolled beneficiaries who received a service within a calendar year for which the Medicaid payment rate is published under paragraph (b)(3)(ii)(B), as specified in proposed § 447.203(b)(3)(ii)(C).

Additionally, in recognition of the importance of services provided to individuals with intellectual or developmental disabilities and in an effort to remain consistent with the proposed HCBS provisions at

[185] Andersen, R.M., and P.L. Davidson. 2007. Improving access to care in America: Individual and contextual indicators. In Changing the U.S. health care system: Key issues in health services policy and management, 3rd edition, Andersen, R.M., T.H. Rice, and G.F. Kominski, eds. San Francisco, CA: John Wiley & Sons.

§ 441.302(k)(3)(i), we are seeking public comment on whether we should propose a similar provision that would require at least 80 percent of all Medicaid FFS payments with respect to personal care, home health aide, and homemaker services provided by individual providers and providers employed by an agency must be spent on compensation for direct care workers.

In paragraph (b)(4), we propose to require the State agency to publish the initial comparative payment rate analysis and payment rate disclosure of its Medicaid payments in effect as of January 1, 2025, as required under § 447.203(b)(2) and (b)(3), by no later than January 1, 2026. Thereafter, the State agency would be required to update the comparative payment rate analysis and payment rate disclosure no less than every 2 years, by no later than January 1 of the second year following the most recent update. The comparative payment rate analysis and payment rate disclosure would be required to be published consistent with the publication requirements described in proposed § 447.203(b)(1) for payment rate transparency data.

As previously discussed in this proposed rule, we propose that the Medicaid payment rates included in the initial comparative payment rate analysis and payment rate disclosure would be those in effect as of January 1, 2025. Specifically, for the comparative payment rate analysis, we propose States would conduct a retrospective analysis to ensure CMS can publish the list of E/M CPT/HCPCS codes for the comparative payment rate analysis and States have timely access to all information required to complete comparative payment rate analysis. As described in paragraph (b)(3)(i)(C), we propose States would compare their Medicaid payment rates to the Medicare non-facility payment rates effective for the same time period for the same set of E/M CPT/HCPCS codes, therefore, the Medicare non-facility payment rates as published on the Medicare PFS for the same time period as the State's Medicaid payment rates would need to be available to States in a timely manner for their analysis and disclosure to be conducted and published as described in paragraph (b)(4). Medicare publishes its annual PFS final rule in November of each year and the Medicare non-facility payment rates as listed on the Medicare PFS are effective the following January 1. For example, the 2025 Medicare PFS final rule would be published in November 2024 and the Medicare non-facility payment rates as listed on the Medicare PFS would be effective January 1, 2025, so States would compare their Medicaid payment rates effective as of January 1, 2025, to the Medicare PFS payment rates effective January 1, 2025 when submitting the initial comparative payment rate analysis that is due on January 1, 2026.

Also previously discussed in this proposed rule, we intend to publish the initial and subsequent updates to the list of E/M CPT/HCPCS codes subject to the comparative payment rate analysis in a timely manner that allows States approximately one full calendar year between the publication of the CMS-published list of E/M CPT/HCPCS codes and the due date of the comparative payment rate analysis. Because the list of E/M CPT/HCPCS codes is derived from the relevant calendar year's Medicare PFS, the Medicare non-facility payment rates the State would need to include in their comparative payment rate analysis would also be available to States. We expect approximately one full calendar year of the CMS-published list of E/M CPT/HCPCS codes and Medicare non-facility payment rates as listed on the Medicare PFS being available to States would provide the States with sufficient time to develop and publish their comparative payment rate analyses as described in paragraph (b)(4). We considered proposing the same due date and effective time period for Medicaid and Medicare payment rates where the initial publication of the comparative payment rate analysis would be due January 1, 2026, and would contain payment rates effective January 1, 2026; however, we believe a two month time period between Medicare publishing its PFS payment rates in November and the PFS payment rates taking effect on January 1 would be an insufficient amount of time for CMS to publish the list of E/M CPT/HCPCS codes subject to the comparative payment rate analysis and for States to develop and publish their comparative payment rate analyses by January 1. While the proposed payment rate disclosure would not require a comparison to Medicare, we are proposing to use the same due date and effective period of Medicaid payment rates for both the proposed comparative payment rate analysis and payment rate disclosure to maintain consistency.

We expect the proposed initial publication timeframe to provide sufficient time for States to gather necessary data, perform, and publish the first required comparative payment rate analysis and payment rate disclosure. We determined this timeframe was sufficient based on implementation experience from the AMRP process, where we initially proposed a 6-month timeframe between the January 4, 2016 effective date of the 2015 final rule with comment period in the **Federal Register**, and the due date of the first AMRP, July 1, 2016. At the time, we believed that this timeframe would be sufficient for States to conduct their first review for service categories newly subject to ongoing AMRP requirements; however, after receiving several public comments from States on the 2015 final rule with comment period that State agency staff may have difficulty developing and submitting the initial AMRPs within the July 1, 2016 timeframe, we modified the policy as finalized in the 2016 final rule.[186] Specifically, we revised the deadline for submission of the initial AMRP until October 1, 2016 and we made a conforming change to the deadline for submission in subsequent review periods at § 447.203(b)(5)(i) to October 1.[187] We also found that, despite this additional time, some State were still late in submitting their first AMRP to us. Therefore, we believe that proposing an initial publication date of January 1, 2026, thereby providing States with approximately 2 years between the effective date of the final rule, if this proposal is finalized, and the due date of the first comparative payment rate analysis and payment rate disclosure, would be sufficient. In alignment with the proposed payment rate transparency requirements, if this rule is finalized at a time that does not allow for States to have a period of 2 years from the effective date of the final rule and the proposed January 1, 2026 date to publish the initial comparative payment rate analysis and payment rate disclosure, then we would propose an alternative date of July 1, 2026 for the initial comparative payment rate analysis and payment rate disclosure and for the initial comparative payment rate analysis and payment rate disclosure to include Medicaid payment rates approved as of July 1, 2025 to allow more time for States to comply with the initial comparative payment rate analysis and payment rate disclosure requirements. We acknowledge that the date of the initial comparative payment rate analysis and payment rate disclosure publication is subject to change based on the final rule publication schedule and effective date, if this rule is finalized. If further adjustment is necessary beyond the July 1, 2026 timeframe to allow more time for States to comply with the payment rate transparency requirements, then we would adjust date of the initial payment

[186] 81 FR 21479 at 21479–21480.

[187] 81 FR 21479 at 21480.

rate transparency publication in 6-month intervals, as appropriate.

Also, in § 447.203(b)(4), we propose to require the State agency to update the comparative payment rate analysis and payment rate disclosure no less than every 2 years, by no later than January 1 of the second year following the most recent update. We propose that the comparative payment rate analysis and payment rate disclosure would be required to be published consistent with the publication requirements described in proposed paragraph (b)(1) for payment rate transparency data. After publication of the 2011 proposed rule, and as we worked with States to implement the current AMRP requirements after publication of the 2015 final rule with comment period, many States expressed concerns that the current requirements of § 447.203, specifically those in current § 447.203(b)(6) that impose additional analysis and monitoring requirements in the case of provider rate reductions or restructurings that could result in diminished access, are overly burdensome. As described in the 2018 and 2019 proposed rules, ''a number of States expressed concern regarding the administrative burden associated with the requirements of § 447.203, particularly those States with a very high beneficiary enrollment in comprehensive, risk-based managed care and a limited number of beneficiaries receiving care through a FFS delivery system.'' [188] [189]

Additionally, from our implementation experience, we learned that the triennial due date for updated AMRPs required by current § 447.203(b)(5)(ii) was too infrequent for States or CMS to identify and act on access concerns identified by the AMRPs. For example, one State timely submitted its initial ongoing AMRP on October 1, 2016, consistent with the requirements in § 447.203(b)(1) through (5), and timely submitted its first AMRP update (the next ongoing AMRP) 3 years later, on October 1, 2019. The 2016 AMRP included data about beneficiary utilization and Medicaid-participating providers accepting new Medicaid patients from 2014 to 2015 (the most recent data available at the time the State was developing the AMRP), while the 2019 AMRP update included similar data for 2016 to 2017 (the most recent data then available). The 2019 AMRP showed that the number of Medicaid-participating providers accepting new Medicaid patients significantly dropped in 2016, and the State received a considerable number of public comments during the 30-day public comment period for the 2019 AMRP update prior to submission to us per the requirements in § 447.203(b) and (b)(2). This data lag between a drop in Medicaid-participating providers accepting new Medicaid patients in 2016 and CMS receiving the next AMRP update with information about related concerns in 2019 illustrates how the infrequency of the triennial due date for the AMRP updates could allow a potential access concern to develop without notice by the State or CMS in between the due dates of the ongoing AMRP updates. Although § 447.203(b)(7) currently requires States to have ongoing mechanisms for beneficiary and provider input on access to care, and States are expected to promptly respond to concerns expressed through these mechanisms that cite specific access problems, beneficiaries and providers themselves may not be aware of even widespread access issues if such issues are not noticed before published data reveal them.

We also learned from our AMRP implementation experience that the timing of the ongoing AMRP submissions required by current § 447.203(b)(5)(ii) and access reviews associated with rate reduction or restructuring SPA submissions required by § 447.203(b)(6) have led to confusion about the due date and scope of routine, ongoing AMRP updates and SPA-connected access review submissions, particularly when States were required to submit access reviews within the 3-year period between AMRP updates when proposing a rate reduction or restructuring SPA, per the requirements in current § 447.203(b)(6). For example, one State timely submitted its initial ongoing AMRP on October 1, 2016, consistent with the requirements in § 447.203(b)(1) through (5), then the State submitted a SPA that proposed to reduce provider payment rates for physical therapy services with an effective date of July 1, 2018, along with an access review for the affected service completed within the prior 12 months, consistent with the requirements in § 447.203(b)(6). The State's access review submission consisted of its 2016 AMRP submission, updated with data from the 12 months prior to this SPA submission, with the addition of physical therapy services for which the SPA proposed to reduce rates. Because the State submitted an updated version of its 2016 AMRP in 2018 in support of the SPA submission, the State was confused whether its next AMRP update submission was due in 2019 (3 years from 2016), or in 2021 (3 years from 2018). Based on the infrequency of a triennial due date for AMRP updates and the numerous instances of similar State confusion during the implementation process for the AMRPs, we identified that the triennial timeframe was insufficient for the proposed comparative payment rate analysis and payment rate disclosure. As we considered a new timeframe for updates to the comparative payment rate analysis and payment rate disclosure to propose in this rulemaking, we initially considered proposing to require annual updates. However, we believe annual updates would add unnecessary administrative burden as annual updates would be too frequent because many States do not update their Medicaid fee schedule rates for the codes subject to the comparative payment rate analysis and payment rate disclosure on an annual basis.

As proposed, the payment rates for the categories of services subject to the proposed comparative payment rate analysis and payment rate disclosure are for office-based visits and, in our experience, the Medicaid payment rates generally do not change much over time due to the nature of an office visit.[190] Office visits primarily include vitals being taken and the time a patient meets with a physician or NPP; therefore, States would likely have a considerable amount of historical payment data for supporting the current payment rates for such services. Given the relatively stable nature of payment rates for office visits, we aim to help ensure the impact of the comparative payment rate analysis is maximized for ensuring compliance with section 1902(a)(30)(A) of the Act while minimizing unnecessary burden on States by holding all States to a proposed update frequency of 2 years to capture all Medicaid (and corresponding Medicare) payment rate changes.

As this proposed rule strives to reduce the amount of administrative burden from AMRPs on States while also fulfilling our oversight responsibilities, we believe updating the comparative payment rate analysis and

[188] 83 FR 12696 at 12697.

[189] 84 FR 33722 at 33723.

[190] We acknowledge that Medicaid primary care payment increase, a provision in the Patient Protection and Affordable Care Act (ACA, Pub. L. 111–148, as amended), temporarily raised Medicaid physician fees for evaluation and management services (Current Procedural Terminology codes 99201–99499) and vaccine administration services and counseling related to children's vaccines (Current Procedural Terminology codes 90460, 90461, and 90471–90474). This provision expired on December 31, 2014. *https://www.macpac.gov/wp-content/uploads/2015/03/An-Update-on-the-Medicaid-Primary-Care-Payment-Increase.pdf.*

payment rate disclosure no less than every 2 years achieves an appropriate balance between administrative burden and our oversight responsibilities with regard to section 1902(a)(30)(A) of the Act. We intend for the comparative payment rate analysis and payment rate disclosure States develop and publish to be time-sensitive and useful sources of information and analysis to help ensure compliance with section 1902(a)(30)(A) of the Act. If this proposal is finalized, both the comparative payment rate analysis and payment rate disclosure would provide the State, CMS, and other interested parties with cross-sectional data of Medicaid payment rates at various points in time. This data could be used to track Medicaid payment rates over time as a raw dollar amount and as a percentage of Medicare non-facility payment rates as listed on the Medicare PFS as well as changes in the number of Medicaid-paid claims volume and number of Medicaid enrolled beneficiaries who received a service over time. The availability of this data could be used to inform State policy changes, to compare payment rates across States, or be used for research on Medicaid payment rates and policies. While we believe the comparative payment rate analysis and payment rate disclosure would provide useful and actionable information to States, we do not want to overburden States with annual updates to the comparative payment rate analysis and payment rate disclosure. As we are proposing to replace the triennial AMRP process with less administratively burdensome processes (payment rate transparency publication, comparative payment rate analysis, payment rate disclosure, and State analysis procedures for rate reductions and restructurings) for ensuring compliance with section 1902(a)(30)(A) of the Act, we believe annual updates to the comparative payment rate analysis and payment rate disclosure would negate at least a portion of the decrease in administrative burden from eliminating the AMRP process.

With careful consideration, we believe that our proposal to require updates to the comparative payment rate analysis and payment rate disclosure to occur no less than every 2 years is reasonable. We expect the proposed biennial publication requirement for the comparative payment rate analysis and payment rate disclosure after the initial publication date would be feasible for State agencies, provide a straightforward timeline for updates, limit unnecessary State burden, help ensure public payment rate transparency, and enable us to conduct required oversight. We are seeking public comment on the proposed timeframe for the initial publication and biennial update requirements for the comparative payment rate analysis and payment rate disclosure as proposed in § 447.203(b)(4).

Lastly, we also propose in paragraph (b)(4) to require States to publish the comparative payment rate analysis and payment rate disclosure consistent with the publication requirements described in proposed paragraph (b)(1) for payment rate transparency data. Paragraph (b)(1) would require the website developed and maintained by the single State Agency to be accessible to the general public. We are proposing States utilize the same website developed and maintained by the single State Agency to publish their Medicaid FFS payment rates and their comparative payment rate analysis and payment rate disclosure. We are seeking public comment on the proposed required location for States to publish their comparative payment rate analysis and payment rate disclosure proposed in § 447.203(b)(4).

In § 447.203(b)(5), we propose a mechanism to ensure compliance with paragraphs (b)(1) through (b)(4). Specifically, we propose that, if a State fails to comply with the payment rate transparency and comparative payment rate analysis and payment rate disclosure requirements in paragraphs (b)(1) through (b)(4) of proposed § 447.203, including requirements for the time and manner of publication, that, under section 1904 of the Act and procedures set forth in regulations at 42 CFR part 430 subparts C and D, future grant awards may be reduced by the amount of FFP we estimate is attributable to the State's administrative expenditures relative to the total expenditures for the categories of services specified in paragraph (b)(2) of proposed § 447.203 for which the State has failed to comply with applicable requirements, until such time as the State complies with the requirements. We also propose that unless otherwise prohibited by law, FFP for deferred expenditures would be released after the State has fully complied with all applicable requirements. This proposed enforcement mechanism is similar in structure to the mechanism that applies with respect to the Medicaid Disproportionate Share Hospital (DSH) reporting requirements in § 447.299(e), which specifies that State failure to comply with reporting requirements will lead to future grant award reductions in the amount of FFP CMS estimates is attributable to expenditures made for payments to the DSH hospitals as to which the State has not reported properly. We are proposing this long-standing and effective enforcement mechanism in this proposed rule because we believe it is proportionate and clear, and to remain consistent with other compliance actions we take for State non-compliance with statutory and regulatory requirements. We are seeking public comment on the proposed method for ensuring compliance with the payment rate transparency and comparative payment rate analysis and payment rate disclosure requirements, as specified in proposed § 447.203(b)(5).

A fundamental element of ensuring access to covered services is the sufficiency of a provider network. As discussed elsewhere in this rule, the HCBS direct care workforce is currently experiencing notable worker shortages.[191] A robust workforce providing HCBS allows more beneficiaries to obtain necessary services in home and community-based settings. We are proposing to use data-driven benchmarks in requiring comparative payment rate analyses relative to Medicare non-facility payment rates for the categories of service specified in proposed § 447.203(b)(2)(i) through (iii), but Medicare non-facility payment rates are generally not relevant in the context of HCBS, as discussed earlier in this section. Furthermore, data alone cannot replace the lived experience of direct care workers and recipients of the services they provide.

Understanding how Medicaid payment rates compare in different geographic areas of a State and across State programs is also an important access to care data point for covered benefits where Medicaid is a predominant payer of services, as in the case of HCBS. In the absence of HCBS coverage and a lack of available payment rate and claims utilization data from other health payers, such as Medicare or private insurers, and with the significant burden and potential infeasibility associated with gathering payment data for individuals who pay out of pocket (that is, self-pay), we believe it would be a reasonable standard for States to compare their rates to geographically similar State Medicaid program payment rates as a basis for understanding compliance with section 1902(a)(30)(A) of the Act for those services. In addition, even for services where other payers establish

[191] *https://www.macpac.gov/wp-content/uploads/2022/03/MACPAC-brief-on-HCBS-workforce.pdf.*

payment rates, comparisons to rates paid by other geographically similar States could be important to understanding compliance with section 1902(a)(30)(A) of the Act since Medicaid beneficiaries may have unique health care needs that are not typical of the general population in particular geographic areas.

Section 2402(a) of the Affordable Care Act directs the Secretary to promulgate regulations ensuring that all States develop service systems that, among other things, improve coordination and regulation of providers of HCBS to oversee and monitor functions, including a complaint system, and ensure that there are an adequate number of qualified direct care workers to provide self-directed services. This statutory mandate, coupled with the workforce shortages exacerbated by the COVID–19 pandemic, necessitates action specific to direct care workers. As such, we are proposing to require States to establish an interested parties' advisory group to advise and consult on FFS rates paid to direct care workers providing self-directed and agency-directed HCBS, at a minimum for personal care, home health aide, and homemaker services as described in § 440.180(b)(2) through (4), and States may choose to include other HCBS. The definition of direct care workers is proposed elsewhere in this rule under § 441.302(k)(1)(ii). We propose to utilize that definition, to consider a direct care worker a registered nurse, licensed practical nurse, nurse practitioner, or clinical nurse specialist who provides nursing services to Medicaid-eligible individuals receiving HCBS; a licensed nursing assistant who provides such services under the supervision of a registered nurse, licensed practical nurse, nurse practitioner, or clinical nurse specialist; a direct support professional; a personal care attendant; a home health aide; or other individuals who are paid to provide services to address activities of daily living or instrumental activities of daily living directly to Medicaid-eligible individuals receiving HCBS available under part 441, subpart G. A direct care worker may be employed by a Medicaid provider, State agency, or third party; contracted with a Medicaid provider, State agency, or third party; or delivering services under a self-directed service model.

We propose that the group would consult on rates for service categories under the Medicaid State plan, section 1915(c) waiver and demonstration programs, as applicable, where payments are made to individual providers or providers employed by an agency for, at a minimum, the previously described types of services, including for personal care, home health aide, and homemaker services provided under sections 1905(a), 1915(i), 1915(j), and 1915(k) State plan authorities, and section 1915(c) waivers. These proposed requirements also would extend to rates for HCBS provided under section 1115 demonstrations, as is typical for rules pertaining to HCBS authorized using demonstration authority. The interested parties advisory group may consult on other HCBS, at the State's discretion.

Specifically, in § 447.203(b)(6), we propose that the State agency would be required to establish an advisory group for interested parties to advise and consult on provider rates with respect to service categories under the Medicaid State plan, section 1915(c) waiver and demonstration programs, as applicable, where payments are made to the direct care workers specified in § 441.302(k)(1)(ii) for the self-directed or agency-directed services found at § 440.180(b)(2) through (4). The interested parties' advisory group would be required to include, at a minimum, direct care workers, beneficiaries and their authorized representatives, and other interested parties. ''Authorized representatives'' refers to individuals authorized to act on the behalf of the beneficiary, and other interested parties may include beneficiary family members and advocacy organizations. To the extent a State's MAC established under proposed § 431.12, if finalized, meets the requirements of this regulation, the State could utilize that committee for this purpose. However, we note the roles of the MAC under proposed § 431.12 and the interested party advisory group under proposed § 447.203(b)(6) would be distinct, and the existence or absence of one committee or group (for example, if one of these proposals is not finalized) would not affect the requirements with respect to the other as established in a final rule.

We further propose in § 447.203(b)(6)(iii) that the interested parties' advisory group would advise and consult with the Medicaid agency on current and proposed payment rates, HCBS payment adequacy data as required at § 441.311(e), and access to care metrics described in § 441.311(d)(2), associated with services found at § 440.180(b)(2) through (4), to ensure the relevant Medicaid payment rates are sufficient to ensure access to homemaker services, home health aide services, and personal care services for Medicaid beneficiaries at least as great as available to the general population in the geographic area and to ensure an adequate number of qualified direct care workers to provide self-directed personal assistance services.

In proposed § 447.203(b)(6)(iv), we propose that the interested parties advisory group would meet at least every 2 years and make recommendations to the Medicaid agency on the sufficiency of State plan, 1915(c) waiver, and demonstration direct care worker payment rates, as applicable. The State agency would be required to ensure the group has access to current and proposed payment rates, HCBS provider payment adequacy minimum performance and reporting standards as described in § 441.311(e), and applicable access to care metrics for HCBS as described in § 441.311(d)(2) to produce these recommendations. These materials would be required to be made be available with sufficient time for the advisory group to consider them, formulate recommendations, and transmit those recommendations to the State. If the State has asked the group to consider a proposed rate change, they would need to provide the group with sufficient time to review and produce a recommendation within the State's intended rate adjustment schedule. This would be necessary because the group's recommendation would be considered part of the interested parties input described in proposed §§ 447.203(c)(4) and 447.204(b)(3), which States would be required to consider and analyze. The interested parties' advisory group would make recommendations to the Medicaid agency on the sufficiency of the established and proposed State plan, section 1915(c) waiver and demonstration payment rates, as applicable. In other words, the group would provide information to the State regarding whether, based on the group's knowledge and experience, current payment rates are sufficient to enlist a sufficiently large work force to ensure beneficiary access to services, and whether a proposed rate change would be consistent with a sufficiently large work force or would disincentivize participation in the work force in a manner that might compromise beneficiary access.

We propose to require States to convene this interested parties' advisory group every 2 years, at a minimum, to advise and consult on current and suggested payment rates and the sufficiency of these rates to ensure access to HCBS for beneficiaries consistent with section 1902(a)(30)(A) of the Act. This timing aligns with the comparative payment rate analysis and payment rate disclosure publication requirements proposed in § 447.203(b)(4), although we note that

this would be a minimum requirement and a State may find that more frequent meetings would be necessary or helpful for the advisory group to provide meaningful and actionable feedback. We further propose that the process by which the State selects its advisory group members and convenes meetings would be required to be made publicly available, but other matters, such as the tenure of members, would be left to the State's discretion.

Finally, in § 447.203(b)(6)(v), we propose that the Medicaid agency would be required to publish the recommendations of the interested parties' advisory group consistent with the publication requirements described in paragraph (b)(1) of this section for payment rate transparency data, within 1 month of when the group provides the recommendation to the agency. We intend that States would consider, but not be required to adopt, the recommendations of the advisory group. Under this proposal, the work of the advisory group would be regarded as an element of the State's overall rate-setting process. Additionally, the feedback of this advisory group would not be required for rate changes. That is to say, should a State need or want to adjust rates and it is not feasible to obtain a recommendation from the advisory group in a particular instance, the State would still be permitted to submit its rate change SPA to CMS. However, to the extent the group comments on proposed rate changes, its feedback would be considered part of the interested parties input described in proposed §§ 447.203(c)(4) and 447.204(b)(3), which States would be required to consider and analyze, and submit such analysis to us, in connection with any SPA submission that proposes to reduce or restructure Medicaid service payment rates. In addition, by way of clarification, we intend that the advisory group would be permitted to suggest alternate rates besides those proposed by the State for consideration.

We are seeking public comment on the proposed interested parties advisory group and about whether other categories of services should be included in the requirement for States to consult with the interested parties advisory group.

3. State Analysis Procedures for Rate Reduction or Restructuring (§ 447.203(c))

As stated previously, the Supreme Court's Armstrong decision underscored the importance of CMS' administrative review of Medicaid payment rates to ensure compliance with section 1902(a)(30)(A) of the Act. CMS' oversight role is particularly important when States propose to reduce provider payment rates or restructure provider payments, since provider payment rates can affect provider participation in Medicaid, and therefore, beneficiary access to care. In § 447.203(c), we propose a process for State access analyses that would be required whenever a State submits a SPA proposing to reduce provider payment rates or restructure provider payments.

As noted previously, the 2015 final rule with comment period required that, for any SPA proposing to reduce provider payment rates or restructure provider payments in circumstances when the changes could result in diminished access, States must submit a detailed analysis of access to care under §§ 447.203(b)(1) and (b)(6) and 447.204(b)(1). This analysis includes, under current § 447.203(b)(1), the extent to which beneficiary needs are fully met; the availability of care through enrolled providers to beneficiaries in each geographic area, by provider type and site of service; changes in beneficiary utilization of covered services in each geographic area; the characteristics of the beneficiary population (including considerations for care, service and payment variations for pediatric and adult populations and for individuals with disabilities); and actual or estimated levels of provider payment available from other payers, including other public and private payers, by provider type and site of service. Currently, this information is required for any SPA that proposes to reduce provider payment rates or restructure provider payments in circumstances when the changes could result in diminished access, regardless of the provider payment rates or levels of access to care before the proposed reduction or restructuring.

Following the implementation of the 2015 final rule with comment period, as we worked with States to implement the AMRP requirements, many States expressed concerns that the requirements that accompany proposed rate reductions or restructurings are overly burdensome. Specifically, States pointed to instances where proposed reductions or restructurings are nominal, or where rate changes are made via the application of a previously approved rate methodology, such as when the State's approved rate methodology ties Medicaid payment rates to a Medicare fee schedule and the Medicare payment rate is reduced. We acknowledged these concerns through previous proposed rulemaking. In the 2018 proposed rule, we agreed that our experience implementing the AMRP process from the 2015 final rule with comment period raised questions about the benefit of the access analysis when proposed rate changes include nominal rate reductions or restructurings that are unlikely to result in diminished access to care.[192]

We did not finalize the 2018 proposed rule; instead, in response to feedback, we proposed a rescission of the AMRP process in the 2019 proposed rule.[193] In that proposed rule, we indicated that future guidance would be forthcoming to provide information on the required data and analysis that States might submit with rate reduction or restructuring SPAs in place of the AMRPs to support compliance with section 1902(a)(30)(A) of the Act.[194] We did not finalize the rescission proposed in the 2019 proposed rule. Although we are concerned that the current AMRP process is overly burdensome for States and CMS in relation to the benefit obtained in helping ensure compliance with the access requirement in section 1902(a)(30)(A) of the Act, our 2018 and 2019 proposed rules did not adequately consider our need for information and analysis from States seeking to reduce provider payment rates or restructure provider payments to enable us to determine that the statutory access requirement is met when making SPA approval decisions.

To improve the efficiency of our administrative procedures and better inform our SPA approval decisions, this proposed rule would establish standard information that States would be required to submit with any proposed rate reductions or proposed payment restructurings in circumstances when the changes could result in diminished access, including a streamlined set of data when the reductions or restructurings are nominal, the State rates are above a certain percentage of Medicare payment rates, and there are no evident access concerns raised through public processes; and an additional set of data elements that would be required when States propose FFS provider payment rate reductions or restructurings in circumstances when the changes could result in diminished access and these criteria are not met. For both sets of required or potentially required elements, we are proposing to standardize the data and information States would be required to submit with rate reduction or restructuring SPAs. Although the AMRP processes have helped to improve our administrative

[192] 83 FR 12696 at 12697.

[193] 84 FR 3372.2.

[194] Id at 33723.

reviews and helped us make informed SPA approval determinations, the procedures within this proposed rule would provide us with similar information in a manner that reduces State burden. Additionally, the proposed procedures would provide States increased flexibility to make program changes with submission of streamlined supporting data to us when current Medicaid rates and proposed changes fall within specified criteria that create a reasonable presumption that proposed reductions or restructuring would not reduce beneficiary access to care in a manner inconsistent with section 1902(a)(30)(A) of the Act.

This proposed rule seeks to achieve a more appropriate balance between reducing unnecessary burden for States and CMS, and ensuring that we have the information necessary to make appropriate determinations for whether a rate reduction or restructuring SPA might result in beneficiary access to covered services failing to meet the standard in section 1902(a)(30)(A) of the Act. In § 447.203(c), we propose to establish analyses that States would be required to perform, document, and submit concurrently with the submission of rate reduction and rate restructuring SPAs, with additional analyses required in certain circumstances due to potentially increased access to care concerns.

We are proposing a two-tiered approach for determining the level of access analysis States would be required to conduct when proposing provider payment rate reductions or payment restructurings. The first tier of this approach, proposed at § 447.203(c)(1), sets out three criteria for States to meet when proposing payment rate reductions or payment restructurings in circumstances when the changes could result in diminished access that, if met, would not require a more detailed analysis to establish that the proposal meets the access requirement in section 1902(a)(30)(A) of the Act. The State agency would be required to provide written assurance and relevant supporting documentation that the three criteria specified in those paragraphs are met, as well as a description of the State's procedures for monitoring continued compliance with section 1902(a)(30)(A) of the Act. As explained in more detail later in this section, these criteria proposed in § 447.203(c)(1) represent thresholds we believe would likely assure that Medicaid payment rates would continue to be sufficient following the change to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area.

We note that, in the course of our review of a payment SPA that meets these criteria, as with any SPA review, we may need to request additional information to ensure that all Federal SPA requirements are met. We also note that meeting the three criteria described in proposed § 447.203(c)(1) does not guarantee that the SPA would be approved, if other applicable Federal requirements are not met. Furthermore, if any criterion in the first tier is not met, we propose a second tier in § 447.203(c)(2), which would require the State to conduct a more extensive access analysis in addition to providing the results of the analysis in the first tier. A detailed discussion of the second tier follows the details of the first tier in this section.

Under proposed § 447.203(c)(1)(i), the State would be required to provide a supported assurance that Medicaid payment rates in the aggregate (including base and supplemental payments) following the proposed reduction or restructuring for each benefit category affected by the proposed reduction or restructuring would be at or above 80 percent of the most recently published Medicare payment rates for the same or a comparable set of Medicare-covered services.

In proposed § 447.203(c)(1)(i), we mean for ''benefit category'' to refer to all individual services under a category of services described in section 1905(a) of the Act for which the State is proposing a payment rate reduction or restructuring. Comparing the payment rates in the aggregate would involve first performing a comparison of the Medicaid to the Medicare payment rate on a code-by-code basis, meaning CPT, CDT, or HCPCS as applicable, to derive a ratio for individual constituent services, and then the ratios for all codes within the benefit category would be averaged by summing the individual ratios then dividing the sum by the number of ratios. For example, if the State is seeking to reduce payment rates for a subset of physician services, the State would review all current payment rates for all physician services and determine if the proposed reduction to the relevant subset of codes would result in an average Medicaid payment rate for all physician services that is at or above 80 percent of the average corresponding Medicare payment rates. For supplemental payments, we are relying upon the definition of supplemental payments in section 1903(bb)(2) of the Act, which defines supplemental payments as ''a payment to a provider that is in addition to any base payment made to the provider under the State plan under this title or under demonstration authority . . . [b]ut such term does not include a disproportionate share hospital payment made under section 1923 [of the Act].'' With the inclusion of supplemental payments, States would need to aggregate the supplemental payments paid to qualifying providers during the State fiscal year and divide by all providers' total service volume (including service volume of providers that do not qualify for the supplemental payment) to establish an aggregate, per-service supplemental payment amount, then add that amount to the State's fee schedule rate to compare the aggregate Medicaid payment rate to the corresponding Medicare payment rate. As this supportive assurance in proposed § 447.203(c)(1)(i) is expected to be provided with an accompanying SPA, CMS may ask the State to explain how the analysis was conducted if additional information is needed as part of the analysis of the SPA. We are requesting comment on the proposed § 447.203(c)(1)(i) supported assurance that Medicaid payment rates in the aggregate (including base and supplemental payments) following the proposed reduction or restructuring for each benefit category affected by the proposed reduction or restructuring would be at or above 80 percent of the most recently published Medicare payment rates for the same or a comparable set of Medicare-covered services should include a weighted average of the payment rate analysis by service volume, number of beneficiaries receiving the service, and total amount paid by Medicaid for the code in a year using State's Medicaid utilization data from the MMIS claims system rather than using a straight code-by-code analysis.

We understand that this approach may have a smoothing effect on the demonstrated overall levels of Medicaid payment within a benefit category under the State plan. In many circumstances, only a subset of providers are recipients of Medicaid supplemental payments with the rest of the providers within the benefit category simply receiving the State plan fee schedule amount. This could result in a demonstration showing the Medicaid payments being high relative to Medicare, but the actual payments to a large portion of the providers would be less than the overall demonstration would suggest. As an alternative, we considered whether to adopt separate comparisons for

providers who do and who do not receive supplemental payments, where a State makes supplemental payments for a service to some but not all providers of that service. We are requesting comments on the proposed approach and this alternative.

We selected FFS Medicare, as opposed to Medicare Advantage, as the proposed payer for comparison for a number of reasons. A threshold issue is payment rate data availability: private payer data may be proprietary or otherwise limited in its availability for use by States. In addition, Medicare sets its prices rather than negotiating them through contracts with providers, and is held to many similar statutory standards as Medicaid with respect to those prices, such as efficiency, access, and quality.[195] For example, section 1848(g)(7) of the Act directs the Secretary of HHS to monitor utilization and access for Medicare beneficiaries provided through the Medicare fee schedule rates, and directs that the Medicare Payment Advisory Commission (MedPAC) shall comment on the Secretary's recommendations. In developing its comments, MedPAC convenes and consults a panel of physician experts to evaluate the implications of medical utilization patterns for the quality of and access to patient care. In a March 2001 report, MedPAC summarized its evaluation of Medicare rates, stating ''Medicare buys health care products and services from providers who compete for resources in private markets. To ensure beneficiaries' access to high-quality care, Medicare's payment systems therefore must set payment rates for health care products and services that are: high enough to stimulate adequate numbers of providers to offer services to beneficiaries, sufficient to enable efficient providers to supply high-quality services, given the trade-offs between cost and quality that exist with current technology and local supply conditions for labor and capital, and low enough to avoid imposing unnecessary burdens on taxpayers and beneficiaries through the taxes and premiums they pay to finance program spending.'' [196] Medicare's programmatic focus on beneficiary access aligns with the requirements of section 1902(a)(30)(A) of the Act.

In addition, Medicare fee schedule rates are stratified by geographic areas within the States, which we seek to consider, as well to ensure that payment rates are consistent with section 1902(a)(30)(A) of the Act. The Medicare PFS pricing amounts are adjusted to reflect the variation in practice costs from area to area. Medicare established GPCI for every Medicare payment locality for each of the three components of a procedure's relative value unit (that is, the RVUs for work, practice expense, and malpractice). The current Medicare PFS locality structure was implemented in 2017 in accordance with the Protecting Access to Medicare Act of 2014 (PAMA 2014). Under the current locality structure, there are 112 total PFS localities.[197]

When considering geography in their rate analyses, CMS expects States to conduct a code-by-code analysis of the ratios of Medicaid-to-Medicare provider payment rates for all applicable codes within the benefit category, either for each of the GPCIs within the State, or by calculating an average Medicare rate across the GPCIs within the State (such as in cases where a State does not vary its rates by region). In cases where a State does vary its Medicaid rates based on geography, but that variation does not align with the Medicare GPCI, the State should utilize the Medicare payment rates as published by Medicare for the same geographical location as the Medicaid base payment rates to achieve an equivalent comparison and align the Medicare GPCI to the locality of the Medicaid payment rates, using the county and locality information provided by Medicare for the GPCIs, for purposes of creating a reasonable comparison of the payment rates.[198] To conduct such an analysis that meets the requirements of proposed § 447.203(c)(1)(i), States may compare the Medicaid payment rates applicable to the same Medicare GPCI to each Medicare rate by GPCI individually, and then aggregate that comparison into an average rate comparison for the benefit category. To the extent that Medicaid payment rates do not vary by geographic locality within the State, the State may also calculate a Statewide average Medicare rate based upon all of the rates applicable to the GPCIs within that State, and compare that average Medicare rate to the average Medicaid rate for the benefit category.

Once we decided to propose using Medicare payment rates as a point of comparison, we needed to decide what threshold ratio of proposed Medicaid to Medicare payment rates should trigger additional consideration and review for potential access issues. First, we considered how current levels of Medicaid payment compares to the Medicare payment for the same services. In a 2021 *Health Affairs* article, Zuckerman, et al, found that ''Medicaid physician fees were 72 percent of Medicare physician fees for twenty-seven common procedures in 2019.'' [199] This ratio varied by service type. For example, ''the 2019 Medicaid-to-Medicare fee index was lower for primary care (0.67) than for obstetric care (0.80) or for other services (0.78).'' The authors also found that ''between 2008 and 2019 Medicare and Medicaid fees both increased (23.6 percent for Medicare fees and 19.9 percent for Medicaid fees), leaving the fee ratios similar.'' [200]

Next, considering that Medicaid rates are generally lower than Medicare, we wanted to examine the relationship between these rates and a beneficiary's ability to access covered services. This led us to first look into a comparison of physician new patient acceptance rates based on a prospective new patient's payer. In a June 2021 fact sheet, the Medicaid and CHIP Payment and Access Commission (MACPAC) found ''in 2017 (the most recent year available), physicians were significantly less likely to accept new patients insured by Medicaid (74.3 percent) than those with Medicare (87.8 percent) or

[195] *https://www.healthcarevaluehub.org/advocate-resources/publications/medicare-rates-benchmark-too-much-too-little-or-just-right.*

[196] MedPAC. Report to the Congress: Medicare Payment Policy, March 2001. *https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/Mar01Ch1.pdf.* Accessed December 20, 2022.

[197] Section 220(b) of PAMA 204 added section 1848(e)(6) of the Act, which requires that, for services furnished on or after January 1, 2017, the locality definitions for California, which has the most unique locality structure, be based on the Metropolitan Statistical Area (MSA) delineations as defined by the Office of Management and Budget (OMB). The resulting modifications to California's locality structure increased its number of localities from 9 under the previous structure to 27 under the MSA-based locality structure (operational note: for the purposes of payment the actual number of localities under the MSA-based locality structure is 32). Of the 112 total PFS localities, 34 localities are Statewide areas (that is, only one locality for the entire State). There are 75 localities in the other 16 States, with 10 States having 2 localities, 2 States having 3 localities, 1 State having 4 localities, and 3 States having 5 or more localities. The District of Columbia, Maryland, and Virginia suburbs, Puerto Rico, and the Virgin Islands are additional localities that make up the remainder of the total of 112 localities. Medicare PFS Locality Configuration. *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Locality.* Accessed December 21, 2022.

[198] *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Locality.*

[199] Zuckerman, S. et al. ''Medicaid Physician Fees Remained Substantially Below Fees Paid By Medicare in 2019,'' Health Affairs, Volume 40, Number 2, February 2021. Available at *https://doi.org/10.1377/hlthaff.2020.00611 (accessed December 23, 2022).*

[200] Id.

private insurance (96.1 percent).'' [201] MACPAC found this to be true ''regardless of physician demographic characteristics (age, sex, region of the country); and type and size of practice.'' [202]

We then wanted to confirm whether this was related to the rates themselves. In a 2019 *Health Affairs* article, the authors found that, ''higher payment continues to be associated with higher rates of accepting new Medicaid patients . . . physicians most commonly point to low payment as the main reason they choose not to accept patients insured by Medicaid.'' [203] The study found that physicians in States that pay above the median Medicaid-to-Medicare fee ratio accepted new Medicaid patients at higher rates than those in States that pay below the median, with acceptance rates increasing by nearly 1 percentage point (0.78) for every percentage point increase in the fee ratio.[204]

Similarly, in a 2020 study published by the *National Bureau of Economic Research,* researchers found that there was a positive association between increasing Medicaid physician fees and increased likelihood of having a usual source of care, improved access to specialty doctor care, and large improvements in caregivers' satisfaction with the adequacy of health coverage, among children with special health care needs with a public source of health coverage.[205] Further, Berman, et al, focused on pediatricians looked at Medicaid-Medicare fee ratio quartiles and found that the percent of pediatricians accepting all Medicaid patients and relative pediatrician participation in Medicaid increased at each quartile, but improvement was most significant up to the third quartile.[206] According to the Kaiser Family Foundation, in 2016, following the expiration of section 1202 of the Affordable Care Act (Pub. L. 111–148), which amended section 1902(a)(13) of the Act to implement a temporary payment floor for certain Medicaid primary care physician services, the third quartile of States had Medicaid-Medicare fee ratios of between 79 and 86 percent for all services provided under all State Medicaid fee-for-service programs.[207] Importantly, considering the proposed requirements at paragraph (c) pertain to proposed payment rate reductions or payment restructurings in circumstances when the changes could result in diminished access, multiple recent studies have also shown that the association between Medicaid physician fees and measures of beneficiary access are consistent whether physician payments are increased or decreased to reach a particular level at which access is assessed.[208]

The Kaiser Family Foundation found that 23 States have Medicaid-to-Medicare fee ratios of at least 80 percent for all services, 17 States have fee ratios of 80 percent for primary care services, 32 States have fee ratios of 80 percent for obstetric care, and 27 States have fee ratios of 80 percent for other services.[209] Additional studies support the Holgash and Heberlein findings that physicians most commonly point to low payment as the main reason they choose not to accept patients insured by Medicaid, showing that States with a Medicaid to Medicare fee ratio at or above 80 percent show improved access for children to a regular source of care,[210] and decreased use of hospital-based facilities, versus States with a lower Medicaid to Medicare fee ratio.

In general, we are concerned that higher rates of acceptance by some providers of new patients with payers other than Medicaid (specifically, Medicare and private coverage), and indications by some providers that low Medicaid payments are a primary reason for not accepting new Medicaid patients, may suggest that some beneficiaries could have a more difficult time accessing covered services than other individuals in the same geographic area. We are encouraged by findings that suggest that some increases in Medicaid payment rates may drive increases in provider acceptance of new Medicaid patients, with one study finding that new Medicaid patient acceptance rates increased by 0.78 percent for every percentage point increase in the Medicaid-to-Medicare fee ratio, for certain providers for certain States above the median Medicaid-to-Medicare fee ratio.[211] [212] In line with the Berman study, which found that increases in the percentage of pediatricians participating in Medicaid and of pediatricians accepting new Medicaid patients occurred with Medicaid payment rate increases at each quartile of the Medicaid-to-Medicare fee ratio but were most significant up to the third quartile, we believe that beneficiaries in States that provide this level of Medicaid payment generally may be less likely to encounter access to care issues at rates higher than the general population.[213] In line with the Kaiser Family Foundation reporting of the Medicaid-to-Medicare fee ratio third quartile as ranging from 79 to 86 percent in 2016, depending on the service, we believe that a minimum 80 percent Medicaid-to-Medicare fee ratio is a reasonable threshold to propose in § 447.203(c)(1)(i) as one of three criteria State proposals to reduce or restructure provider payments would be required to meet to qualify for the proposed streamlined documentation process.[214] As documented by the Kaiser Family Foundation, many States currently satisfy this ratio for many Medicaid-covered services, and according to findings by Zuckerman, et al. in *Health Affairs,* in 2019, the average nationwide fee ratio for obstetric care met this

[201] MACPAC. ''Physician Acceptance of New Medicaid Patients: Finding from the National Electronic Health Records Survey.'' June. 2021. Available at *https://www.macpac.gov/wp-content/uploads/2021/06/Physician-Acceptance-of-New-Medicaid-Patients-Findings-from-the-National-Electronic-Health-Records-Survey.pdf* (accessed December 23, 2023).

[202] Id.

[203] Holgash, K. and Martha Heberlein, ''Physician Acceptance Of New Medicaid Patients: What Matters And What Doesn't.'' *Health Affairs,* April 10, 2019. Available at *https://www.healthaffairs.org/do/10.1377/forefront.20190401.678690/full/* (accessed February 22, 2023).

[204] Id.

[205] Chatterji, P. et al. ''Medicaid Physician Fees and Access to Care Among Children with Special Health Care Needs'' National Bureau of Economic Research, Working Paper 26769, February 2020, p. 2–54. Medicaid Physician Fees and Access to Care among Children with Special Health Care Needs | NBER. Accessed June 16, 2022.

[206] Berman, S., et al. ''Factors that Influence the Willingness of Private Primary Care Pediatricians to Accept More Medicaid Patients'' *Pediatrics.*

[207] *https://www.kff.org/medicaid/state-indicator/medicaid-to-medicare-fee-index.*

[208] Candon, M., et al. ''Declining Medicaid Fees and Primary Care Appointment Availability for New Medicaid Patients'' *JAMA Internal Medicine,* Volume 178, Number 1, January 2018, p. 145–146. Available at *https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2663253.* Accessed June 16, 2022.

[209] *https://www.kff.org/medicaid/state-indicator/medicaid-to-medicare-fee-index.*

[210] Chatterji, P. et al. ''Medicaid Physician Fees and Access to Care Among Children with Special Health Care Needs'' National Bureau of Economic Research, Working Paper 26769, February 2020, p. 2–54. Available at *https://www.nber.org/papers/w26769.* Accessed August 16, 2022.

[211] MACPAC. ''Physician Acceptance of New Medicaid Patients: Finding from the National Electronic Health Records Survey.'' June. 2021. Available at *https://www.macpac.gov/wp-content/uploads/2021/06/Physician-Acceptance-of-New-Medicaid-Patients-Findings-from-the-National-Electronic-Health-Records-Survey.pdf* (accessed December 23, 2023).

[212] Holgash, K. and Martha Heberlein, ''Physician Acceptance Of New Medicaid Patients: What Matters And What Doesn't.'' *Health Affairs,* April 10, 2019. Available at *https://www.healthaffairs.org/do/10.1377/forefront.20190401.678690/full/* (accessed February 22, 2023).

[213] Berman, S., et al. ''Factors that Influence the Willingness of Private Primary Care Pediatricians to Accept More Medicaid Patients'' *Pediatrics.*

[214] *https://www.kff.org/medicaid/state-indicator/medicaid-to-medicare-fee-index.*

proposed threshold.[215] [216] We propose that this percentage would hold across benefit categories, because we did not find any indication that a lower threshold would be adequate, or that a higher threshold would be strictly necessary, to support a level of access to covered services for Medicaid beneficiaries at least as great as for the general population in the geographic area. It is worth noting that the disparities in provider participation for some provider types may be larger than this overview suggests, as such we are proposing a uniform standard in the interest of administrative simplicity, but note that States must meet all three of the criterion in proposed paragraph (c)(1) to qualify for the streamlined analysis process; otherwise, the additional analysis specified in proposed paragraph (c)(2) would be required.

Given the results of this literature review, and by proposing this provision as only one part of a three-part assessment of the likely effect of a proposed payment rate reduction or payment restructuring on access to care, as further discussed in this section, we propose 80 percent of the most recently published Medicare payment rates, as identified on the applicable Medicare fee schedule for the same or a comparable set of Medicare-covered services, as a benchmark for the level of Medicaid payment for benefit categories that are subject to proposed provider payment reductions or restructurings that is likely to enlist enough providers so that care and services are available to Medicaid beneficiaries at least to the extent as to the general population in the geographic area, where the additional tests in proposed § 447.203(c)(1) also are met. The published Medicare payment rates means the amount per applicable procedure code identified on the Medicare fee schedule. The established Medicare fee schedule rate includes the amount that Medicare pays for the claim and any applicable co-insurance and deductible amounts owed by the patient. Medicaid fee-schedule rates should be representative of the total computable payment amount a provider would expect to receive as payment-in-full for the provision of Medicaid services to individual beneficiaries. Section 447.15 defines payment-in-full as ''the amounts paid by the agency plus any deductible, coinsurance or copayment required by the plan to be paid by the individual.'' Therefore, State fee schedule should be inclusive of total base payment from the Medicaid agency plus any applicable coinsurance and deductibles to the extent that a beneficiary is expected to be liable for those payments. If a State Medicaid fee schedule does not include these additional beneficiary cost-sharing payment amounts, then the Medicaid fee schedule amounts would need to be modified to include expected beneficiary cost sharing to align with Medicare's fee schedule.

We note that Medicaid benefits that do not have a reasonably comparable Medicare-covered analogue, and for which a State proposes a payment rate reduction or payment restructuring in circumstances when the changes could result in diminished access, would be subject to the expanded review criteria proposed in § 447.203(c)(2), because the State would be unable to demonstrate its Medicaid payment rates are at or above 80 percent of Medicare payment rates for the same or a comparable set of Medicare-covered services after the payment rate reduction or payment restructuring in circumstances when the changes could result in diminished access. For identifying a comparable set of Medicare-covered services, we would expect to see services that bear a reasonable relationship to each other. For example, the clinic benefit in Medicaid does not have a directly analogous clinic benefit in Medicare. In Medicaid, clinic services generally are defined in § 440.90, as ''preventive, diagnostic, therapeutic, rehabilitative, or palliative services that are furnished by a facility that is not part of a hospital but is organized and operated to provide medical care to outpatients.'' This can include a number of primary care services otherwise available through physician practices and other primary care providers, such as nurse practitioners. Therefore, in seeking to construct a comparable set of Medicare-covered services to which the State could compare its proposed Medicaid payment rates, the State reasonably could include Medicare payment rates for practitioner services, such as physician and nurse practitioner services, or payments for facility-based services that bear a reasonable similarity to clinic services, potentially including those provided in Ambulatory Surgical Centers. We would expect the State to develop a reasonably comparable set of Medicare-covered services to which its proposed Medicaid payment rates could be compared and to include with its submission an explanation of its reasoning and methodology for constructing the Medicare rate to compare Medicaid payment rates to.

In § 447.203(c)(1)(ii), we propose that the State would be required to provide a supported assurance that the proposed reduction or restructuring, including the cumulative effect of all reductions or restructurings taken throughout the State fiscal year, would result in no more than a 4 percent reduction in aggregate FFS Medicaid expenditures for each benefit category affected by proposed reduction or restructuring within a single State fiscal year. The documentation would need to show the change stated as a percentage reduction in aggregate FFS Medicaid expenditures for each affected benefit category. We recognize that the effects of payment rate reductions and payment restructurings on beneficiary access generally cannot be determined through any single measure, and applying a 4 percent threshold without sufficient additional safeguards would not be prudent. Therefore, we are proposing to limit the 4 percent threshold as the cumulative percentage of rate reductions or restructurings applied to the overall FFS Medicaid expenditures for a particular benefit category affected by the proposed reduction(s) or restructuring(s) within each State fiscal year. We are proposing the cumulative application of the threshold to State plan actions taken within a State fiscal year as opposed to a SPA-specific application to avoid circumstances where a State may propose rate reductions or restructurings that cumulatively exceed the 4 percent threshold across multiple SPAs without providing additional analysis.

For example, if a State proposed to reduce payment rates for a broad set of obstetric services by 3 percent in State fiscal year 2023 and had not proposed any other payment changes affecting the benefit category of obstetric care during the same State fiscal year, that payment change would meet the criterion proposed in § 447.203(c)(1)(ii) because it would be expected to result in no more than a 3 percent reduction in aggregate Medicaid expenditures for obstetric care within a State fiscal year. However, if the State had received approval earlier in the State fiscal year to revise its obstetric care payment methodology to include value-based arrangements expected to reduce overall Medicaid expenditures for obstetric care by 2 percent per State fiscal year, then it is likely that the cumulative effect of the proposal to reduce payment rates for a broad set of obstetric services by 3 percent and the Medicaid obstetric care

[215] Id.

[216] Zuckerman, S. et al. ''Medicaid Physician Fees Remained Substantially Below Fees Paid By Medicare in 2019,'' Health Affairs, Volume 40, Number 2, February 2021. Available at *https://doi.org/10.1377/hlthaff.2020.00611* (accessed December 23, 2022).

expenditure reductions under the earlier-approved payment restructuring would result in an aggregate reduction to FFS Medicaid expenditures for obstetric services of more than 4 percent in a State fiscal year. If so, the State's proposal would not meet the criterion proposed in § 447.203(c)(1)(ii), and the proposal would be subject to the additional review criteria proposed in § 447.203(c)(2). The State would need to document for our review whether the three percent payment rate reduction proposal for the particular subset of obstetric services would be likely to result in a greater than 2 percent further reduction in aggregate FFS Medicaid expenditures for obstetric care as compared to the expected expenditures for such services for the State fiscal year before any payment rate reduction or payment restructuring; if this expected aggregate reduction is demonstrated to be 2 percent or less, then the proposal still could meet the criterion proposed in § 447.203(c)(1)(ii).

We propose to codify a 4 percent reduction threshold for aggregate FFS Medicaid expenditures in each benefit category affected by a proposed payment rate reduction or payment restructuring within a State fiscal year. This threshold is consistent with one we proposed in the 2018 proposed rule, which proposed to require the States to submit an AMRP with any SPA that proposed to reduce provider payments by greater than 4 percent in overall service category spending in a State fiscal year or greater than 6 percent across 2 consecutive State fiscal years, or restructure provider payments in circumstances when the changes could result in diminished access.[217] The proposed rule received positive feedback from States regarding its potential for mitigating administrative burden, and providing States with flexibility to administer their programs and make provider payment rate changes. Some States and national organizations requested that we increase the rate reduction threshold to 5 percent and increase the consecutive year threshold to 8 percent.[218] [219] Non-State commenters cautioned CMS against providing too much administrative flexibility and to not abandon the Medicaid access analysis the current regulations require. Commenters also raised that 4 and 6 percent may seem nominal for larger medical practices and health care settings, but for certain physician practices or direct care workers a 6 percent reduction in payment could be considerable.[220] This feedback has been essential in considering how we proceed with this proposed rule, in which we emphasize that the size of the rate reduction threshold proposed in § 447.203(c)(1)(ii) would operate in conjunction with the two other proposed elements in § 447.203(c)(1)(i) and (iii) to qualify the State for a streamlined analysis process and would not exempt the proposal from scrutiny for compliance with section 1902(a)(30)(A) of the Act.

We are proposing a 4 percent threshold on cumulative provider payment rate reductions throughout a single State fiscal year as one of the criteria of the streamlined process in proposed paragraph (c)(1), and therefore, emphasizing that while we believe this payment threshold to be nominal and unlikely to diminish access to care, we propose to include paragraph (c)(1)(i) to require States to review current levels of provider payment in relation to Medicare and propose to include paragraph (c)(1)(iii) to require that States rely on the public process to inform the determination on the sufficiency of the proposed payment rates after reduction or restructuring, with consideration for providers and practice types that may be disproportionately impacted by the State's proposed rate reductions or restructurings.

As previously noted, we would not consider any payment rate reduction or payment rate restructuring proposal to qualify for the streamlined analysis process in the proposed paragraph (c)(1) unless all three of the proposed paragraph (c)(1) criteria are met. Using information from the Kaiser Family Foundation's Medicaid-to-Medicare fee index [221] as an example, only 15 States could have reduced primary care service provider payment rates by up to 4 percent in 2019 and continued to meet the 80 percent of Medicare threshold in proposed paragraph (c)(1). Even those 15 States with rates above the 80 percent of Medicare threshold would be subject to proposed paragraph (c)(2) requirements if the State received significant public feedback that the proposed payment reduction or restructuring would result in an access to care concern, if the State were unable to reasonably respond to or mitigate such concerns. All States with primary care service payment rates below the 80 percent of Medicare threshold, no matter the size of the payment rate reduction or restructuring and no matter whether interested parties expressed access concerns through available public processes, would have to conduct an additional access analysis required under proposed paragraph (c)(2).

We issued SMDL #17–004 to provide States with guidance on complying with regulatory requirements to help States avoid unnecessary burden when seeking approval of and implementing payment changes, because States often seek to make payment rate and/or payment structure changes for a variety of programmatic and budgetary reasons with limited or potentially no effect on beneficiary access to care, and we recognized that State legislatures needed some flexibility to manage State budgets accordingly. We discussed a 4 percent spending reduction threshold with respect to a particular service category in SMDL #17–004 as an example of a targeted reduction where the overall change in net payments within the service category would be nominal and any effect on access difficult to determine (although we reminded States that they should document that the State followed the public process under § 447.204, which could identify access concerns even with a seemingly nominal payment rate reduction). To our knowledge, since the release of SMDL #17–004, the 4 percent threshold for regarding a payment rate reduction as nominal has not resulted in access to care concerns in State Medicaid programs, and it received significant State support for this reason in comments submitted in response to the 2018 proposed rule.[222]

In instances where States submitted payment rate reduction SPAs after the publication of SMDL #17–004, we routinely have asked the State for an explanation of the purpose of the proposed change, whether the FFS Medicaid expenditure impact for the

[217] 83 FR 12696 at 12698.

[218] Connecticut Department of Social Services. Comment Letter on 2018 Proposed Rule (May 21, 2018), *https://downloads.regulations.gov/CMS-2018-0031-0021/attachment_1.pdf.*

[219] National Association of Medicaid Directors. Comment Letter on 2018 Proposed rule (June 1, 2018), *https://downloads.regulations.gov/CMS-2018-0031-0115/attachment_1.pdf.*

[220] American Academy of Family Physicians, Comment Letter on 2018 Proposed Rule (May 21, 2018), *https://downloads.regulations.gov/CMS-2018-0031-0017/attachment_1.pdf.*

[221] *https://www.kff.org/medicaid/state-indicator/medicaid-to-medicare-fee-index/.*

[222] See, for example: Indiana Family and Social Services Administration. Comment Letter on 2018 Proposed Rule (May 24, 2018), *https://downloads.regulations.gov/CMS-2018-0031-0055/attachment_1.pdf;* Colorado Department of Health Care Policy and Financing. Comment Letter on 2018 Proposed Rule (May 24, 2018), *https://downloads.regulations.gov/CMS-2018-0031-0087/attachment_1.pdf;* The Commonwealth of Massachusetts Executive Office of Health and Human Services Office of Medicaid. Comment Letter on 2018 Proposed Rule (May 21, 2018), *https://downloads.regulations.gov/CMS-2018-0031-0020/attachment_1.pdf.*

service category would be within a 4 percent reduction threshold, and for an analysis of public comments received on the proposed change, and approved those SPAs to the extent that the State was able to resolve any potential access to care issues and determined that access would remain consistent for the Medicaid population. For example, of the 849 SPAs approved in 2019, there were 557 State payment rate changes. Of those, 39 were classified as payment rate reductions or methodology changes that resulted in a reduction in overall provider payment. Within those 39, there were 18 SPAs that sought to reduce payments by less than 4 percent of overall spending within the benefit category, most of which were decreases related to changes in Medicare payment formulas. Sixteen of the remaining 21 SPAs fell into an area discussed in SMDL #17–004 as being unlikely to result in diminished access to covered services, where with the State's analytical support, we were able to determine that the payment rates would continue to comply with section 1902(a)(30)(A) of the Act without submitting an AMRP with the SPA. Six of these SPAs represented rate freezes meant to continue forward a prior year's rates or eliminated an inflation adjustment. Six SPAs reduced a payment rate to comply with Federal requirements, such as the Medicaid UPLs in §§ 447.272 and 447.321, the Medicaid DME FFP limit in section 1903(i)(27) of the Act, or the Medicaid hospice rate, per section 1902(a)(13)(B) of the Act. Four SPAs contained reductions that resulted from programmatic changes such as the elimination of a Medicaid benefit or shifting the delivery system for a benefit to coverage by a pre-paid ambulatory health plan. Finally, we found five SPAs for which States were required to submit AMRPs, three of which were submitted to us in 2017 and updated for 2019. Overall, our review of SPAs revealed that smaller reductions may often be a result of elements of the State's approved payment methodology or other requirements that may be outside of the State's control, such as Federal payment limits or changes in the Medicare payment rate formulas that might be incorporated into a State's approved payment methodology, or coding changes that might affect the amount of payment related to the unit of service. We determined, using this information, that it is necessary to provide States with some degree of flexibility in making changes, even if that change is a reduction in provider payment. For example, if a State submits a SPA to reduce or restructure inpatient hospital base or supplemental payments, where inaction on the State's part would result in the State exceeding the applicable UPL, the State would need to reduce inpatient hospital payments or risk a compliance action against the State for violating Medicaid UPL requirements authorized under section 1902(a)(30)(A) of the Act and implementing regulations in 42 CFR 447 subparts C and F. We recognize that this flexibility does not eliminate the need to monitor or consider access to care when making payment rate decisions, but also recognize the need to provide some relief in circumstances where the State must take a rate action to address an issue of compliance with another statutory or regulatory requirement.

Accordingly, we propose that, where a State has provided the information required under proposed paragraphs (c)(1)(i) through (iii), we would consider that the proposed reduction would result in a nominal payment adjustment unlikely to diminish access below the level consistent with section 1902(a)(30)(A) of the Act and would approve the SPA, provided all other criteria for approval also are met, without requiring the additional analysis that otherwise would be required under proposed § 447.203(c)(2).

Finally, in § 447.203(c)(1)(iii), we propose that the State would be required to provide a supported assurance that the public processes described in § 447.203(c)(4) yielded no significant access to care concerns or yielded concerns that the State can reasonably respond to or mitigate, as appropriate, as documented in the analysis provided by the State under § 447.204(b)(3). The State's response to any access concern identified through the public processes, and any mitigation approach, as appropriate, would be expected to be fully described in the State's submission to us.

We note that the proposed requirement in § 447.203(c)(4) would not duplicate the requirements in current § 447.204(a)(2), as the current § 447.204(a)(2) requires States to consider provider and beneficiary input as part of the information that States are required to consider prior to the submission of any SPA that proposes to reduce or restructure Medicaid service payment rates. The proposed § 447.203(c)(4) describes material that States would be required to include with any SPA submission that proposes to reduce or restructure provider payment rates. As discussed in the CMCS informational bulletin dated June 24, 2016,[223] before submitting SPAs to us, States are required under § 447.204(a)(2) to make information available so that beneficiaries, providers, and other interested parties may provide input on beneficiary access to the affected services and the impact that the proposed payment change would have, if any, on continued service access. States are expected to obtain input from beneficiaries, providers, and other interested parties, and analyze the input to identify and address access to care concerns. States must obtain this information prior to submitting a SPA to us and maintain a record of the public input and how the agency responded to the input. When a State submits the SPA to us, § 447.204(b)(3) requires the State to also submit a specific analysis of the information and concerns expressed in input from affected interested parties. We would rely on this and other documentation submitted by the State, including under proposed § 447.203(c)(1)(iii), (c)(2)(vi), and (c)(4), to inform our SPA approval decisions.

In addition, States are required use the applicable public process required under section 1902(a)(13) of the Act, as applicable, and follow the public notice requirement in § 447.205, as well as any other public processes required by State law (for example, State-specified budgetary process requirements), in setting payment rates and methodologies in view of potential access to care concerns. States have an important role in identifying access to care concerns, including through ongoing and collaborative efforts with beneficiaries, providers, and other interested parties. We understand that not every concern would be easily resolvable, but we anticipate that States would be meaningfully engaged with their beneficiary, provider, and other interested party communities to identify and mitigate issues as they arise. As discussed herein, we would consider information about access concerns raised by beneficiaries, providers, and other interested parties when States propose SPAs to reduce Medicaid payment rates or restructure Medicaid payments and would not approve proposals that do not comport with all applicable requirements, including the access standard in section 1902(a)(30)(A) of the Act.

In feedback received regarding implementation of the AMRP

[223] CMCS Informational Bulletin, ''Federal public notice and public process requirements for changes to Medicaid payment rates.'' Published June 24, 2016. *https://www.medicaid.gov/federal-policy-guidance/downloads/cib062416.pdf.* Accessed November 3, 2022.

requirements in the 2015 final rule with comment period, States expressed concern about burdensome requirements to draft, seek public input on, and update their AMRP after receiving beneficiary or provider complaints that were later resolved by the State's engagement with beneficiaries and the provider community. Our proposal to require access review procedures specific to State proposals to reduce payment rates or restructure payments would provide an opportunity for the State meaningfully to address and respond to interested parties' input, and seeks to balance State burden concerns with the clear need to understand the perspectives of interested parties most likely to be affected by a Medicaid payment rate reduction or payment restructuring. Currently, § 447.203(b)(7) requires States to have ongoing mechanisms for beneficiary and provider input on access to care through various mechanisms, and to maintain a record of data on public input and how the State responded to such input, which must be made available to us upon request. We propose to retain this important mechanism and to relocate it to § 447.203(c)(4). Through the cross reference to proposed § 447.203(c)(4) in proposed § 447.203(c)(1)(iii), we would require States to use the ongoing beneficiary and provider feedback mechanisms to aid in identifying and assessing any access to care issues in cooperation with their interested parties' communities, as a component of the streamlined access analysis criteria in proposed § 447.203(c)(1).

Together, we believe the proposed criteria of § 447.203(c)(1)(i) through (iii), where all are met, would establish that a State's proposed Medicaid payment rates and/or payment structure are consistent with the access requirement in section 1902(a)(30)(A) of the Act at the time the State proposes a payment rate reduction or payment restructuring in circumstances when the changes could result in diminished access. Importantly, as noted above, proposed § 447.203(c)(4) (proposed to be relocated from current § 447.203(b)(7)) would ensure that States have ongoing procedures for compliance monitoring independent of any approved Medicaid payment changes.

We previously outlined in SMDL #17–004 several circumstances where Medicaid payment rate reductions generally would not be expected to diminish access: reductions necessary to implement CMS Federal Medicaid payment requirements; reductions that will be implemented as a decrease to all codes within a service category or targeted to certain codes, but for services where the payment rates continue to be at or above Medicare and/or average commercial rates; and reductions that result from changes implemented through the Medicare program, where a State's service payment methodology adheres to the Medicare methodology. This proposed rule would not codify this list of policies that may produce payment rate reductions unlikely to diminish access to Medicaid-covered services. However, as a possible addition to the proposed streamlined access analysis criteria in proposed § 447.203(c)(1), we are requesting comment on whether this list of circumstances discussed in SMDL #17–004 should be included in a new paragraph under proposed § 447.203(c)(1) and, if one or more of these circumstances were applicable, the State's proposal would be considered to qualify for the streamlined analysis process under proposed § 447.203(c)(1) notwithstanding the other proposed criteria in proposed paragraph(c)(1).

Proposed paragraph (c)(1) discusses the full set of written assurances and relevant supporting documentation that States would be required to submit with a proposed payment rate reduction or payment restructuring SPA in circumstances when the changes could result in diminished access, where the requirements in proposed paragraphs (c)(1)(i) through (c)(1)(iii) are met. The inclusion of documentation that confirms all criteria proposed in paragraph (c)(1) are met would exempt the State from the requirements in proposed § 447.203(c)(2), discussed later in this section; however, it would not guarantee SPA approval. Proposed payment rate reduction SPAs and payment rate restructuring SPAs meeting the requirements in proposed § 447.203(c)(1) would still be subject to CMS' standard review requirements for all proposed SPAs to ensure compliance with section 1902(a) of the Act, including implementing regulations in part 430. Specifically, and without limitation, this includes compliance with sections 1902(a)(2) of the Act, requiring financial participation by the State in payments authorized under section 1903 of the Act. CMS reviews SPAs involving payments to ensure that the State has identified an adequate source of non-Federal share financing for payments under the SPA so that section 1902(a)(2) of the Act is satisfied; in particular, section 1903(w) of the Act and its implementing regulations establish requirements for certain non-Federal share financing sources that CMS must ensure are met. We further note that a proposed SPA's failure to meet the criteria in proposed paragraph (c)(1) would not result in automatic SPA disapproval; rather, such proposals would be subject to additional documentation and review requirements, as described in proposed § 447.203(c)(2).

In paragraph (c)(2), we propose the additional, more rigorous State access analysis that States would be required to submit where the State proposes to reduce provider payment rates or restructure provider payments in circumstances when the changes could result in diminished access where the requirements in paragraphs (c)(1)(i) through (iii) are not met. We believe this more rigorous access analysis should be required because we believe that, where the State is unable to demonstrate that the proposed paragraph (c)(1) criteria are met, more scrutiny is needed to ensure that the proposed payment rates and structure would be sufficient to enlist enough providers so that covered services would be available to beneficiaries at least to the same extent as to the general population in the geographic area. Accordingly, we are proposing in § 447.203(c)(2) to have States document current and recent historical levels of access to care, including a demonstration of counts and trends of actively participating providers, counts and trends of FFS Medicaid beneficiaries who receive the services subject to the proposed payment rate reduction or payment restructuring; and service utilization trends, all for the 3-year period immediately preceding the submission date of the proposed rate reduction or payment restructuring SPA, as a condition for approval. As with the current AMRP process, the information provided by the State would serve as a baseline of understanding current access to care within the State's program, from which the State's payment rate reduction or payment restructuring proposal would be scrutinized.

The 2015 final rule with comment period included requirements that the AMRP process include data on the following topics, in current § 447.203(b)(1)(i) through (v): the extent to which beneficiary needs are fully met; the availability of care through enrolled providers to beneficiaries in each geographic area, by provider type and site of service; changes in beneficiary utilization of covered services in each geographic area; the characteristics of the beneficiary population (including considerations for care, service and payment variations for pediatric and adult populations and for

individuals with disabilities); and actual or estimated levels of provider payment available from other payers, including other public and private payers, by provider type and site of service. The usefulness of the ongoing AMRP data was directly related to the quality of particular data measures that States selected to use in their AMRPs, and one of the biggest concerns we heard about the process was that States were not always certain that they were providing us with the relevant data that we needed to make informed decisions about Medicaid access to care because the 2015 final rule provided States with a considerable amount of flexibility in determining the type of data that may be provided in support of the State's access analysis included in their AMRP. In addition, States were required to consult with the State's medical advisory committees and publish the draft AMRP for no less than 30 days for public review and comment, per § 447.203(b). Therefore, the final AMRP, so long as the base data elements were met and supported the State's conclusion that access to care in the Medicaid program met the requirements of section 1902(a)(30)(A) of the Act, then the AMRP was accepted by us. As a result, the AMRPs were often very long and complex documents that sometimes included data that was not necessarily useful for understanding the extent of beneficiary access to services in the State or for making administrative decisions about SPAs. In an effort to promote standardization of data measures and limit State submissions to materials likely to assist in ensuring consistency of payment rates with the requirements of section 1902(a)(30)(A) of the Act, we are proposing to maintain a number of the currently required data elements from the AMRP but to be more precise about the type of information that would be required.

In § 447.203(c)(2), we propose that, for any SPA that proposes to reduce provider payment rates or restructure provider payments in circumstances when the changes could result in diminished access, where the requirements in paragraphs (c)(1)(i) through (iii) are not met, the State would be required to also provide specified information to us as part of the SPA submission as a condition of approval, in addition to the information required under paragraph (c)(1), in a format prescribed by us. Specifically, in § 447.203(c)(2)(i), we propose to require States to provide a summary of the proposed payment change, including the State's reason for the proposal and a description of any policy purpose for the proposed change, including the cumulative effect of all reductions or restructurings taken throughout the current State fiscal year in aggregate FFS Medicaid expenditures for each benefit category affected by proposed reduction or restructuring within a State fiscal year. We are proposing to collect this information for SPAs that require a § 447.203(c)(2) analysis, but for those that meet the criteria proposed under § 447.203(c)(1), we are not proposing to require a summary of the proposed payment change, including the State's reason for the proposal and a description of any policy purpose for the proposed change beyond that which is already provided as part of a normal State plan submission or as may be requested by CMS through the normal State plan review process; we are requesting comment whether these elements should apply to both proposed § 447.203(c)(1) and (c)(2) equally.

In § 447.203(c)(2)(ii), we propose to require the State to provide Medicaid payment rates in the aggregate (including base and supplemental payments) before and after the proposed reduction or restructuring for each benefit category affected by proposed reduction or restructuring, and a comparison of each (aggregate Medicaid payment before and after the reduction or restructuring) to the most recently published Medicare payment rates for the same or a comparable set of Medicare-covered services and, as reasonably feasible, to the most recently available payment rates of other health care payers in the State or the geographic area for the same or a comparable set of covered services. This proposed element is similar to the current § 447.203(b)(1)(v) rate comparison requirement, which requires the AMRP to include ''[a]ctual or estimated levels of provider payment available from other payers, including other public and private payers, by provider type and site of service.'' However, the proposed analysis specifically would require an aggregate comparison including Medicaid base and supplemental payments, as applicable, before and after the proposed reduction or restructuring are implemented, compared to the most recently published Medicare payment rates for the same or comparable set of Medicare-covered services and, as reasonably feasible, to the most recently available payment rates of other health care payers in the State or the geographic area for the same or a comparable set of covered services. We found that, first, States struggled with obtaining and providing private payer data as contemplated by the 2015 final rule with comment period, and, second, States were confused about how to compare Medicaid rates to Medicare rates where there were no comparable services between Medicare and Medicaid. We wanted to acknowledge the feedback we received from States during the AMRP process and modify the requirements in the proposed rule by focusing on the more readily available Medicare payment data as the most relevant payment comparison for Medicaid in this proposed rule, as discussed in detail above. We believe that the E/M CPT/HCPCS code comparison methodology included in the proposed § 447.203(b)(3)(i) and the payment rate disclosure in proposed § 447.203(b)(3)(ii) can serve, at a minimum, as frameworks for States that struggled to compare Medicaid rates to Medicare where there may be no other comparable services between the two programs. Otherwise where comparable services exist, States would be required to compare all applicable Medicaid payment rates within the benefit category to the Medicare rates for the same or comparable services under proposed § 447.203(c)(2)(ii). For reasons mentioned previously in this section, Medicare through MEDPAC engages in substantial analysis of access to care as it reviews payment rates for services, so we believe this is a sufficient benchmark for the Medicaid payment rate analysis.

In § 447.203(c)(2)(iii), we are proposing to require States to provide information about the number of actively participating providers of services in each benefit category affected by the proposed reduction or restructuring. For this purpose, an actively participating provider is a provider that is participating in the Medicaid program and actively seeing and providing services to Medicaid beneficiaries or accepting Medicaid beneficiaries as new patients. The State would be required to provide the number of actively participating providers of services in each affected benefit category for each of the 3 years immediately preceding the SPA submission date, by State-specified geographic area (for example, by county or parish), provider type, and site of service. The State would be required to document observed trends in the number of actively participating providers in each geographic area over this period. The State could provide estimates of the anticipated effect on the number of actively participating providers of services in each benefit category affected by the proposed

reduction or restructuring, by geographic area. This data element is similar to current § 447.203(b)(1)(ii), under which States must analyze the availability of care through enrolled providers to beneficiaries in each geographic area, by provider type and site of service, in the AMRP; however, the proposal would require specific quantitative information describing the number of providers, by geographic area, provider type, and site of service available to furnish services to Medicaid beneficiaries and leaves less discretion to the States on specific data measures. With all of the data elements included in proposed paragraph (c)(2), we are proposing that the data come from the 3 years immediately preceding the State plan amendment submission date, as this would provide us with the most recent data and would allow for considerations for data anomalies that might otherwise distort a demonstration of access to care if only 1 year of data was used.

In § 447.203(c)(2)(iv), we are proposing to require States to provide information about the number of Medicaid beneficiaries receiving services through the FFS delivery system in each benefit category affected by the proposed reduction or restructuring. The State would be required to provide the number of beneficiaries receiving services in each affected benefit category for each of the 3 years immediately preceding the SPA submission date, by State-specified geographic area (for example, by county or parish). The State would be required to document observed trends in the number of Medicaid beneficiaries receiving services in each affected benefit category in each geographic area over this period. The State would be required to provide quantitative and qualitative information about the beneficiary populations receiving services in the affected benefit categories over this period, including the number and proportion of beneficiaries who are adults and children and who are living with disabilities, and a description of the State's consideration of the how the proposed payment changes may affect access to care and service delivery for beneficiaries in various populations. The State would be required to provide estimates of the anticipated effect on the number of Medicaid beneficiaries receiving services through the FFS delivery system in each benefit category affected by the proposed reduction or restructuring, by geographic area. This proposed provision is a combination of current § 447.203(b)(1)(i) and (iv), which require States to provide an analysis of the extent to which beneficiary needs are met, and the characteristics of the beneficiary population (including considerations for care, service and payment variations for pediatric and adult populations and for individuals with disabilities). Even though we are not proposing to require this analysis to be updated broadly with respect to many benefit categories on an ongoing basis, we would require current information on the number of beneficiaries currently receiving services through the FFS delivery system in each benefit category affected by the proposed reduction or restructuring to inform our SPA review process to ensure that the statutory access standard is met. The inclusion of this beneficiary data is relevant because it provides information about the recipients of Medicaid services and where, geographically, these populations reside to ensure that the statutory access standard is met.

In § 447.203(c)(2)(v), we are proposing to require information about the number of Medicaid services furnished through the FFS delivery system in each benefit category affected by the proposed reduction or restructuring. The State would be required to provide the number of Medicaid services furnished in each affected benefit category for each of the 3 years immediately preceding the SPA submission date, by State-specified geographic area (for example, by county or parish), provider type, and site of service. The State would be required to document observed trends in the number of Medicaid services furnished in each affected benefit category in each geographic area over this period. The State would be required to provide quantitative and qualitative information about the Medicaid services furnished in the affected benefit categories over this period, including the number and proportion of Medicaid services furnished to adults and children and who are living with disabilities, and a description of the State's consideration of the how the proposed payment changes may affect access to care and service delivery. The State would be required to provide estimates of the anticipated effect on the number of Medicaid services furnished through the FFS delivery system in each benefit category affected by the proposed reduction or restructuring, by geographic area. This proposed data element is similar to that currently required in § 447.203(b)(1)(iii), which requires an analysis of changes in beneficiary utilization of covered services in each geographic area. However, as stated earlier, the difference here is that this proposed analysis would be limited to the beneficiary populations impacted by the rate reduction or restructuring, for a more narrow set of data points, rather than requiring the State to conduct a full review of the Medicaid beneficiary population every 3 years on an ongoing basis. Even though we are not proposing to require this analysis to be updated broadly with respect to many benefit categories on an ongoing basis, we would require current information on the number and types of Medicaid services being delivered to Medicaid beneficiaries through the FFS delivery system in each benefit category affected by the proposed reduction or restructuring to inform our SPA review process to ensure that the statutory access standard is met. The inclusion of this data is relevant because it provides information about the actual distribution of care received by Medicaid beneficiaries and where, geographically, these services are provided to ensure that the statutory access standard is met.

Finally, in § 447.203(c)(2)(vi), we are proposing to require a summary of, and the State's response to, any access to care concerns or complaints received from beneficiaries, providers, and other interested parties regarding the service(s) for which the payment rate reduction or restructuring is proposed as required under § 447.204(a)(2). This proposed requirement mirrors the requirement in § 447.204(b)(3), which requires that for any SPA submission that proposes to reduce or restructure Medicaid service payment rates, a specific analysis of the information and concerns expressed in input from affected interested parties must be provided at the time of the SPA submission. The new proposed § 447.203(c)(2)(vi) requires the same analysis while providing more detail as to what we expect the State to provide. Specifically, proposed § 447.203(c)(2)(vi) would require information about concerns and complaints from beneficiaries and providers specifically, as well as from other interested parties, and would underscore that the required analysis would be required to include the State's responses.

Where any of the previously discussed proposed data elements requires an analysis of data over a 3-year period, we are proposing this time span to smooth statistical anomalies, and so that data variations can be understood. For example, any 3-year period look-back that includes portions of time

during a public health emergency, such as that for the COVID–19 pandemic, might include much more variation in the access to care measures than periods before or after the public health emergency. By using a 3-year period, it is more likely that the State, CMS, and other interested parties would be able to identify and appropriately account for short term disruptions in access-related measures, for example, when the number of services performed dropped precipitously in 2020 as elective visits and procedures were postponed or canceled due to the public health emergency.[224] If the proposed rule only included a 12-month period, for example, it might not be clear that the data represent an accurate reflection of access to care at the time of the proposed reduction or restructuring. For example, a State may see variation in service utilization if there have been programmatic changes that are introduced over time, such as a move to increase care provided through a managed care delivery system in the State through which the fee-for-service utilization declines steadily until managed care enrollment targets are achieved, but a one-time review of that fee-for-service utilization capturing just a 12-month period might not capture data most reflective of the current fee-for-service utilization demonstrating access to care consistent with section 1902(a)(30)(A) of the Act. We are seeking public comment on the proposed use of a 3-year period where the proposed rule would require data about trends over time in the data elements proposed to be required under § 447.203(c)(2). We are also seeking public comment on the data elements required in § 447.203(c)(2) as additional State rate analysis.

Proposed paragraph (c)(2) would require that States conduct and provide to us a rigorous analysis of a proposed payment rate reduction's or payment restructuring's potential to affect beneficiary access to care. However, by limiting these analyses to only those proposed payment rate reductions and payment restructurings in circumstances when the changes could result in diminished access that do not meet the criteria in proposed paragraph (c)(1), we believe that the requirements proposed in paragraph (c)(2) would help to enable us to determine whether the proposed State Medicaid payment rates and payment methodologies are consistent with section 1902(a)(30)(A) of the Act while minimizing State and Federal administrative burden, to the extent possible. We would use this State-provided information and analysis to help us understand the current levels of access to care in the State's program, and determine, considering the provider, beneficiary, and other interested party input collected through proposed § 447.203(c)(4), whether the proposed payment rate reduction or payment restructuring likely would reduce access to care for the particular service(s) consistent with the statutory standard in section 1902(a)(30)(A) of the Act. If we approve the State's proposal, the data provided would serve as a baseline for prospective monitoring of access to care within the State.

The proposed analysis and documentation requirements in paragraph (c)(2) draw, in part, from the current requirements of the AMRP process in the current § 447.203(b)(1), and reflect the diverse methods and measures that are and can be used to monitor access to care. We also drew on some of the comments received on the 2011 proposed rule, as discussed in the 2015 final rule with comment period, where several commenters recommended that CMS consider identifying a set of uniform measures that States must collect data on or that CMS weighs more heavily in its analysis.[225] We are proposing to provide more specificity on the types of uniform data elements in this proposed rule in § 447.203(c) than is provided under current § 447.203(b)(1). States have shown that they have access to the data listed in the proposed § 447.203(c)(2) when we have requested it during SPA reviews and through the AMRP process, and through this proposed rule, we are proposing to specify the type of data that we would expect States to provide with rate reduction or restructuring SPAs that do not meet the proposed criteria for streamlined analysis under § 447.203(c)(1). As noted elsewhere in the preamble, the ongoing AMRP requirements have presented an administratively burdensome process for States to follow every 3 years, particularly where we did not provide States with the specific direction on the types of data elements we preferred for States to include. However, the data elements involved in the current AMRP process in § 447.203(b)(1) can provide useful information about beneficiary access to care in current § 447.203(b)(1)(i), (iii), and (iv); Medicaid provider availability in current § 447.203(b)(1)(ii); and about payment rates available from other payers, which may affect Medicaid beneficiaries' relative ability to access care, in current § 447.203(b)(1)(v). We found that the AMRPs were most relevant when updated to accompany a submission of rate reduction or restructuring SPAs as specified in the current § 447.203(b)(6); accordingly, to better balance ongoing State and Federal administrative burden with our need to obtain access-related information to inform our approval decisions for payment rate reduction or restructuring SPAs, we are proposing to end the ongoing AMRP requirement but maintain a requirement that States include similar data elements when submitting such SPAs to us that do not qualify for the proposed streamlined analysis process under § 447.203(c)(1).

The proposed analyses in paragraph (c)(2) would enable us to focus our review of Medicaid access to care on proposals that may result in diminished access to care, enabling us to more substantively review a proposed rate reduction's or restructuring's potential impact on access (for example, counts of participating providers), realized access (for example, service utilization trends), and the beneficiary experience of care (for example, characteristics of the beneficiary population, beneficiary utilization data, and information related to feedback from beneficiaries and other interested parties collected during the public process and through ongoing beneficiary feedback mechanisms, along with the State's responses to that feedback), while also being able to more quickly work through a review of nominal rate reduction SPAs for which States have demonstrated certain levels of payment and for which the public process did not generate access to care concerns. By including information on provider type and site of service, we believe States would be able to demonstrate access to the services provided under a specific benefit category within a number different settings across the Medicaid program, such as the availability of physicians services delivered in a physician practice, clinic setting, FQHC or RHC, or even in a hospital-based office setting. We believe that by defining specific data elements which must be provided to support a payment rate reduction SPA would create a more predictable process for States and for CMS in conducting the SPA review than under the current AMRP process in § 447.203(b)(6).

Furthermore, data elements proposed to be required under proposed § 447.203(c)(2) would be based on State-specified geographic stratifications, to help ensure we can perform access

[224] Stuart, B. ''How The COVID–19 Pandemic Has Affected Provision Of Elective Services: The Challenges Ahead.'' *Health Affairs,* October 8, 2020. Available at *https://www.healthaffairs.org/do/10.1377/forefront.20201006.263687* (accessed February 27, 2023).

[225] 80 FR 67576 at 67590.

review consistent with the requirements of section 1902(a)(30)(A) of the Act. We expect that States would have readily available access to geographically differential beneficiary and provider data. Some of this information is available through CMS-maintained resources, such as the Transformed Medicaid Statistical Information System (T–MSIS), and other data is available through the National Plan and Provider Enumeration System (NPPES), but we believe that States should have their own data systems that would allow them to generate the most up-to-date beneficiary utilization and provider enrollment data, stratified by geographic areas within the State. States should use the most recent complete data available for each of the proposed data elements, and each would be required to be demonstrated to CMS by State-specified geographic area. We believe that the geographic stratification would enable CMS to establish a baseline for Medicaid access to care within the geographic areas so that we can determine if current levels of access to care are consistent with section 1902(a)(30)(A) of the Act, and can make future determinations if access is diminished in the future within the geographic area. For all of the data elements in proposed § 447.203(c)(2), the more geographic differentiation that can be provided (that is, the smaller and more numerous the distinct geographic areas of the State that are selected for separate analysis), the more we believe that the State can meaningfully demonstrate that the proposed rate changes are consistent with the access standard in section 1902(a)(30)(A) of the Act, which requires that States assure that payments are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area.

If finalized, we anticipate releasing subregulatory guidance, including a template to support completion of the analysis that would be required under paragraph (c)(2), prior to the beginning date of the *Comparative Payment Rate Analysis Timeframe* proposed in § 447.203(b)(4). In the intervening period, we anticipate working directly with States through the SPA review process to ensure compliance with section 1902(a)(30)(A) of the Act.

In § 447.203(c)(3), we propose mechanisms for ensuring compliance with requirements for State analysis for rate reduction or restructuring, as specified in proposed paragraphs (c)(1) and (c)(2), as applicable. We propose that a State that submits a SPA that proposes to reduce provider payments or restructure provider payments that fails to provide the required information and analysis to support approval as specified in proposed paragraphs (c)(1) and (2), as applicable, may be subject to SPA disapproval under § 430.15(c). Additionally, States that submit relevant information, but where there are unresolved access to care concerns related to the proposed SPA, including any raised by CMS in our review of the proposal and any raised through the public process as specified in proposed paragraph (c)(4) of this section, or under § 447.204(a)(2), may be subject to SPA disapproval under § 430.15(c). Disapproving a SPA means that the State would not have authority to implement the proposed rate reduction or restructuring and would be required to continue to pay providers according to the rate methodology described in the approved State plan. Proposed paragraph (c)(3) would further provide that if, after approval of a proposed rate reduction or restructuring, State monitoring of beneficiary access shows a decrease in Medicaid access to care, such as a decrease in the provider-to-beneficiary ratio for any affected service, or the State or CMS experiences an increase in the number of beneficiary or provider complaints or concerns about access to care that suggests possible noncompliance with the access requirements in section 1902(a)(30)(A) of the Act, we may take a compliance action. As described in § 447.204(d), compliance actions would be carried out using the procedures described in § 430.35.

As discussed in the prior section, we are proposing to move current § 447.203(b)(7) to proposed § 447.203(c)(4). We are not proposing any changes to the public process described in current paragraph (b)(7). If the other provisions of this proposed rule are finalized, we would redesignate paragraph (b)(7) as paragraph (c)(4). The ability for providers and beneficiaries to provide ongoing feedback to the State regarding access to care and a beneficiary's ability to access Medicaid services is essential to the Medicaid program in that it provides the primary interested parties the opportunity to communicate with the State and for the State to track and take account of those interactions in a meaningful way. The ongoing mechanisms for provider and beneficiary feedback must be retained in this proposed rule as this process serves an important role in determining whether or not the public has raised concerns regarding access to Medicaid-covered services, which would inform the State's approach to ongoing Medicaid provider payment rates and methodologies, and whether related proposals would be approvable.

We are proposing to move current § 447.203(b)(8) to proposed § 447.203(c)(5) to better organize § 447.203 to reflect the policies in this proposed rule. We are not proposing any changes to the methods for addressing access questions and remediation of inadequate access to care, as described in current paragraph (b)(8). If the other provisions of this proposed rule are finalized, we would redesignate paragraph (b)(8) as paragraph (c)(5). It is important to retain this provision because we acknowledge that there may be access issues that come about apart from a specific State payment rate action, and there must be mechanisms through which those issues can be identified and corrective action taken.

Finally, we are proposing to move current § 447.204(d) to proposed § 447.203(c)(6). We believe the subject matter, of compliance actions for an access deficiency, is better aligned to the proposed changes in § 447.203. We are not proposing any changes to defining the remedy for the identification of an unresolved access deficiency, as described in current § 447.204(d). If the other provisions of this proposed rule are finalized, we would redesignate § 447.204(d) as paragraph (c)(6).

We are seeking public comment on our proposed procedures and requirements for State analysis for payment rate reduction or payment restructuring SPAs, including the qualification criteria for streamlined analysis proposed in § 447.203(c)(1), the proposed additional analysis elements in § 447.203(c)(2) for those proposed payment rate reductions or payment restructurings that do not meet the criteria in paragraph (c)(1), the proposed methods for ensuring compliance in § 447.203(c)(3), the proposed mechanisms for ongoing beneficiary and provider input in § 447.203(c)(4), the proposed methods to address access questions and remediation of inadequate access to care in § 447.203(c)(5), and the proposed compliance actions for access deficiencies in § 447.203(c)(6).

4. Medicaid Provider Participation and Public Process To Inform Access to Care (§ 447.204)

In § 447.204, we propose conforming changes to reflect proposed changes in § 447.203, if finalized. These conforming edits are limited to § 447.204(a)(1) and (b) and are necessary

for consistency with the newly proposed changes in § 447.203(b). The remaining paragraphs of § 447.204 would be unchanged.

Specifically, we propose to update the language of § 447.204(a)(1), which currently references § 447.203, to reference § 447.203(c). Because we are proposing wholesale revisions to § 447.203(b) and the addition of § 447.203(c), the proposed data and analysis referenced in the current citation to § 447.203 would be located more precisely in § 447.203(c). Current § 447.204(b)(1) refers to the State's most recent AMRP performed under current § 447.203(b)(6) for the services at issue in the State's payment rate reduction or payment restricting SPA; we propose to remove this requirement to align with our proposal to rescind the AMRP requirements in current § 447.203(b). Current § 447.204(b)(2) and (3) require the State to submit with such a payment SPA an analysis of the effect of the change in the payment rates on access and a specific analysis of the information and concerns expressed in input from affected interested parties; we believe these current requirements are addressed in proposed § 447.203(c)(1) and (2), as applicable. We believe that the continued inclusion of these paragraphs (b)(2) and (3) would be unnecessary or redundant in light of the proposals in § 447.203(c)(1) and (2), if finalized. The objective processes proposed under § 447.203(c)(1) and (2), which would require States to submit quantitative and qualitative information with a proposed payment rate reduction or payment restructuring SPA, would be sufficient for us to obtain the information necessary to assess the State's proposal with the same or similar information as currently is required under § 447.204(b)(2) and (3).

With the removal of § 447.204(b)(1) through (b)(3), we propose to revise § 447.204(b) to read, ''[t]he State must submit to us with any such proposed State plan amendment affecting payment rates documentation of the information and analysis required under § 447.203(c) of this chapter.''

Finally, as noted in the previous section, we propose to remove and relocate § 447.204(d), as we felt the nature of that provision is better suited to codification in § 447.203(c)(6).

We are seeking public comment on the proposed amendments to § 447.204.

III. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 *et seq.*), we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. To fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the PRA requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our Agency.
- The accuracy of our estimate of the information collection Burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements (see section III.E. of this preamble for further information). Comments, if received, will be responded to within the subsequent final rule.

A. Wage Estimates

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' (BLS's) May 2021 National Occupational Employment and Wage Estimates for all salary estimates (*http://www.bls.gov/oes/current/oes_nat.htm*). In this regard, Table 1 presents BLS' mean hourly wage, our estimated cost of fringe benefits and other indirect costs [226] (calculated at 100 percent of salary), and our adjusted hourly wage.

TABLE 1—NATIONAL OCCUPATIONAL EMPLOYMENT AND WAGE ESTIMATES

Occupation title	Occupational code	Mean hourly wage ($/hr)	Fringe benefits and other indirect costs ($/hr)	Adjusted hourly wage ($/hr)
Administrative Services Manager	11–3012	54.34	54.34	108.68
Business Operations Specialist	13–1000	38.64	38.64	77.28
Business Operations Specialist, All Other	13–1199	38.10	38.10	76.20
Chief Executive	11–1011	102.41	102.41	204.82
Compensation, Benefits, and Job Analyst	13–1141	35.49	35.49	70.98
Computer and Information Analyst	15–1210	50.40	50.40	100.80
Computer Programmer	15–1251	46.46	46.46	92.92
Data Entry Keyers	43–9021	17.28	17.28	34.56
General and Operations Manager	11–1021	55.41	55.41	110.82
Human Resources Manager	11–3121	65.67	65.67	131.34
Management Analyst	13–1111	48.33	48.33	96.66
Social and Community Service Managers	11–9151	36.92	36.92	73.84
Social Science Research Assistants	19–4061	27.13	27.13	54.26
Statistician	15–2041	47.81	47.81	95.62
Survey Researcher	19–3022	31.10	31.10	62.20
Training and Development Specialist	13–1151	32.51	32.51	65.02

For States and the private sector the employee hourly wage estimates have been adjusted by a factor of 100 percent. This is necessarily a rough adjustment, both because fringe benefits and other indirect costs vary significantly across employers, and because methods of estimating these costs vary widely across studies. Nonetheless, we believe

[226] *https://aspe.hhs.gov/reports/valuing-time-us-department-health-human-services-regulatory-impact-analyses-conceptual-framework.*

that there is no practical alternative and that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

We believe that the costs for beneficiaries undertaking administrative and other tasks on their own time is a post-tax hourly wage rate of $20.71/hr.

We adopt an hourly value of time based on after-tax wages to quantify the opportunity cost of changes in time use for unpaid activities. This approach matches the default assumptions for valuing changes in time use for individuals undertaking administrative and other tasks on their own time, which are outlined in an ASPE report on ''Valuing Time in U.S. Department of Health and Human Services Regulatory Impact Analyses: Conceptual Framework and Best Practices.'' [*] We start with a measurement of the usual weekly earnings of wage and salary workers of $998. [**] We divide this weekly rate by 40 hours to calculate an hourly pre-tax wage rate of $24.95. We adjust this hourly rate downwards by an estimate of the effective tax rate for median income households of about 17 percent, resulting in a post-tax hourly wage rate of $20.71. We adopt this as our estimate of the hourly value of time for changes in time use for unpaid activities.[227] [228] Unlike our State and private sector wage adjustments, we are not adjusting beneficiary wages for fringe benefits and other indirect costs since the individuals' activities, if any, would occur outside the scope of their employment.

B. Adjustment to State Cost Estimates

To estimate the financial burden on States, it was important to consider the Federal government's contribution to the cost of administering the Medicaid program. The Federal government provides funding based on an FMAP that is established for each State, based on the per capita income in the State as compared to the national average. FMAPs range from a minimum of 50 percent in States with higher per capita incomes to a maximum of 83 percent in States with lower per capital incomes. For Medicaid, all States receive a 50 percent FMAP for administration. States also receive higher Federal matching rates for certain systems improvements, redesign, or operations. As such, and taking into account the Federal contribution to the costs of administering the Medicaid programs for purposes of estimate State burden with respect to collection of information, we elected to use the higher end estimate that the States would contribute 50 percent of the costs, even though the burden would likely be much smaller.

C. Proposed Information Collection Requirements (ICRs)

1. ICRs Regarding Medicaid Advisory Committee and Beneficiary Advisory Group (§ 431.12)

The following proposed changes will be submitted to OMB for review under control number 0938–TBD (CMS–10845). At this time, the control number is to be determined (TBD). OMB will assign the control number upon their clearance of this new collection of information request. The control number will be set out in the subsequent final rule (CMS–2442–F).

Currently, most States have an established Medicaid Advisory Committee (MAC, previously known as a Medical Care Advisory Committee, or MCAC) whereby each State has the discretion on how to operate its MAC. A small number of States also use consumer advisory subcommittees as part of their MACs, similar to the Beneficiary Advisory Groups (BAGs) in proposed § 431.12. We reviewed data from 10 States to determine the current status of MACs and to determine the burden needed to comply with the proposed § 431.12 requirements across 50 States and the District of Columbia.

Under the proposed provision, States would be required to:

- Appoint members to the MAC and BAG on a rotating and continuous basis.
- Develop and publish a process for MAC and BAG member recruitment and appointment and selection of MAC and BAG leadership.
- Develop and publish:

++ Bylaws for governance of the MAC.

++ A current list of MAC and BAG membership.

++ Past meeting minutes, including a summary from the most recent BAG Meeting.

- Develop, publish, and implement a regular meeting schedule for the MAC and BAG.

Additionally, the State must provide and post to its website an annual report written by the MAC to the State describing its activities, topics discussed, recommendations. The report must also include actions taken by the State based on the MAC recommendations.

The proposed requirements would require varying levels of effort by States. For example, a handful of States already have a BAG. However, we believe that most States will be required to create new structures and processes. The majority of States reviewed are already meeting some of the new proposed requirements for MACs, such as publication of meeting schedules, publication of membership lists, and publication of bylaws. However, all MAC bylaws would need to be updated to meet the new proposed requirements. Our review showed that most States are not currently publishing their recruitment and appointment processes for MAC members, and those that did would need to update these processes to meet the new proposed requirements. About half of the States reviewed published meeting minutes with responses and State actions, as required under the new proposed requirements. But only one State reviewed published an annual report, so this will likely be a new requirement for almost all State MACs. States will not need to modify or build a reporting systems to create and post these annual reports. Due to the wide range in the use and maturity of current MCACs across the States, we are providing a range of estimates to address these variations. We recognize that some States, which do not currently operate a MCAC, will have a higher burden to implement the requirements of § 431.12 to shift to the MAC and BAG structure. However, our research showed that the majority of States do have processes and procedures for their current MCACs, which will require updating, but at a much lower burden. Therefore, we believe it is appropriate to offer average low and high burden estimates.

For a low estimate, we estimate it would take a team of business operations specialists 120 hours at $76.20/hr to develop and publish the processes and report. In aggregate, we estimate an annual burden of 6,120 hours (120 hr/response × 51 responses) at a cost of $466,344 (6,120 hr × $76.20/hr). We also estimate that it would take 40 hours at $131.34/hr for a human resources manager to review and approve bylaws and help with recruitment and appointment and selection of MAC and BAG leadership which would occur every 2 years. In aggregate, we estimate a biennial burden of 2,040 hours (40 hr/response × 51

[227] Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation. 2017. ''Valuing Time in U.S. Department of Health and Human Services Regulatory Impact Analyses: Conceptual Framework and Best Practices.'' *https://aspe.hhs.gov/reports/valuing-time-us-department-health-human-services-regulatory-impact-analyses-conceptual-framework.*

[228] U.S. Bureau of Labor Statistics. Employed full time: Median usual weekly nominal earnings (second quartile): Wage and salary workers: 16 years and over [LEU0252881500A], retrieved from FRED, Federal Reserve Bank of St. Louis; *https://fred.stlouisfed.org/series/LEU0252881500A.* Annual Estimate, 2021.

responses) at a cost of $267,934 (2,040 hr × $131.34/hr). Additionally, we estimate it would take 10 hours at $110.82/hr for an operations manager to review the updates and prepare the required reports for annual publication. In aggregate, we estimate an annual burden of 510 hours (10 hr/response × 51 responses) at a cost of $56,518 (510 hr × $110.82/hr).

We derived the high estimate by doubling the hours from the low estimate. We used this approach because all States already have a MCAC requirement which means the type of work being discussed is already underway in most States and that there is reference point for the type of work described. For example, we estimate it would take a team of business operations specialists 240 hours at $76.20/hr to develop and publish the processes and annual report. In aggregate, we estimate an annual burden of 12,240 hours (240 hr/response × 51 responses) at a cost of $932,688 (12,240 hr × $76.20/hr). We also estimate that it would take 80 hours at $131.34/hr for a human resources manager to review and approve bylaws and help with recruitment and appointment and selection of MAC and BAG leadership which would occur every 2 years. In aggregate, we estimate a biennial burden of 4,080 hours (80 hr/response × 51 responses) at a cost of $535,867 (4,080 hr × $131.34). Additionally, we estimate it would take 20 hours at $110.82/hr for an operations manager to review the updates and prepare the required annual report for publication. In aggregate, we estimate an annual burden of 1,020 hours (20 hr/response × 51 responses) at a cost of $113,036 (1,020 hr × $110.82/hr).

We have summarized the total burden in Table 2. To be conservative and not underestimate our burden analysis, we are using the high end of our estimates to score the PRA-related impact of the proposed requirements.

TABLE 2—SUMMARY OF BURDEN ESTIMATES FOR MEDICAL CARE ADVISORY COMMITTEE REQUIREMENTS

Requirement	Number of respondents	Total responses	Frequency	Time per response (hr)	Total time (hr)	Wage ($/hr)	Total cost ($)	State share ($)
§ 431.12 (develop/publish report)	51	51	Annual	240	12,240	76.20	932,688	466,344
§ 431.12 (review/approve bylaws)	51	51	Biennial	80	4,080	131.34	535,867	267,934
§ 431.12 (review updates/prepare reports)	51	51	Annual	20	1,020	110.82	113,036	56,518
Total	51	153	Varies	Varies	17,340	Varies	1,581,591	790,795

2. ICRs Regarding Person-Centered Service Plans (§ 441.301(c)(3); Cross-Referenced to §§ 441.450(c), 441.540(c), and 441.725(c), and Part 438)

The following proposed changes will be submitted to OMB for their approval after this proposed rule is finalized and our survey instrument has been developed. The survey instrument and burden will be made available to the public for their review under the standard non-rule PRA process which includes the publication of 60- and 30-day **Federal Register** notices. In the meantime, we are setting out our preliminary burden figures (see below) as a means of scoring the impact of this rule's proposed changes. The availability of the survey instrument and more definitive burden estimates will be announced in both **Federal Register** notices. The CMS ID number for that collection of information request is CMS–10854 (OMB control number 0938–TBD). Since this would be a new collection of information request, the OMB control number has yet to be determined (TBD) but will be issued by OMB upon their approval of the new collection of information request.

Section 1915(c)(1) of the Act requires that services provided through section 1915(c) waiver programs be provided under a written plan of care (hereinafter referred to as ''person-centered service plans'' or ''service plans''). Existing Federal regulations at § 441.301(c) address the person-centered planning process and include a requirement at § 441.301(c)(3) that the person-centered service plan be reviewed and revised upon reassessment of functional need, at least every 12 months, when the individual's circumstances or needs change significantly or at the request of the individual.

In 2014, we released guidance for section 1915(c) waiver programs [229] (hereinafter the ''2014 guidance'') that included expectations for State reporting of State-developed performance measures to demonstrate compliance with section 1915(c) of the Act and the implementing regulations in part 441, subpart G through six assurances, including assurances related to person-centered service plans. The 2014 guidance also indicated that States should conduct systemic remediation and implement a Quality Improvement Project when they score below an 86 percent threshold on any of their performance measures. Based on feedback CMS obtained during various public engagement activities conducted with States and other interested parties over the past several years about the reporting discussed in the 2014 guidance, as well as feedback received through the RFI [230] discussed earlier about the need to standardize reporting and set minimum standards for HCBS, we are proposing a different approach for States to demonstrate that they meet the statutory requirements in section 1915(c) of the Act and the regulatory requirements in part 441, subpart G, including the requirements regarding assurances around service plans.

Within this rule we propose to replace expectations for State reporting of State-developed performance measures and the 86 percent performance threshold included in the 2014 guidance and codify requirements for reporting on standardized measures and a minimum performance level for States to demonstrate that they meet the existing person-centered service plan requirements at § 441.301(c)(3). Specifically, at new § 441.301(c)(3)(ii)(A), we propose to require that States demonstrate that a reassessment of functional need was conducted at least annually for at least 90 percent of individuals continuously enrolled in the waiver for at least 365 days. We also propose, at new § 441.301(c)(3)(ii)(B), to require that States demonstrate that they reviewed the person-centered service plan and revised the plan as appropriate based on the results of the required reassessment of functional need at least every 12 months for at least 90 percent of individuals continuously enrolled in the waiver for at least 365 days. At

[229] Modifications to Quality Measures and Reporting in § 1915(c) Home and Community-Based Waivers. March 2014. Accessed at *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/3-cmcs-quality-memo-narrative_0_2.pdf.*

[230] CMS Request for Information: Access to Coverage and Care in Medicaid & CHIP. February 2022. For a full list of question from the RFI, see *https://www.medicaid.gov/medicaid/access-care/downloads/access-rfi-2022-questions.pdf.*

§ 441.311(b)(3), we propose to modernize the service plan reporting requirement by standardizing State reporting through new Federal reporting requirements. These performance and reporting requirements, in combination with other proposed requirements [231] identified throughout this proposed rule, are intended to supersede and fully replace existing reporting requirements and required performance levels for section 1915(c) waiver programs, which were established through the 2014 guidance discussed earlier.[232] We propose to apply these requirements to services delivered under FFS or managed care delivery systems. Further, we propose to apply the proposed requirements at § 441.301(c)(3) to sections 1915(j), (k), and (i) State plan services by cross-referencing at §§ 441.450(c), 441.540(c), and 441.725(c), respectively. In addition, we propose to reposition, specify, and remove extraneous language from § 441.301(c)(1).

a. One Time Person-Centered Service Plan Requirements: State (§ 441.301(c)(3))

As discussed above, at new § 441.301(c)(3)(ii)(A), we propose to require that States demonstrate that a reassessment of functional need was conducted at least annually for at least 90 percent of individuals continuously enrolled in the waiver for at least 365 days. We also propose, at new § 441.301(c)(3)(ii)(B), to require that States demonstrate that they reviewed the person-centered service plan and revised the plan as appropriate based on the results of the required reassessment of functional need at least every 12 months for at least 90 percent of individuals continuously enrolled in the waiver for at least 365 days. The burden associated with the person-centered service plan reporting requirements proposed at § 441.301(c)(3)(ii)(A) and (B) will affect the 48 States (including the District of Columbia) that deliver HCBS under sections 1915(c), (i), (j), or (k) authorities.[233] We anticipate that States will need to update State policy and oversight and monitoring processes related to the codification of the new 90 percent minimum performance level associated with requirements.

However, because we are codifying a minimum performance level associated with existing regulations but not otherwise changing the regulatory requirements under § 441.301(c)(3)(ii)(A) and (B), we do not estimate any additional burden related to those requirements. We also hold that there is no additional burden associated with repositioning, specifying, and removing extraneous language from the regulatory text at § 441.301(c)(1). In this regard we are only estimating burden for updating State policy and oversight and monitoring processes related to the codification of the new 90 percent minimum performance level associated with requirements.

We estimate it would take 8 hours at $108.68/hr for an administrative services manager to update State policy and oversight and monitoring processes, 2 hours at $110.82/hr for a general and operations manager to review and approve the updates to State policy and oversight and monitoring processes, and 1 hour at $204.82/hr for a chief executive to review and approve the updates to State policy and oversight and monitoring processes. In aggregate, we estimate a one-time burden of 528 hours (48 States × [8 hr + 2 hr + 1 hr]) at a cost of $62,203 (48 States × [(8 hr × $108.68/hr) + (2 hr × $110.82/hr) + (1 hr × $204.82/hr)]). Taking into account the Federal contribution to Medicaid administration, the estimated State share of this cost would be $31,102 ($62,203 × 0.50).

TABLE 3—SUMMARY OF ONE-TIME BURDEN ESTIMATES FOR STATES FOR THE PERSON-CENTERED SERVICE PLAN REQUIREMENTS AT § 441.301(c)(3)

Requirement	Number of respondents	Total responses	Frequency	Time per response (hr)	Total time (hr)	Wage ($/hr)	Total cost ($)	State share ($)
Update State policy and oversight and monitoring processes.	48	48	Once	8	384	108.68	41,733	20,867
Review and approval of State policy update at the management level.	48	48	Once	2	96	110.82	10,639	5,319
Review and approval of State policy update at the chief executive level.	48	48	Once	1	48	204.82	9,831	4,916
Total	48	144	Once	11	528	Varies	62,203	31,102

b. One Time Person-Centered Service Plan Requirements: Managed Care Entities (§ 441.301(c)(3))

As discussed earlier in sections II.B.1 of this preamble, we are proposing to also apply, to managed care delivery systems, the requirements at § 441.301(c)(3) to demonstrate that a reassessment of functional need was conducted at least annually for at least 90 percent of individuals continuously enrolled in the waiver for at least 365 days and to demonstrate that they reviewed the person centered service plan and revised the plan as appropriate based on the results of the required reassessment of functional need at least every 12 months for at least 90 percent of individuals continuously enrolled in the waiver for at least 365 days. As with the burden estimate for States, we do not estimate an ongoing burden related to the codification of a minimum performance level associated with the requirements at § 441.301(c)(3).

For managed care entities we estimate it would take 5 hours at $108.68/hr for an administrative services manager to update organizational policy and oversight and monitoring processes related to the codification of a new minimum performance level and 1 hour at $204.82/hr for a chief executive to review and approve the updates to organizational policy and oversight and monitoring processes. In aggregate, we estimate a one-time burden of 966 hours (161 managed care entities × [5 hr + 1 hr]) at a cost of $120,463 (161 managed care entities × [(5 hr × $108.68/hr) + (1 hr × $204.82/hr)]).

[231] The other requirements relate to incident management, critical incident, person centered planning, and service provision compliance reporting; reporting on the HCBS Quality Measure Set; access reporting; and payment adequacy reporting.

[232] Modifications to Quality Measures and Reporting in § 1915(c) Home and Community-Based Waivers. March 2014 Accessed at *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/3-cmcs-quality-memo-narrative_0_71.pdf.*

[233] Arizona, Rhode Island, and Vermont do not have HCBS programs under any of these authorities.

TABLE 4—SUMMARY OF ONE-TIME BURDEN ESTIMATES FOR MANAGED CARE ENTITIES (MCES) FOR THE PERSON-CENTERED SERVICE PLAN REQUIREMENTS AT § 441.301(c)(3)

Requirement	Number of respondents	Total responses	Frequency	Time per response (hr)	Total time (hr)	Wage ($/hr)	Total cost ($)	State share ($)
Update organizational policy and oversight and monitoring processes.	161	161	Once	5	805	108.68	87,487	n/a
Review and approval of policy and oversight and monitoring processes.	161	161	Once	1	161	204.82	32,976	n/a
Total	161	322	Once	6	966	Varies	120,463	n/a

3. ICRs Regarding Grievance System (§ 441.301(c)(7); Cross-Referenced to §§ 441.464(d)(2)(v), 441.555(b)(2)(iv), and 441.745(a)(1)(iii), and Part 438)

At § 441.301(c)(7), we propose to require that States establish grievance procedures for Medicaid beneficiaries receiving section 1915(c) waiver program services through a FFS delivery system to file a complaint or expression or dissatisfaction related to the State's or a provider's compliance with the person-centered planning and service plan requirements at § 441.301(c)(1) through (3) and the HCBS settings requirements at § 441.301(c)(4) through (6).

Proposed § 441.301(c)(7)(vii) lists proposed recordkeeping requirements related to grievances. Specifically, at § 441.301(c)(7)(vii)(A), we propose to require that States maintain records of grievances and review the information as part of their ongoing monitoring procedures. At § 441.301(c)(7)(vii)(B)(*1*) through (*7*), we propose to require that the record of each grievance must contain the following information at a minimum: a general description of the reason for the grievance, the date received, the date of each review or review meeting (if applicable), resolution and date of the resolution of the grievance (if applicable), and the name of the beneficiary for whom the grievance was filed. Further, at § 441.301(c)(7)(vii)(C), we propose to require that grievance records be accurately maintained and in a manner that would be available upon our request.

We also propose to apply these proposed requirements in § 441.301(c)(7) to sections 1915(j), (k), and (i) State plan services by cross-referencing at §§ 441.464(d)(2)(v), 441.555(b)(2)(iv), and 441.745(a)(1)(iii), respectively. However, to avoid duplication with the grievance requirements at part 438, subpart F, we do not propose to apply these requirements to managed care delivery systems.

The following proposed changes will be submitted to OMB for their approval after this proposed rule is finalized and our reporting tools and survey instrument has been developed. The survey instrument and burden will be made available to the public for their review under the standard non-rule PRA process which includes the publication of 60- and 30-day **Federal Register** notices. In the meantime, we are setting out our preliminary burden figures (see below) as a means of scoring the impact of this rule's proposed changes. The availability of the survey instrument and more definitive burden estimates will be announced in both **Federal Register** notices. The CMS ID number for that collection of information request is CMS–10854 (OMB control number 0938–TBD). Since this would be a new collection of information request, the OMB control number has yet to be determined (TBD) but will be issued by OMB upon their approval of the new collection of information request.

a. States

The burden associated with the grievance system requirements proposed at § 441.301(c)(7) will affect the 48 States (including the District of Columbia) that deliver at least some HCBS under sections 1915(c), (i), (j), or (k) authorities through FFS delivery systems.[234] [235] While some States may have existing grievance systems in place for their FFS delivery systems, we are unable to determine the number of States with existing grievance systems or whether those grievance systems would meet the proposed requirements at § 441.301(c)(7). As a result, we do not take this information into account in our burden estimate. We estimate a one-time and on-going burden to implement these requirements at the State level.

Specifically, States will have to: (1) develop and implement policies and procedures; (2) establish processes and data collection tools for accepting, tracking, and resolving, within required timeframes, beneficiary grievances, including processes and tools for: providing beneficiaries with reasonable assistance with filing a grievance, for accepting grievances orally and in writing, for reviewing grievance resolutions with which beneficiaries are dissatisfied, and for providing beneficiaries with a reasonable opportunity to present evidence and testimony and make legal and factual arguments related to their grievance; (3) inform beneficiaries, providers, and subcontractors about the grievance system; and (4) develop beneficiary notices; and collect and maintain information on each grievance, including the reason for the grievance, the date received, the date of each review or review meeting (if applicable), resolution and date of the resolution of the grievance (if applicable), and the name of the beneficiary for whom the grievance was filed.

i. One-Time Grievance System Requirements: States (§ 441.301(c)(7))

With regard to the one-time requirements, we estimate it would take: 240 hours at $108.68/hr for an administrative services manager to draft policy and procedure content, prepare notices and informational materials, draft rules for publication, and conduct public hearings; 100 hours at $92.92/hr for a computer programmer to build, design, and operationalize internal systems for data collection and tracking; 120 hours at $65.02/hr for a training and development specialist to develop and conduct training for staff; 40 hours at $110.82/hr for a general and operations manager to review and approve policies, procedures, rules for publication, notices, and training materials; and 20

[234] Arizona, Rhode Island, and Vermont do not have HCBS programs under any of these authorities.

[235] While some States deliver the vast majority of HCBS through managed care delivery systems, States would be subject to these requirements if they deliver any HCBS under section 1915(c), (i), (j), or (k) authorities through a fee-for service delivery system. Based on data showing that the percent of LTSS expenditures delivered through managed LTSS delivery systems varied between 3 percent and 93 percent in 2019 across all States with managed LTSS, we assume that all States deliver at least some HCBS through fee-for-service delivery systems (*https://www.medicaid.gov/medicaid/long-term-services-supports/downloads/ltssexpenditures2019.pdf*). We anticipate that the burden associated with implementing these requirements will be lower for States that deliver the vast majority of HCBS through managed care delivery systems.

hours at $204.82/hr for a chief executive to review and approve all operations associated with this collection of information requirement. In aggregate, we estimate a one-time burden of 24,960 hours (520 hr × 48 States) at a cost of $2,481,926 (48 States × [(240 hr × $108.68/hr) + (100 hr × $92.92/hr) + (120 hr × $65.02/hr) + (40 hr × $110.82/hr) + (20 hr × $204.82/hr)]). Taking into account the Federal contribution to Medicaid administration, the estimated State share of this cost would be $1,240,963 ($2,481,926 × 0.50).

TABLE 5—SUMMARY OF ONE-TIME BURDEN ESTIMATES FOR STATES FOR THE GRIEVANCE SYSTEM REQUIREMENTS AT § 441.301(c)(7)

Requirement	Number of respondents	Total responses	Frequency	Time per response (hr)	Total time (hr)	Wage ($/hr)	Total cost ($)	State share ($)
Draft policy and procedures, rules for publication; prepare beneficiary notices, informational materials; conduct public hearings.	48	48	Once	240	11,520	108.68	1,251,994	625,997
Build, design, operationalize internal systems for data collection and tracking.	48	48	Once	100	4,800	92.92	446,016	223,008
Develop and conduct training for staff	48	48	Once	120	5,760	65.02	374,515	187,258
Review and approve policies, procedures, rules for publication, notices, and training materials at the management level.	48	48	Once	40	1,920	110.82	212,774	106,387
Review and approve all operations in collection of information requirement at the chief executive level.	48	48	Once	20	960	204.82	196,627	98,314
Total	48	240	Once	520	24,960	Varies	2,481,926	1,240,964

ii. Ongoing Grievance System Requirements: States (§ 441.301(c)(7))

With regard to the on-going requirements, we estimate that approximately 2 percent of 1,460,363 Medicaid beneficiaries who receive HCBS under section 1915(c), (i), (j), or (k) authorities through FFS delivery systems annually [236] will file a grievance or appeal (29,207 grievances = 1,460,363 × 0.02).[237] We estimate it would take: 0.333 hours or 20 minutes at $76.20/hr for a business operations specialist to collect the required information for each grievance from the beneficiary, 0.166 hours or 10 minutes at $34.56/hr for a data entry worker to record the required information on each grievance, 20 hours at $92.92/hr for a computer programmer to maintain the system for storing information on grievances, 12 hours at $110.82/hr for a general and operations manager to monitor and oversee the collection and maintenance of the required information, and 2 hours at $204.82/hr for a chief executive to review and approve all operations associated with this collection of information requirement. In aggregate, we estimate an on-going burden of 16,206 hours at a cost of $1,081,374 ([(29,207 grievances × 0.333 hr × $76.20/hr) + (29,207 grievances × 0.166 hr × $34.56/hr) + (48 States × 20 hr × $92.92/hr) + (48 States × 12 hr × $110.82/hr) + (48 States × 2 hr × $204.82/hr)]). Taking into account the Federal contribution to Medicaid administration, the estimated State share of this cost would be $540,687 ($1,081,374 × 0.50) per year.

TABLE 6—SUMMARY OF ONGOING BURDEN FOR STATES FOR THE GRIEVANCE SYSTEM REQUIREMENTS AT § 441.301(c)(7)

Requirement	Number of respondents	Total responses	Frequency	Time per response (hr)	Total time (hr)	Wage ($/hr)	Total cost ($)	State share ($)
Collect required grievance data and information	48	29,207	On occasion	0.333	9,726	76.20	741,116	370,558
Enter required grievance data and information into data collection and tracking system.	48	29,207	On occasion	0.166	4,848	34.56	167,559	83,780
Perform maintenance on system for storing data and information on grievances.	48	48	Annually	20	960	92.92	89,203	44,602
Monitor and oversee the collection and maintenance of the required information at the management level.	48	48	Annually	12	576	110.82	63,832	31,916
Review and approve all operations associated with collection of information requirement at the executive level.	48	48	Annually	2	96	204.82	19,663	9,831
Total	48	58,558	Varies	Varies	16,206	Varies	1,081,374	540,687

4. ICRs Regarding Incident Management System (§ 441.302(a)(6); Cross-Referenced to §§ 441.464(e), 441.570(e), 441.745(a)(1)(v), and Part 438)

At § 441.302(a)(6), we propose to require that States provide an assurance that they operate and maintain an incident management system that identifies, reports, triages, investigates, resolves, tracks, and trends critical incidents. At § 441.302(a)(6)(i)(A), we propose to establish a minimum standard definition of a critical incident. At § 441.302(a)(6)(i)(B), we propose to require that States have electronic incident management systems that, at a minimum, enable electronic collection, tracking (including of the status and

[236] *https://www.medicaid.gov/medicaid/long-term-services-supports/downloads/ltss-user-brief-2019.pdf.*

[237] We based this percent on an estimate of the percent of Medicaid beneficiaries that file appeals and grievances in Medicaid managed care in Supporting Statement A for the information collection requirements for the Medicaid managed care file rule (CMS–2408–F, RIN 0938–AT40). See *https://omb.report/icr/202205-0938-015/doc/121334100* for more information.

resolution of investigations), and trending of data on critical incidents. At § 441.302(a)(6)(i)(C), we propose to require States to require providers to report to States any critical incidents that occur during the delivery of section 1915(c) waiver program services as specified in a waiver participant's person-centered service plan, or are a result of the failure to deliver authorized services. At § 441.302(a)(6)(i)(D), we propose to require that States use claims data, Medicaid Fraud Control Unit data, and data from other State agencies such as Adult Protective Services or Child Protective Services to the extent permissible under applicable State law to identify critical incidents that are unreported by providers and occur during the delivery of section 1915(c) waiver program services, or as a result of the failure to deliver authorized services. At § 441.302(a)(6)(i)(E), we propose to require that States share information on the status and resolution of investigations if the State refers critical incidents to other entities for investigation. We also propose, at § 441.302(a)(6)(i)(F), to require States to separately investigate critical incidents if the investigative agency fails to report the resolution of an investigation within State-specified timeframes. At § 441.302(a)(6)(i)(G), we propose to require that States meet the reporting requirements at § 441.311(b)(1) related to the performance of their incident management systems. We also propose to codify minimum performance levels to demonstrate that States meet the requirements at § 441.302(a)(6). These performance and reporting requirements, in combination with other proposed requirements identified throughout this proposed rule, are intended to supersede and fully replace existing reporting requirements and required performance levels for section 1915(c) waiver programs, which were established in 2014.[238]

At § 441.302(a)(6)(iii), we propose to apply these requirements to services delivered under FFS or managed care delivery systems. We also propose to apply the proposed requirements § 441.302(a)(6) to sections 1915(j), (k), and (i) State plan services by cross-referencing at §§ 441.570(e), 441.464(e), and 441.745(a)(1)(v), respectively.

The following proposed changes will be submitted to OMB for their approval after this proposed rule is finalized and our survey instrument has been developed. The survey instrument and burden will be made available to the public for their review under the standard non-rule PRA process which includes the publication of 60- and 30-day **Federal Register** notices. In the meantime, we are setting out our preliminary burden figures (see below) as a means of scoring the impact of this rule's proposed changes. The availability of the survey instrument and more definitive burden estimates will be announced in both **Federal Register** notices. The CMS ID number for that collection of information request is CMS–10854 (OMB control number 0938–TBD). Since this would be a new collection of information request, the OMB control number has yet to be determined (TBD) but will be issued by OMB upon their approval of the new collection of information request.

a. States

The burden associated with the incident management system requirements proposed at § 441.302(a)(6) will affect the 48 States (including Washington, DC) that deliver HCBS under section 1915(c), (i), (j), or (k) authorities.[239] We estimate a one-time and on-going burden to implement these requirements at the State level. The burden for the proposed reporting requirements at § 441.311(b)(1) is included in the ICR #8, which is the ICRs Regarding Compliance Reporting (§ 441.311(b)).

All of the States impacted by § 441.302(a)(6)(i)(B), requiring that States use an information system, as defined in 45 CFR 164.304 and compliant with 45 CFR part 164, have existing incident management systems in place. However, we assume that all States will need to make at least some changes to their existing systems to fully comply with the proposed requirements. Specifically, States will have to update State policies and procedures; implement new or update existing electronic incident management systems; publish revised provider requirements through State notice and publication processes; update provider manuals and other policy guidance; amend managed care contracts; collect required information from providers; use other required data sources to identify unreported incidents; and share information with other entities in the State responsible for investigating critical incidents.

i. One Time Incident Management System Requirements: States (§ 441.302(a)(6))

With regard to the one-time requirements related to proposed § 441.302(a)(6), we estimate it would take: 120 hours at $108.68/hr for an administrative services manager to draft policy content, prepare notices and draft rules for publication, conduct public hearings, and draft contract modifications for managed care plans; 20 hours at $96.66/hr for a management analyst to update provider manuals; 80 hours at $65.02/hr for a training and development specialist to develop and conduct training for providers; 80 hours at $76.20/hr for a business operations specialist to establish processes for information sharing with other entities; 80 hours at $100.80/hr for a computer and information analyst to build, design, and implement reports for using claims and other data to identify unreported incidents; 24 hours at $110.82/hr for a general and operations manager to review and approve managed care contract modifications, policy and rules for publication, and training materials; and 10 hours at $204.82/hr for a chief executive to review and approve all operations associated with this requirement.

In aggregate, we estimate a one-time burden of 19,872 hours (414 hr × 48 States) at a cost of $1,874,125 (48 States × [(120 hr × $108.68/hr) + (20 hr × $96.66/hr) + (80 hr × $65.02/hr) + (80 hr × $76.20/hr) + (80 hr × $100.80/hr) + (24 hr × $110.82/hr) + (10 hr × $204.82/hr)]). Taking into account the Federal contribution to Medicaid administration, the estimated State share of this cost would be $937,063 ($1,874,125 × 0.50).

In addition, we estimate that States, based on the results of the incident management system assessment discussed earlier in section II.B.3. of this preamble, that 82 percent of States, or 39 States (48 States × 0.82), would need to update existing electronic incident management systems, while the remaining 9 States would need to implement new electronic incident management systems, to meet the proposed requirement at § 441.302(a)(6)(i)(B). We estimate based on information reported by some States in spending plans for section 9817 of the American Rescue Plan Act of 2021 that the cost per State to update existing electronic systems is $2 million while the cost per State to implement new electronic systems is $5 million.[240] In

[238] Modifications to Quality Measures and Reporting in § 1915(c) Home and Community-Based Waivers. March 2014 Accessed at *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/3-cmcs-quality-memo-narrative_0_71.pdf.*

[239] Arizona, Rhode Island, and Vermont do not have HCBS programs under any of these authorities.

[240] Enhanced Federal Financial Participation (FFP) is available at a 90 percent Federal Medical

Continued

aggregate, we estimate a one-time technology burden of $123,000,000 [($2,000,000 × 39 States) + ($5,000,000 × 9 States)]. Taking into account the Federal contribution to Medicaid administration, the estimated State share of this cost would be $ 61,500,000 ($123,000,000 × 0.50).

TABLE 7—SUMMARY OF ONE-TIME BURDEN FOR STATES FOR THE INCIDENT MANAGEMENT SYSTEM REQUIREMENTS (§ 441.302(a)(6))

Requirement	Number of respondents	Total responses	Frequency	Time per response (hr)	Total time (hr)	Wage ($/hr)	Total cost ($)	State share ($)
Draft policy content, prepare notices and draft rules for publication, conduct public hearings, and draft contract modifications for managed care plans.	48	48	Once	120	5,760	108.68/hr	625,997	312,998
Update provider manuals	48	48	Once	20	960	96.66/hr ...	92,794	46,397
Develop and conduct training for providers ..	48	48	Once	80	3,840	65.02/hr ...	249,677	124,838
Establish processes for information sharing with other entities.	48	48	Once	80	3,840	76.20/hr ...	292,608	146,304
Build, design, and implement reports for using claims and other data to identify unreported incidents.	48	48	Once	80	3,840	100.80/hr	387,072	193,536
Review and approve managed care contract modifications, policy and rules for publication, and training materials at the management level.	48	48	Once	24	1,152	110.82/hr	127,665	63,832
Review and approve all operations associated with this requirement at the executive level.	48	48	Once	10	480	204.82/hr	98,314	49,157
Subtotal Labor-Related Burden	*48*	*336*	*Once*	*Varies*	*19,872*	*Varies*	*1,874,125*	*937,063*
Update existing electronic incident management systems.	39	39	Once	n/a	n/a	2,000,000/system.	78,000,000	39,000,000
Implement new electronic systems	9	9	Once	n/a	n/a	5,000,000/system.	45,000,000	22,500,000
Subtotal Non-Labor Burden	*48*	*48*	*Once*	*n/a*	*n/a*	*Varies*	*123,000,000*	*61,500,000*
Total	48	384	Once	414	19,872	Varies	124,874,125	62,437,063

ii. Ongoing Incident Management System Requirements: States (§ 441.302(a)(6))

With regard to the ongoing requirements § 441.302(a)(6), we estimate that there are 0.5 critical incidents annually [241] for each of the 1,889,640 Medicaid beneficiaries who receive HCBS under sections 1915(c), (i), (j), or (k) authorities annually, or 944,820 (1,889,640 × 0.5) critical incidents annually.[242] We further estimate that, based on data on unreported incidents, these requirements will result in the identification of 30 percent more critical incidents annually, or 283,446 (944,820 × 0.3) critical incidents; [243] that 76 percent, or 215,419 (283,446 × 0.76) will be reported for individuals enrolled in FFS delivery systems; [244] and that 10 percent of those for individuals enrolled in FFS delivery systems (21,542 = 215,419 × 0.1) will be made through provider reports and 90 percent (193,877 = 215,419 × 0.9) through claims identification and other sources.[245] We estimate 0.166 hr or 10 minutes at $34.56/hr for a data entry worker to record the information on each reported critical incident reported by providers for individuals enrolled in FFS delivery systems. In aggregate, we estimate an ongoing burden each year of 3,576 hours (21,542 incidents × 0.166 hr) at a cost of $123,587 (3,576 hr × $34.56/hr) to record the information on each reported critical incident reported by providers for individuals enrolled in FFS delivery systems. While States can establish different processes for the reporting of critical incidents for individuals enrolled in managed care, we assume for the purpose of this analysis that the States would delegate provider reporting critical incidents and identification of critical incidents through claims and other data sources to managed care entities and that the managed care entities would be responsible for reporting the identified critical incidents to the State.[246] We further assume that the information reported by managed care entities to the State and identified by the State through claims and other data sources would be in an electronic form. For the 68,027 more critical incidents for individuals enrolled in managed care (283,446 more critical incidents identified × 24 percent

Assistance Percentage (FMAP) rate for the design, development, or installation of improvements of mechanized claims processing and information retrieval systems, in accordance with applicable Federal requirements. Enhanced FFP at a 75 percent FMAP rate is also available for operations of such systems, in accordance with applicable Federal requirements. However, the receipt of these enhanced funds is conditioned upon States meeting a series of standards and conditions to ensure investments are efficient and effective. As a result, we do not assume for the purpose of this burden estimate that States will qualify for the enhanced Federal match. This estimate overestimates State burden to the extent that States qualify for the enhanced Federal match.

[241] Data on the number of critical incidents is limited. We base our estimate on available public information, such as *https://oig.hhs.gov/oas/reports/region7/71806081.pdf* and *https://dhs.sd.gov/servicetotheblind/docs/2015%20CIR%20Annual%20Trend%20Analysis.pdf.*

[242] *https://www.medicaid.gov/medicaid/long-term-services-supports/downloads/ltss-user-brief-2019.pdf.*

[243] Data on the number of unreported critical incidents is limited. We base our estimate on available public information, such as *https://pennlive.com/news/2020/01/possible-abuse-of-group-home-residents-wasnt-adequately-tracked-in-pa-federal-audit.html* and *https://www.kare11.com/article/news/local/federal-audit-finds-maine-dhhs-failed-to-investigate-multiple-deaths-critical-incidents/97-463258015.*

[244] *https://www.medicaid.gov/medicaid/long-term-services-supports/downloads/ltss-user-brief-2019.pdf.*

[245] Data is limited on the identification of critical incidents through various data sources. We conservatively assume that 25 percent of more critical incidents identified as a result of these requirements will be reported by providers even though claims data will likely identify a substantially higher of percentage of claims than will be reported by providers.

[246] Addressing Critical Incidents in the MLTSS Environment: Research Brief, ASPE, *https://aspe.hhs.gov/reports/addressing-critical-incidents-mltss-environment-research-brief-0.*

for individuals enrolled in managed care), and the 193,877 more critical incidents identified through claims and other data sources for individuals enrolled in FFS (283,446 more critical incidents identified × 76 percent for individuals enrolled in FFS × 90 percent identified through claims and other sources), we estimate 2 minutes (0.0333 hr) at $34.56/hr for a data entry worker to record the information on each of these 261,904 critical incidents (68,027 + 193,877). In aggregate, for § 441.302(a)(6), we estimate an ongoing annual burden of 8,721 hours (261,904 incidents × 0.0333 hr) at a cost of $301,398 (8,721 hr × $34.56/hr) on these critical incidents.

In total, for § 441.302(a)(6), we estimate an ongoing burden each year of 12,297 hours (3,576 hours + 8,721 hours) at a cost of $424,985 ($123,587 + $301,398) to record the information on all critical incidents for individuals enrolled in FFS and managed care delivery systems across all States. We further estimate it would take 12 hours at $76.20/hr for a business operations specialist to maintain processes for information sharing with other entities; 20 hours at $100.80/hr for a computer and information analyst to update and maintain reports for using claims and other data to identify unreported incidents; 24 hours at $110.82/hr for a general and operations manager to monitor the operations associated with this requirement; and 4 hours at $204.82/hr for a chief executive to review and approve all operations associated with this collection of information requirement in each State. In aggregate, we estimate an ongoing burden of 15,177 hours ([60 hr × 48 States] + 12,297 hr) at a cost of $732,617 ($424,985 + [48 States × ((12 hr × $76.20/hr) + (20 hr × $100.80/hr) + (24 hr × $110.82/hr) + 4 hr × $204.82/hr)]). In addition, we estimate an on-going annual technology-related cost of $500,000 per State for States to maintain their electronic incident management systems. In aggregate, we estimate an ongoing burden of $24,000,000 ($500,000 × 48 States) for States to maintain their electronic incident management systems. In total, we estimate an ongoing annual burden of 15,177 hours at a cost $24,732,617 ($732, 617 + $24,000,000). Taking into account the Federal contribution to Medicaid administration, the estimated State share of this cost would be $12,366,309 ($24,732,617 × 0.50). Taking into account the Federal contribution to Medicaid administration, the estimated State share of this cost would be $12,366,309 ($24,732,617 × 0.50).

TABLE 8—SUMMARY OF ONGOING BURDEN FOR STATES FOR THE INCIDENT MANAGEMENT SYSTEM REQUIREMENTS AT PROPOSED § 441.302(a)(6)

Requirement	Number of respondents	Total responses	Frequency	Time per response (hr)	Total time (hr)	Wage ($/hr)	Total cost ($)	State share ($)
Record the information on each reported critical incident reported by providers for individuals enrolled in FFS delivery systems.	48	21,542	Annually	0.166	3,576	34.56/hr	123,587	61,793
Record the information on critical incidents for individuals enrolled in managed care and critical incidents identified through claims and other data sources for individuals enrolled in FFS.	48	261,904	Annually	0.033	8,721	34.56/hr	301,398	150,699
Maintain processes for information sharing with other entities.	48	48	Annually	12	576	76.20/hr	43,891	21,946
Update and maintain reports for using claims and other data to identify unreported incidents.	48	48	Annually	20	960	100.80/hr	96,768	48,384
Monitor operations associated with this requirement at the management level.	48	48	Annually	24	1,152	110.82/hr	127,664.64	63,832
Review and approve all operations associated with this collection of information requirement at the executive level.	48	48	Annually	4	192	204.82/hr	39,325.44	19,662.72
Subtotal: Labor Related Burden.	*48*	*283,638*	*Annually .....*	*Varies*	*15,177*	*Varies .....*	*732,634*	*366,317*
Maintain electronic incident management systems (specifically, § 441.302(a)(6)(i)(B)).	48	48	Annually	n/a	n/a	500,000/system.	24,000,000	12,000,000
Total Technology Cost	*48*	*48*	*Annually .....*	*n/a*	*n/a*	*500,000/system.*	*24,000,000*	*12,000,000*
Total	48	283,638	Annually	Varies	15,177	Varies	24,732,634	12,366,317

b. Service Providers and Managed Care Contractors

The burden associated with this proposed rule would affect service providers that provide HCBS under sections 1915(c), (i), (j), and (k) authorities, as well as managed care entities that contract with the States to provide managed long-term services and supports.

The following discussion estimates an ongoing burden for service providers to implement these requirements and both a one-time and ongoing burden for managed care contractors.

i. On-Going Incident Management System Requirements: Service Provider

To estimate the number of service providers that would be impacted by this proposed rule, we used unpublished data from the Provider Relief Fund to estimate that there are 19,677 providers nationally across all payers delivering the types of HCBS that are delivered under sections 1915(c), (i), (j), and (k) authorities. We then prorate the number to estimate the number of providers in the 48 States that are subject to this requirement (19,677 providers nationally × 48 States subject to the proposed requirement/51 States = 18,520 providers). We used data from the Centers for Disease Control and Prevention [247] to estimate the percentage of these HCBS providers that participate in Medicaid and, due to uncertainty in the data and differences in provider definitions, estimate both a lower and upper range of providers affected. At a low end of 78 percent Medicaid participation, we estimate that there are 14,446 providers impacted (18,520 providers × 0.78), while at a high end of 85 percent participation, we estimate that there are 15,742 providers impacted (18,520 providers × 0.85). To be conservative and not underestimate our projected burden analysis, we are using the high end of our estimates to score the PRA-related impact of the proposed requirements.

As discussed earlier, we estimate that providers will report 10 percent, or 28,345, of the more critical incidents (283,446 more critical incidents × 0.10) identified annually as a result of these requirements. Based on these figures, we estimate that, on average, each provider will report 1.8 (28,345 incidents/15,742 providers) more critical incidents annually. We further estimate that, on average, it would take a provider 1 hour at $110.82/hr for a general and operations manager to collect the required information and report the information to the State or to the managed care entity as appropriate for each incident.[248] In aggregate, for § 441.302(a)(6), we estimate an ongoing burden of 28,345 hours (28,345 incidents × 1 hr) at a cost of $3,141,193 (28,345 hr × $110.82/hr).

TABLE 9—SUMMARY OF ONGOING BURDEN FOR SERVICE PROVIDERS FOR THE INCIDENT MANAGEMENT SYSTEM REQUIREMENTS

Requirement	Number of respondents	Total responses	Frequency	Time per response (hr)	Total time (hr)	Wage ($/hr)	Total cost ($)	State share ($)
Collect the required information and report the information to the State or to the managed care entity (§ 441.302(a)(6)(i)(C)).	15,742 providers.	28,345 incidents.	Annually	1	28,345	110.82	3,141,193	n/a
Total	15,742 providers.	28,345 incidents.	Annually	1	28,345	110.82	3,141,193	n/a

ii. One Time Incident Management System Requirements: Managed Care Entities (§ 441.302(a)(6))

As required under proposed § 441.302(a)(6), while States can establish different processes for the reporting of critical incidents for individuals enrolled in managed care, we assume for the purpose of this analysis that the States would delegate provider reporting of critical incidents and identification of critical incidents through claims and other data sources to managed care entities and that the managed care entities would be responsible for reporting the identified critical incidents to the State.[249] We further assume that the information reported by managed care entities to the State would be in an electronic form.

We estimated that there are 161 managed long-term services and supports plans providing services across 25 States.[250] With regard to the one-time requirements at § 441.302(a)(6), we estimate it would take: 20 hours at $108.68/hr for an administrative services manager to draft policy for contracted providers; 20 hours at $96.66/hr for a management analyst to update provider manuals; 40 hours at $65.02/hr for a training and development specialist to develop and conduct training for providers; 80 hours at $100.80/hr for a computer and information analyst to build, design, and implement reports for using claims and other data to identify unreported incidents; and 6 hours at $204.82/hr for a chief executive to review and approve all operations associated with this requirement. In aggregate, we estimate a one-time burden of 26,726 hours (161 managed care entities × 166 hr) at a cost of $2,576,084 (161 managed care entities × [(20 hr × $108.68/hr) + (20 hr × $96.66/hr) + (40 hr × $65.02/hr) + (80 hr × $100.80/hr) + (6 hr × $204.82/hr)]).

TABLE 10—SUMMARY OF ONE-TIME BURDEN FOR MANAGED CARE ENTITIES (MCES) FOR THE INCIDENT MANAGEMENT SYSTEM REQUIREMENTS AT § 441.302(a)(6)

Requirement	Number of respondents	Total responses	Frequency	Time per response (hr)	Total time (hr)	Wage ($/hr)	Total cost ($)	State share ($)
Draft policy for contracted providers	161	161	Once	20	3,220	108.68	349,950	n/a
Update provider manuals	161	161	Once	20	3,220	96.66	311,245	n/a
Develop and conduct training for providers	161	161	Once	40	6,440	65.02	418,729	n/a
Build, design, and implement reports for using claims and other data to identify unreported incidents.	161	161	Once	80	12,880	100.80	1,298,304	n/a

[247] *https://www.cdc.gov/nchs/data/series/sr_03/sr03_43-508.pdf.*

[248] The actual amount of time for each incident will vary depending on the nature of the critical incident and the specific reporting requirements of each State and managed care entity. This estimate assumes that some critical incidents will take substantially less time to report, while others could take substantially less time.

[249] Addressing Critical Incidents in the MLTSS Environment: Research Brief, available at *https://aspe.hhs.gov/reports/addressing-critical-incidents-mltss-environment-research-brief-0.*

[250] ''A View from the States: Key Medicaid Policy Changes: Results from a 50-State Medicaid Budget Survey for State Fiscal Years 2019 and 2020,'' *https://www.kff.org/report-section/a-view-from-the-states-key-medicaid-policy-changes-long-term-services-and-supports/.*

TABLE 10—SUMMARY OF ONE-TIME BURDEN FOR MANAGED CARE ENTITIES (MCES) FOR THE INCIDENT MANAGEMENT SYSTEM REQUIREMENTS AT § 441.302(a)(6)—Continued

Requirement	Number of respondents	Total responses	Frequency	Time per response (hr)	Total time (hr)	Wage ($/hr)	Total cost ($)	State share ($)
Review and approve all operations associated with this requirement.	161	161	Once	6	966	204.82	197,856	n/a
Total	161	805	Once	Varies	26,726	Varies	2,576,084	n/a

iii. Ongoing Incident Management System Requirements: Managed Care Entities (§ 441.302(a)(6))

The on-going burden to managed care entities consists of the collection and maintenance of information on critical incidents. As noted earlier, we estimate that these requirements will result in the identification of 283,446 more critical incidents annually than are currently identified by States. We further estimate that 24 percent, or 68,027 (283,446 × 0.24), will be reported for individuals enrolled in managed care delivery systems [251] and that 10 percent, or 6,803 (68,027 × 0.10), will be made through provider reports and 90 percent, or 61,224 (68,027 × 0.90), through claims identification and other sources.[252] We estimate that it would take 0.166 hr at $34.56/hr for a data entry worker to record the information on each reported critical incident reported by providers (§ 441.302(a)(6)(i)(B)(*2*)). In aggregate, we estimate an ongoing burden of 1,129 hours (6,803 critical incidents made through provider reports × 0.166 hr) at a cost of $39,018 (1,129 hr × $34.56/hr). We also estimate that it would take: 20 hours at $100.80/hr for a computer and information analyst to update and maintain reports for using claims and other data to identify unreported incidents (§ 441.302(a)(6)(i)(B)(*3*)); 6 hours at $110.82/hr for a general and operations manager to monitor the operations associated with this requirement and report the information to the State (§ 441.302(a)(6)(i)(E)); and 1 hour at $204.82/hr for a chief executive to review and approve all operations associated with this collection of information requirement (§ 441.302(a)(6)(i)(G)). In aggregate, we estimate an ongoing burden of 5,476 hours (1,129 hr + [161 managed care entities × 27 hr]) at a cost of $503,622 ($39,018 + (161 managed care entities × [(20 hr × $100.80/hr) + (6 hr × $110.82/hr) + (1 hr × $204.82/hr)]).

TABLE 11—SUMMARY OF ONGOING BURDEN FOR MANAGED CARE ENTITIES (MCES) FOR THE INCIDENT MANAGEMENT SYSTEM REQUIREMENTS

Requirement	Number of respondents	Total responses	Frequency	Time per response (hr)	Total time (hr)	Wage ($/hr)	Total cost ($)	State share ($)
Record the information on each reported critical incident reported by providers (§ 441.302(a)(6)(i)(B)(2)).	161	6,803	Annually	0.166	1,129	34.56	39,029	n/a
Update and maintain reports for using claims and other data to identify unreported incidents (§ 441.302(a)(6)(i)(B)(3)).	161	161	Annually	20	3,220	100.80	324,576	n/a
Monitor the operations associated with this requirement and report the information to the State (§ 441.302(a)(6)(i)(E)).	161	161	Annually	6	966	110.82	107,052	n/a
Review and approve all operations associated with this requirement (§ 441.302(a)(6)(i)(G)).	161	161	Annually	1	161	204.82	32,976	n/a
Total	161	7,286	Annually	Varies	5,476	Varies	503,633	n/a

5. ICRs Regarding HCBS Payment Adequacy (§§ 441.302(k) and 441.311(e); Cross-Referenced to §§ 441.464(f), 441.570(f) and 441.745(a)(1)(iv), and Part 438)

This proposed rule would update § 441.302, by adding new paragraph (k)(2), which would require that at least 80 percent of Medicaid payments for the following services be spent on compensation, as defined at § 441.302(k)(1)(i), to direct care workers for the following services: homemaker services, home health aide services, and personal care services.

Proposed § 441.302(k)(1)(i) defines compensation to include salary, wages, and other remuneration as defined by the Fair Labor Standards Act and implementing regulations (29 U.S.C. 201 *et seq.,* 29 CFR parts 531 and 778); benefits (such as health and dental benefits, sick leave, and tuition reimbursement); and the employer share of payroll taxes for direct care workers delivering services authorized under section 1915(c) of the Act. Proposed § 441.302(k)(1)(ii) defines direct care workers to include workers who provide nursing services, assist with activities of daily living (such as mobility, personal hygiene, eating), or provide support with instrumental activities of daily living (such as cooking, grocery shopping, managing finances). Specifically, direct care workers include nurses (registered nurses, licensed practical nurses, nurse practitioners, or clinical nurse specialists) who provide nursing services to Medicaid-eligible individuals receiving HCBS, licensed or certified nursing assistants, direct support professionals, personal care attendants, home health aides, and other individuals who are paid to directly provide services to Medicaid beneficiaries receiving HCBS to address activities of daily living or instrumental activities of daily living. Direct care

[251] *https://www.medicaid.gov/medicaid/long-term-services-supports/downloads/ltss-user-brief-2019.pdf.*

[252] Data is limited on the identification of critical incidents through various data sources. We conservatively assume that 25 percent of additional critical incidents identified as a result of these requirements will be reported by providers even though claims data will likely identify a substantially higher of percentage of claims than will be reported by providers.

workers include individuals employed by a Medicaid provider, State agency, or third party; contracted with a Medicaid provider, State agency, or third party; or delivering services under a self-directed service model.

To demonstrate compliance with the requirements proposed at § 441.302(k), new reporting requirements are proposed at § 441.311(e). Specifically, States would be required to report separately on the percent of payments that are spent on the direct care workforce for HCBS services. The services are found at § 440.180(b)(2) through (4), and include: homemaker services, home health aide services, and personal care services. Separate reporting would be required on payment for services that are self-directed.

The following proposed changes will be submitted to OMB for their approval after this proposed rule is finalized and our survey instrument has been developed. The survey instrument will be made available to the public for their review under the standard non-rule PRA process which includes the publication of 60- and 30-day **Federal Register** notices. In the meantime, we are setting out our preliminary burden figures (see below) as a means of scoring the impact of this rule's proposed changes. The availability of the survey instrument and more definitive burden estimates will be announced in both **Federal Register** notices. The CMS ID number for that collection of information request is CMS–10854 (OMB control number 0938–TBD). Since this would be a new collection of information request, the OMB control number has yet to be determined (TBD) but will be issued by OMB upon their approval of the new collection of information request.

a. States

The burden associated with the proposed requirements would affect the 48 States (including Washington, DC) that deliver HCBS under sections 1915(c), (i), (j), or (k) authorities.[253] [254] We estimate both a one-time and ongoing burden to implement these requirements at the State level. Specifically, under proposed §§ 441.302(k) and 441.311(e), States would have to: (1) draft new policy (one-time); (2) publish the provider requirements through State notice and publication processes (one-time); (3) update provider manuals and other policy guidance for each of the services subject to the requirement (one-time); (4) inform providers of services through State notification processes, both initially and annually (one-time and ongoing); (5) collect the information from providers for each service required (ongoing); (6) aggregate the data broken down by each service as well as self-directed services (ongoing); (7) derive an overall percentage for each service including self-directed services (ongoing); and (8) report to us on an annual basis (ongoing).

i. One Time HCBS Payment Adequacy Requirements: State Burden

With regard to the one-time requirements, we estimate it would take: 80 hours at $108.68/hr for an administrative services manager to: draft policy content, prepare notices and draft rules for publication, conduct public hearings, and draft contract modifications for managed care plans; 30 hours at $96.66/hr for a management analyst to update provider manuals for each of the affected services, and draft provider agreement amendments; 25 hours at $92.92/hr for a computer programmer to build, design, and operationalize internal systems for collection, aggregation, stratification by service, reporting, and creating remittance advice; 60 hours at $65.02/hr for a training and development specialist to develop and conduct training for providers; 6 hours at $110.82/hr for a general and operations manager to: review, approve managed care contract modifications, policy and rules for publication, and training materials; and 3 hours at $204.82/hr for a chief executive to review and approve all operations associated with this requirement. In aggregate, we estimate a one-time burden of 9,792 hours (204 hr × 48 States) at a cost of $916,693 (48 States × [(80 hr × $108.68/hr) + (30 hr × $96.66/hr) + (25 hr × $92.92/hr) + (60 hr × $65.02/hr) + (6 hr × $110.82/hr) + (3 hr × $204.82/hr)]). Taking into account the Federal contribution to Medicaid administration, the estimated State share of this cost would be $458,347 ($916,693 × 0.50).

TABLE 12—SUMMARY OF ONE-TIME BURDEN FOR STATES FOR THE HCBS PAYMENT ADEQUACY REQUIREMENTS AT §§ 441.302(k) AND 441.311(e)

Requirement	Number of respondents	Total responses	Frequency	Time per response (hr)	Total time (hr)	Wage ($/hr)	Total cost ($)	State share ($)
Draft policy content, prepare notices and draft rules for publication, conduct public hearings; and draft contract modifications for managed care plans.	48	48	Once	80	3,840	108.68	417,331	208,666
Update provider manuals for each of the affected services, draft provider agreement amendment.	48	48	Once	30	1,440	96.66	139,190	69,595
Build, design, and operationalize internal systems for collection, aggregation, stratification by service, reporting, and creating remittance advice.	48	48	Once	25	1,200	92.92	111,504	55,752
Develop and conduct training for providers	48	48	Once	60	2,880	65.02	187,258	93,629
Review, approve managed care contract modifications, policy and rules for publication, and training materials.	48	48	Once	6	288	110.82	31,916	15,958.08
Review and approve all operations associated with this requirement.	48	48	Once	3	144	204.82	29,494	14,747
Total	48	288	Once	Varies	9,792	Varies	916,693	458,347

[253] Arizona, Rhode Island, and Vermont do not have HCBS programs under any of these authorities.

[254] For purposes of this burden analysis, we are not taking into consideration temporary wage increases or bonus payments that have been or are being made.

ii. Ongoing HCBS Payment Adequacy Requirements: State Burden

With regard to the on-going requirements, we estimate it would take 6 hours at $92.92/hr for a computer programmer to: (1) collect the information from all providers for each service required; (2) aggregate and stratify by each service as well as self-directed services; (3) derive an overall percentage for each service including self-directed services; and (4) develop report to CMS on an annual basis. We also estimate it would take 2 hours at $110.82/hr by a general and operations manager to review, verify, and approve reporting to CMS and 1 hour at $204.82/hr for a chief executive to review and approve all operations associated with this requirement. In aggregate, we estimate an ongoing burden of 432 hours (9 hr × 48 States) at a cost of $47,231 (48 States × [(6 hr × $92.92/hr) + (2 hr × $110.82/hr) + (1 hr × $204.82/hr)]). Taking into account the Federal contribution to Medicaid administration, the estimated State share of this cost would be $23,616 ($47,231 × 0.50) per year.

TABLE 13—SUMMARY OF ONGOING BURDEN FOR STATES FOR THE HCBS PAYMENT ADEQUACY REQUIREMENTS AT §§ 441.302(k) AND 441.311(e)

Requirement	Number of respondents	Total responses	Frequency	Time per response (hr)	Total time (hr)	Wage ($/hr)	Total cost ($)	State share ($)
Collect information from providers; aggregate and stratify data as required; derive an overall percentage for each service; and develop report annually.	48	48	Annually	6	288	92.92	26,761	13,380
Review, verify and approve reporting to CMS	48	48	Annually	2	96	110.82	10,639	5,319
Review and approve all operations associated with this requirement.	48	48	Annually	1	48	204.82	9,831	4,916
Total	48	144	Annually	Varies	432	Varies	47,231	23,616

b. Service Providers and Managed Care Contractors

The burden associated with this proposed rule will affect both service providers that provide the services listed at § 440.180(b)(2) through (4) across HCBS programs as well as managed care entities that contract with the States to provide managed long-term services and supports. We estimate both a one-time and ongoing burden to implement the reporting requirements § 441.311(e) for both service providers and managed care contractors.

To estimate the number of service providers that will be impacted by this proposed rule, we used unpublished data from the Provider Relief Fund to estimate that there are 14,444 providers nationally across all payers delivering homemaker, home health aide, and/or personal care services. We then prorate the number to estimate the number of providers in the 48 States that are subject to this requirement (14,444 providers nationally × 48 States subject to the proposed requirement/51 States = 13,594 providers). We used data from the Centers for Disease Control and Prevention [255] to estimate the percentage of these HCBS providers that participate in Medicaid and, due to uncertainty in the data and differences in provider definitions, estimate both a lower and upper range of providers affected. At a low end of 78 percent Medicaid participation, we estimate that there are 10,603 providers impacted (13,594 × 0.78), while at a high end of 85 percent participation, we estimate that there are 11,555 providers impacted (13,594 × 0.85). To be conservative and not underestimate our projected burden analysis, we are using the high end of our estimates to score the PRA-related impact of the proposed requirements.

i. One Time HCBS Payment Adequacy Requirements: Service Providers (§ 441.311(e))

With regard to the one-time requirements, we estimate it would take: 35 hours at $70.98/hr for a compensation, benefits and job analysis specialist to calculate compensation, as defined by § 441.302(k)(1)(i) for each direct care worker defined at § 441.302(k)(1)(ii); 40 hours at $92.92/hr for a computer programmer to build, design and operationalize an internal system to calculate each direct care worker's compensation as a percentage of total revenues received, aggregate the sum of direct care worker compensation as an overall percentage, and separate self-directed services to report to the State; and 8 hours at $110.82/hr for a general and operations manager to review and approve reporting to the State. In aggregate, we estimate a one-time burden of 959,065 hours (11,555 providers × 83 hr) at a cost of $81,897,911 (11,555 providers × [(35 hr × $70.98/hr) + (40 hr × $92.92/hr) + (8 hr × $110.82/hr)]).

TABLE 14—SUMMARY OF ONE-TIME BURDEN FOR SERVICE PROVIDERS FOR THE HCBS PAYMENT ADEQUACY REQUIREMENTS AT § 441.311(e)

Requirement	Number of respondents	Total responses	Frequency	Time per response (hr)	Total time (hr)	Wage ($/hr)	Total cost ($)	State share ($)
Calculate compensation for each direct care worker	11,555	11,555	Once	35	404,425	70.98	28,706,087	n/a
Build, design and operationalize an internal system for reporting to the State.	11,555	11,555	Once	40	462,200	92.92	42,947,624	n/a
Review and approve reporting to the State	11,555	11,555	Once	8	92,440	110.82	10,244,200	n/a
Total	11,555	34,665	Once	Varies	959,065	Varies	81,897,911	n/a

[255] *https://www.cdc.gov/nchs/data/series/sr_03/sr03-047.pdf.*

ii. Ongoing HCBS Payment Adequacy Requirements: Service Providers (§ 441.311(e))

With regard to the on-going requirements, we estimate it would take 8 hours at $70.98/hr for a compensation, benefits, and job analysis specialist to account for new hires and/or contracted employees; 8 hours at $92.92/hr for a computer programmer to calculate compensation, aggregate data, and report to the State as required; and 5 hours at $110.82/hr for a general and operations manager to review and approve reporting to the State. In aggregate, we estimate an on-going burden of 242,655 hours (11,555 providers × 21 hr) at a cost of $21,553,542 (11,555 providers × [(8 hr × $70.98/hr) + (8 hr × $92.92/hr) + (5 hr × $110.82/hr)]).

TABLE 15—SUMMARY OF ONGOING BURDEN FOR SERVICE PROVIDERS FOR THE HCBS PAYMENT ADEQUACY REQUIREMENTS AT § 441.311(e)

Requirement	Number of respondents	Total responses	Frequency	Time per response (hr)	Total time (hr)	Wage ($/hr)	Total cost ($)	State share ($)
Account for new hires and/or contracted employees.	11,555	11,555	Once	8	92,440	70.98	6,561,391	n/a
Calculate compensation, aggregate data, and report to the State.	11,555	11,555	Once	8	92,440	92.92	8,589,525	n/a
Review and approve reporting to the State	11,555	11,555	Once	5	57,775	110.82	6,402,626	n/a
Total	11,555	34,665	Once	Varies	242,655	Varies	21,553,542	n/a

iii. One Time HCBS Payment Adequacy Requirements: Managed Care Entities (§ 441.311(e))

As noted earlier, the burden associated with this proposed rule will affect managed care entities (see section d, below) that contract with the States to provide managed long-term services and supports. We estimate that there are 161 managed long-term services and supports plans providing services across 25 States.[256] We estimate both a one-time and ongoing burden for managed care entities to implement these requirements. Specifically, managed care entities would have to: (1) draft new policy (one-time); (2) update provider manuals for each of the services subject to the requirement (one-time); (3) inform providers of requirements (one-time and ongoing); (4) collect the information from providers for each service required (ongoing); (5) aggregate the data as required by the States (ongoing); and (6) report to the State on an annual basis (ongoing).

With regard to the one-time requirements, we estimate it would take 40 hours at $108.68/hr for an administrative services manager to draft policy for contracted providers; 25 hours at $92.92/hr for a computer programmer to build, design, and operationalize internal systems for data collection, aggregation, stratification by service, and reporting; 30 hours at $65.02/hr for a training and development specialist to develop and conduct training for providers; and 3 hours at $204.82/hr for a chief executive to review and approve reporting to the State. In aggregate, we estimate a one-time burden of 15,778 hours (161 MCEs × 98 hr) at a cost of $1,486,877 (161 MCEs × [(40 hr × $108.68/hr) + (25 hr × $92.92/hr) + (30 hr × $65.02/hr) + (3 hr × $204.82/hr)]).

TABLE 16—SUMMARY OF ONE-TIME BURDEN FOR MANAGED CARE ENTITIES (MCES) FOR THE HCBS PAYMENT ADEQUACY REQUIREMENTS AT § 441.311(e)

Requirement	Number of respondents	Total responses	Frequency	Time per response (hr)	Total time (hr)	Wage ($/hr)	Total cost ($)	State share ($)
Draft policy for contracted providers	161	161	Once	40	6,440	108.68	699,899	n/a
Build, design, and operationalize internal systems for data collection, aggregation, stratification by service, and reporting.	161	161	Once	25	4,025	92.92	374,003	n/a
Develop and conduct training for providers	161	161	Once	30	4,830	65.02	314,047	n/a
Review and approve reporting to the State	161	161	Once	3	483	204.82	98,928	n/a
Total	161	644	Once	Varies	15,778	Varies	1,486,877	n/a

iv. Ongoing HCBS Payment Adequacy Requirements: Managed Care Entities (§ 441.311(e))

With regard to the ongoing requirements, we estimate it would take: 6 hours at $92.92/hr for a computer programmer to: (1) collect the information from all providers for each service required, (2) aggregate and stratify data as required, and (3) develop report to the State on an annual basis; and 2 hours at $204.82/hr for a chief executive to review and approve the reporting to the State. In aggregate, we estimate an ongoing burden of 1,288 hours (161 MCEs × 8 hr) at a cost of $155,713 (161 MCEs × [(6 hr × $92.92/hr) + (2 hr × $204.82/hr)]).

[256] *https://www.kff.org/report-section/a-view-from-the-states-key-medicaid-policy-changes-long-term-services-and-supports/;* Profiles & Program Features | Medicaid.

TABLE 17—SUMMARY OF ONGOING BURDEN FOR MANAGED CARE ENTITIES (MCES) FOR THE HCBS PAYMENT ADEQUACY REQUIREMENTS AT § 441.311(e)

Requirement	Number of respondents	Total responses	Frequency	Time per response (hr)	Total time (hr)	Wage ($/hr)	Total cost ($)	State share ($)
Collect information from providers; aggregate and stratify data as required; and develop report annually.	161	161	Annually ...	6	966	92.92	89,760	n/a
Review and approve the report	161	161	Annually ...	2	322	204.82	65,952	n/a
Total	161	322	Annually ...	Varies	1,288	Varies	155,713	n/a

6. ICRs Regarding Supporting Documentation for HCBS Access (§§ 441.303(f)(6) and 441.311(d)(1))

Section 1915(c) of the Act authorizes States to set enrollment limits or caps on the number of individuals served in a waiver, and many States maintain waiting lists of individuals interested in receiving waiver services once a spot becomes available. States vary in the way they maintain waiting lists for section 1915(c) waivers, and if a waiting list is maintained, how individuals may join the waiting list. Some States permit individuals to join a waiting list as an expression of interest in receiving waiver services, while other States require individuals to first be determined eligible for waiver services to join the waiting list. States have not been required to submit any information on the existence or composition of waiting lists, which has led to gaps in information on the accessibility of HCBS within and across States. Further, feedback obtained during various interested parties' engagement activities conducted with States and other interested parties over the past several years about reporting requirements for HCBS, as well as feedback received through the RFI[257] discussed earlier, indicate that there is a need to improve public transparency and processes related to States' HCBS waiting lists.

We propose to amend § 441.303(f)(6) by adding language to the end of the regulatory text: ''If the State has a limit on the size of the waiver program and maintains a list of individuals who are waiting to enroll in the waiver program, the State must meet the reporting requirements at § 441.311(d)(1).''

For States that limit or cap enrollment in a section 1915(c) waiver and maintain a waiting list, States would be required to provide a description annually on how they maintain the list of individuals who are waiting to enroll in a section 1915(c) waiver program. The description must include, but not be limited to, information on whether the State screens individuals on the waiting list for eligibility for the waiver program, whether the State periodically re-screen individuals on the waiver list for eligibility, and the frequency of re-screening, if applicable. In addition, States would be required to report of the number of people on the waiting list if applicable, as well as the average amount of time that individuals newly enrolled in the waiver program in the past 12 months were on the waiting list, if applicable.

The following proposed changes will be submitted to OMB for their approval after this proposed rule is finalized and our survey instrument has been developed. The survey instrument and burden will be made available to the public for their review under the standard non-rule PRA process which includes the publication of 60- and 30-day **Federal Register** notices. In the meantime, we are setting out our preliminary burden figures (see below) as a means of scoring the impact of this rule's proposed changes. The availability of the survey instrument and more definitive burden estimates will be announced in both **Federal Register** notices. The CMS ID number for that collection of information request is CMS–10854 (OMB control number 0938–TBD). Since this would be a new collection of information request, the OMB control number has yet to be determined (TBD) but will be issued by OMB upon their approval of the new collection of information request.

a. One Time Waiting List Reporting Requirements: States (§ 441.311(d)(1))

The one-time State burden associated with the waiting list reporting requirements proposed in § 441.311(d)(1) will affect the 39 State Medicaid programs with waiting lists for section 1915(c) waivers.[258] We estimate both a one-time and ongoing burden to implement these requirements at the State level. Specifically, States will have to query their databases or instruct their contractors to do so to collect information on the number of people on existing waiting lists and how long they wait; and write or update their existing waiting list policies and the information collected. In some States, HCBS waivers are administered by more than one operating agency, in these cases each will have to report this data up to the Medicaid agency for submission to us.

With regard to the one-time requirements, we estimate it would take: 16 hours at $108.68/hr for an administrative services manager to write or update State policy, direct information collection, compile information, and produce a report; 20 hours at $92.92/hr for a computer programmer or contractor to query internal systems for reporting requirements; 3 hours at $110.82/hr for a general and operations manager to review and approve report; and 2 hours at $204.82/hr for a chief executive to review and approve all reports associated with this requirement. In aggregate, we estimate a burden of 1,599 hours (39 States × 41 hr) at a cost of $169,236 (39 States × [(16 hr × $108.68/hr) + (20 hr × $92.92/hr) + (3 hr × $110.82/hr) + (2 hr × $204.82/hr)]). Taking into account the Federal contribution to Medicaid administration, the estimated State share of this cost would be $84,618 ($169,236 × 0.50).

Assuming no changes to the State waiting list policies, each year States would only need to update the report to reflect the number of people on the list of individuals who are waiting to enroll in the waiver program and average amount of time that individuals newly enrolled in the waiver program in the past 12 months were on the list.

[257] CMS Request for Information: Access to Coverage and Care in Medicaid & CHIP. February 2022. For a full list of question from the RFI, see *https://www.medicaid.gov/medicaid/access-care/downloads/access-rfi-2022-questions.pdf.*

[258] *https://www.kff.org/report-section/state-policy-choices-about-medicaid-home-and-community-based-services-amid-the-pandemic-issue-brief/.*

TABLE 18—SUMMARY OF ONE-TIME BURDEN FOR STATES FOR THE WAITING LIST REPORTING REQUIREMENTS AT § 441.311(d)(1)

Requirement	Number of respondents	Total responses	Frequency	Time per response (hr)	Total time (hr)	Wage ($/hr)	Total cost ($)	State share ($)
Write or update State policy, direct information collection, compile information, and produce a report.	39	39	Once	16	624	108.68	67,816	33,908
Query internal systems for reporting requirements	39	39	Once	20	780	92.92	72,478	36,239
Review and approve report at management level	39	39	Once	3	117	110.82	12,966	6,483
Review and approve all reports associated with this requirement at the executive level.	39	39	Once	2	78	204.82	15,976	7,988
Total	39	156	Once	Varies	1,599	Varies	169,236	84,618

b. Ongoing Waiting List Reporting Requirements: States (§ 441.311(d)(1))

With regard to the on-going burden for the section 1915(c) waiver waiting list reporting requirements at § 441.311(d)(1), we estimate it would take: 4 hours at $108.68/hr for an administrative services managers across relevant operating agencies to direct information collection, compile information, and produce a report; 6 hours at $92.92/hr for a computer programmer or contractor to query internal systems for reporting requirements; 3 hours at $110.82/hr for a general and operations manager to review and approve report; and 2 hours at $204.82/hr for a chief executive to review and approve all reports associated with this requirement. In aggregate, we estimate a burden of 585 hours (39 States × 15 hr) at a cost of $67,639 (39 States × [(4 hr × $108.68/hr) + (6 hr × $92.92/hr) + (3 hr × $110.82/hr) + (2 hr × $204.82/hr)]. Taking into account the Federal contribution to Medicaid administration, the estimated State share of this cost would be $33,820 ($67,639 × 0.50) per year.

TABLE 19—SUMMARY OF ONGOING BURDEN FOR STATES FOR THE WAITING LIST REPORTING REQUIREMENTS AT § 441.311(d)(1)

Requirement	Number of respondents	Total responses	Frequency	Time per response (hr)	Total time (hr)	Wage ($/hr)	Total cost ($)	State share ($)
Direct information collection, compile information, and produce a report.	39	39	Annually	4	156	108.68	16,954	8,477
Query internal systems for reporting requirements	39	39	Annually	6	234	92.92	21,743	10,872
Review and approve report at the management level	39	39	Annually	3	117	110.82	12,966	6,483
Review and approve all reports associated with this requirement at the executive level.	39	39	Annually	2	78	204.82	15,976	7,988
Total	39	156	Annually	Varies	585	Varies	67,639	33,820

7. ICRs Regarding Additional HCBS Access Reporting (§ 441.311(d)(2)(i))

Additional HCBS access reporting is proposed at § 441.311(d)(2)(i). States would be required to report annually on the average amount of time from when homemaker services, home health aide services, or personal care services, listed in § 440.180(b)(2) through (4), are initially approved to when services began for individuals newly approved to begin receiving services within the past 12 months. For this specific metric, States will be allowed to report on a statistically valid random sample of individuals newly approved to begin receiving these services within the past 12 months.

Proposed § 441.311(d)(2)(ii) would require States to report annually on the percent of authorized hours for homemaker services, home health aide services, or personal care, as listed in § 440.180(b)(2) through (4), that are provided within the past 12 months. States will have the option to report on a statistically valid random sample of individuals authorized to receive these services within the past 12 months, rather than all individuals authorized to receive these services within the past 12 months.

The following proposed changes will be submitted to OMB for their approval after this proposed rule is finalized and our survey instrument has been developed. The survey instrument and burden will be made available to the public for their review under the standard non-rule PRA process which includes the publication of 60- and 30-day **Federal Register** notices. In the meantime, we are setting out our preliminary burden figures (see below) as a means of scoring the impact of this rule's proposed changes. The availability of the survey instrument and more definitive burden estimates will be announced in both **Federal Register** notices. The CMS ID number for that collection of information request is CMS–10854 (OMB control number 0938–TBD). Since this would be a new collection of information request, the OMB control number has yet to be determined (TBD) but will be issued by OMB upon their approval of the new collection of information request.

The burden associated with the proposed additional HCBS access reporting requirements at § 441.311(d)(2) would affect the 48 States (including Washington DC) that deliver HCBS under sections 1915(c), (i), (j), or (k) authorities.[259] Specifically, States will have to query their databases or instruct their contractors to do so to collect information on the average amount of time from which homemaker services, home health aide services, or personal care services, as listed in § 440.180(b)(2) through (4), are initially approved to when services began, for individuals newly approved to begin receiving services within the past 12 months, and the percent of authorized hours for these services that are provided within the past 12 months. We expect many States will need to analyze report this metric for a statistically valid random sample of beneficiaries. They will then need to produce a report for

[259] Arizona, Rhode Island, and Vermont do not have HCBS programs under any of these authorities.

us within such information. For States with managed long-term services and supports, they would need to direct managed care entities to report this information up to them.

We estimate one-time and ongoing burden to implement the requirements at § 441.311(d)(2) at the State level.

a. One-Time HCBS Access Reporting Requirements: States (§ 441.311(d)(2))

With regard to the one-time burden related to the HCBS access reporting requirements, we estimate it would take: 20 hours at $108.68/hr for an administrative services manager across relevant operating agencies to direct information collection, compile information, and produce a report; 60 hours at $92.92/hr for a computer programmer or contractor to analyze service authorization and claims data; 40 hours at $95.62/hr for a statistician to conduct data sampling; 3 hours at $110.82/hr for a general and operations manager to review and approve report; and 2 hours at $204.82/hr for a chief executive to review and approve all reports associated with this requirement. In aggregate, we estimate a one-time burden of 6,000 hours (48 States × 125 hr) at a cost of $591,154 (48 States × [(20 hr × $108.68/hr) + (60 hr × $92.92/hr) + (40 hr × $95.62/hr) + (3 hr × $110.82/hr) + (2 hr × $204.82/hr)]). Taking into account the Federal contribution to Medicaid administration, the estimated State share of this cost would be $295,577 ($591,154 × 0.50) per year.

TABLE 20—SUMMARY OF ONE-TIME BURDEN FOR STATES FOR THE HCBS ACCESS REPORTING REQUIREMENTS AT § 441.311(d)(2)

Requirement	Number of respondents	Total responses	Frequency	Time per response (hr)	Total time (hr)	Wage ($/hr)	Total cost ($)	State share ($)
Direct information collection, compile information, and produce a report.	48	48	Once	20	960	108.68	104,333	52,166
Analyze service authorization and claims data	48	48	Once	60	2,880	92.92	267,610	133,805
Conduct data sampling	48	48	Once	40	1,920	95.62	183,590	91,795
Review and approve report at the management level	48	48	Once	3	144	110.82	15,958	7,979
Review and approve all reports associated with this requirement at the executive level.	48	48	Once	2	98	204.82	19,663	9,831
Total	48	240	Once	Varies	6,000	Varies	591,154	295,577

b. Ongoing HCBS Access Reporting Requirements: States (§ 441.311(d)(2))

With regard to the on-going burden related to the HCBS access reporting requirements for States, we estimate it would take: 10 hours at $108.68/hr for an administrative services manager to direct information collection, compile information, and produce a report; 20 hours at $92.92/hr for a computer programmer or contractor to analyze service authorization and claims data; 10 hours at $95.62/hr for a statistician to conduct data sampling; 3 hours at $110.82/hr for a general and operations manager to review and approve report; and 2 hours at $204.82/hr for a chief executive to review and approve all reports associated with this requirement. In aggregate, we estimate a burden of 2,160 hours (48 States × 45 hr) at a cost of $222,888 (48 States × [(10 hr × $108.68/hr) + (20 hr × $92.92/hr) + (10 hr × $95.62/hr) + (3 hr × $110.82/hr) + (2 hr × $204.82/hr)]). Taking into account the Federal contribution to Medicaid administration, the estimated State share of this cost would be $111,444 ($222,888 × 0.50) per year.

TABLE 21—SUMMARY OF ONGOING BURDEN FOR STATES FOR THE HCBS ACCESS REPORTING REQUIREMENTS AT § 441.311(d)(2)

Requirement	Number of respondents	Total responses	Frequency	Time per response (hr)	Total time (hr)	Wage ($/hr)	Total cost ($)	State share ($)
Direct information collection, compile information, and produce a report.	48	48	Annually	10	480	108.68	52,166	26,083
Analyze service authorization and claims data	48	48	Annually	20	960	92.92	89,203	44,601
Conduct data sampling	48	48	Annually	10	480	95.62	45,898	22,949
Review and approve report at the management level	48	48	Annually	3	144	110.82	15,958	7,979
Review and approve all reports associated with this requirement at the executive level.	48	48	Annually	2	96	204.82	19,663	9,831
Total	48	240	Annually	Varies	2,160	Varies	222,888	111,444

c. One-Time HCBS Access Reporting Requirements: Managed Care Entities (§ 441.311(d)(2))

With regard to the one-time proposed HCBS access reporting requirements at § 441.311(d)(2) for managed care entities, we estimate it would take: 10 hours at $108.68/hr for an administrative services manager to direct information collection, compile information, and produce a report to the State; 35 hours at $92.92/hr for a computer programmer to analyze service authorization and claims data; 10 hours at $95.62/hr for a statistician to conduct data sampling; and 2 hours at $204.82/hr for a chief executive review and approval. In aggregate, we estimate a one-time burden of 9,177 hours (161 MCEs × 57 hr) at a cost of $918,479 (161 MCEs × [(10 hr × $108.68/hr) + (35 hr × $92.92/hr) + (10 hr × $95.62/hr) + (2 hr × $204.82/hr)]).

TABLE 22—SUMMARY OF ONE-TIME BURDEN FOR MANAGED CARE ENTITIES FOR THE HCBS ACCESS REPORTING REQUIREMENTS AT § 441.311(d)(2)

Requirement	Number of respondents	Total responses	Frequency	Time per response (hr)	Total time (hr)	Wage ($/hr)	Total cost ($)	State share ($)
Direct information collection, compile information, and produce a report to the State.	161	161	Once	10	1,610	108.68	174,975	n/a
Analyze service authorization and claims data	161	161	Once	35	5,635	92.92	523,604	n/a
Conduct data sampling	161	161	Once	10	1,610	95.62	153,948	n/a
Review and approve report	161	161	Once	2	322	204.82	65,952	n/a
Total	161	644	Once	Varies	9,177	Varies	918,479	n/a

d. Ongoing HCBS Access Reporting Requirements: Managed Care Entities (§ 441.311(d)(2))

With regard to the ongoing requirements associated with the annual collection, aggregation, and reporting the HCBS access measures at § 441.311(d)(2), we estimate it would require: 4 hours at $108.68/hr for an administrative services manager to direct information collection, compile information, and produce a report to the State; 20 hours at $92.92/hr for a computer programmer to analyze service authorization and claims data; 8 hours at $95.62/hr for a statistician to conduct data sampling; and 2 hours at $204.82/hr for a chief executive to review and approve. In aggregate, we estimate a burden of 5,474 hours (161 MCEs × 34 hr) at a cost of $558,303 (161 MCEs × [(4 hr × $108.68/hr) + (20 hr × $92.92/hr) + (8 hr × $95.62/hr) + (2 hr × $204.82/hr)]).

TABLE 23—SUMMARY OF ONGOING BURDEN FOR MANAGED CARE ENTITIES (MCES) FOR ADDITIONAL HCBS ACCESS REPORTING REQUIREMENTS AT § 441.311(d)(2)

Requirement	Number of respondents	Total responses	Frequency	Time per response (hr)	Total Trtime (hr)	Wage ($/hr)	Total cost ($)	State share ($)
Direct information collection, compile information, and produce a report to the State.	161	161	Annually	4	644	108.68	69,990	n/a
Analyze service authorization and claims data	161	161	Annually	20	3,220	92.92	299,202	n/a
Conduct data sampling	161	161	Annually	8	1,288	95.62	123,159	n/a
Review and approve report	161	161	Annually	2	322	204.82	65,952	n/a
Total	161	644	Annually	Varies	5,474	Varies	558,303	n/a

8. ICRs Regarding Compliance Reporting (§ 441.311(b))

a. Ongoing Incident Management System Assessment Requirements: States (§ 441.311(b)(1))

Through proposed updates to § 441.311(b)(1), as described in proposed § 441.302(a)(6), this proposed rulemaking aims to standardize CMS expectations and State reporting requirements to ensure that States operate and maintain an incident management system that identifies, reports, triages, investigates, resolves, tracks, and trends critical incidents. The proposed updates were informed by the responses to the HCBS Incident Management Survey (CMS–10692; OMB 0938–1362) recently released to States.

The following proposed changes will be submitted to OMB for their approval after this proposed rule is finalized and our survey instrument has been developed. The survey instrument and burden will be made available to the public for their review under the standard non-rule PRA process which includes the publication of 60- and 30-day **Federal Register** notices. In the meantime, we are setting out our preliminary burden figures (see below) as a means of scoring the impact of this rule's proposed changes. The availability of the survey instrument and more definitive burden estimates will be announced in both **Federal Register** notices. The CMS ID number for that collection of information request is CMS–10692 (OMB control number 0938–1362). We estimate that the proposed reporting requirement at § 441.311(b)(1) would apply to the 48 States (including Washington, DC) that deliver HCBS under sections 1915(c), (i), (j), or (k) authorities. Some States employ the same incident management system across their waivers, while others employ an incident management system specific to each waiver and will require multiple assessments to meet the proposed requirements at § 441.311(b)(1). Based on the responses to the previously referenced survey, we are estimating that on average States will conduct assessments on two incident management systems, totaling approximately 96 unique required assessments (48 State Medicaid programs × 2 incident management system assessments per State). Because the requirements proposed by § 441.311(b)(1) would be required every 24 months, we estimate 48 assessments on an annual basis (96 unique assessments every 2 years). With regard to the ongoing requirements, we estimate that it would take 1.5 hours at $73.84/hr for a social/community service manager to gather information and complete the required assessment; and 0.5 hours at $110.82/hr for a general and operations manager to review and approve the assessment. In aggregate, we estimate an ongoing annual burden of 96 hours (48 States × 2 hr) at a cost of $7,976 (48 States × [(1.5 hr × $73.84/hr) + (0.5 hr × $110.82/hr)]). Taking into account the Federal contribution to Medicaid administration, the estimated State share of this cost would be $3,988 ($7,976 × 0.50) per year.

TABLE 24—SUMMARY OF THE ONGOING BURDEN FOR STATES FOR THE PROPOSED INCIDENT MANAGEMENT SYSTEM ASSESSMENT REQUIREMENTS AT § 441.311(b)(1)

Requirement	Number of respondents	Total responses	Frequency	Time per response (hr)	Total time (hr)	Wage ($/hr)	Total cost ($)	State share ($)
Gather information and complete the required assessment.	48	48	Annually	1.5	72	73.84	5,316	2,658
Review and appprove the assessment	48	48	Annually	0.5	24	110.82	2,660	1,330
Total	48	96	Annually	Varies	96	Varies	7,976	3,988

b. Reporting on Critical Incidents (§ 441.311(b)(2)), Person-Centered Planning (§ 441.311(b)(3)), and Type, Amount, and Cost of Services (§ 441.311(b)(4))

This proposed rulemaking codifies existing compliance reporting requirements on Critical Incidents, Person-Centered Planning, and Type, Amount, and Cost of Services. This includes codifying minimum performance standards at § 441.311(b)(2) and (3) and making updates to critical incident and person-centered planning requirements previously described in 2014 guidance,[260] and moving the existing requirement at § 441.302(h)(1) to report on type, amount, and cost of services to § 441.311(b)(4) as part of the new consolidated compliance reporting section at § 441.311.

This proposed rule would remove our currently approved burden and replace it with the burden associated with the proposed amendments to § 441.311(b)(2) through (4). In aggregate, the change would remove 11,132 hours (253 waivers × 44 hr) and $860,281 (11,132 hr × $77.28/hr for a business operations specialist). Taking into account the Federal contribution to Medicaid administration, the estimated State share of this cost reduction would be minus $430,140 (−$860,281 × 0.50).

TABLE 25—SUMMARY OF THE REMOVAL OF APPROVED ONGOING BURDEN FOR FORM 372(S) AS A RESULT OF THE PROPOSED REQUIREMENTS AT § 441.311(b)(2) THROUGH (b)(4)

Requirement	Number of respondents	Total responses	Frequency	Time per response (hr)	Total time (hr)	Wage ($/hr)	Total cost ($)	State share ($)
Remove currently approved burden under control number 0938–0272 (CMS–372(S)).	48	253	Annually	(44)	(11,132)	77.28	(860,281)	(430,140)
Total	48	253	Annually	(44)	(11,132)	77.28	(860,281)	(430,140)

We expect to revise the Form CMS–372(S) and the form's instructions based on the proposed reporting requirements. The following proposed changes will be submitted to OMB for their approval after this proposed rule is finalized and our survey instrument has been developed. The survey instrument and burden will be made available to the public for their review under the standard non-rule PRA process which includes the publication of 60- and 30-day **Federal Register** notices. In the meantime, we are setting out our preliminary burden figures (see below) as a means of scoring the impact of this rule's proposed changes. The availability of the survey instrument and more definitive burden estimates will be announced in both **Federal Register** notices. The CMS ID number for that collection of information request is CMS 0938–0272 (CMS–372(S)). The proposed consolidated reporting requirements at § 441.311(b)(2) through (4) also assume that 48 States (including Washington, DC) are required to submit the Form CMS–372(S) Report on an annual basis. However, a separate form would no longer be required for each of the 253 approved waivers currently in operation. We estimate a burden of 50 hours for a business operations specialist to draft each Form CMS–372(S) Report submission. The per response increase reflects the proposed increase to the minimum State quality performance level for person-centered planning (at proposed § 441.301(c)(3)(ii)) and critical incident reporting (at proposed § 441.302(a)(6)(ii)) from the 86 percent threshold established by the 2014 guidance to 90 percent in this proposed rule. This slight increase to the minimum performance level will help ensure that States are sufficiently meeting all section 1915(c) waiver requirements but may also increase the evidence that some States may need to submit to document that appropriate remediation is being undertaken to resolve any compliance deficiencies. As a result, we now estimate a total of 50 hours for each Form CMS–372(S) Report submission, comprised of 30 hours of recordkeeping, collection and maintenance of data, and 20 hours of record assembly, programming, and completing the Form CMS–372(S) Report in the required format. We also estimate 3 hours at $110.82/hr for a general and operations manager to review and approve the report to CMS; and 2 hours at $204.82/hr for a chief executive to review and approve all reports associated with this requirement.

[260] *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/3-cmcs-quality-memo-narrative_0_71.pdf.*

TABLE 26—SUMMARY OF THE NEW BURDEN FOR FORM 372(S) ANNUAL REPORT ON HCBS WAIVERS, INCLUSIVE OF UPDATES TO PROPOSED § 441.311(b)(2) THROUGH (4)

Requirement	Number of respondents	Total responses	Frequency	Time per response (hr)	Total time (hr)	Wage ($/hr)	Total cost ($)	State share ($)
Draft Form CMS 372(S) Report submission	48	48	Annually	50	2,400	77.28	185,472	92,736
Review and approve the report at the management level.	48	48	Annually	3	144	110.82	15,958	7,979
Review and approve all reports associated with this requirement at the executive level.	48	48	Annually	2	96	204.82	19,663	9,831
Total	48	144	Annually	Varies	2,640	Varies	221,093	110,546

The net change resulting from reporting requirements on critical incidents, person-centered service planning, and type, amount, and cost of services, proposed by § 441.311(b)(2) through (4) is a burden decrease of 8,492 hours and $319,594 (State share).

9. ICRs Regarding Reporting on the Home and Community-Based Services (HCBS) Quality Measure Set (§ 441.311(c))

a. States

At § 441.311(c), we propose to require that States report every other year on the HCBS Quality Measure Set, which is described in section II.B.8. of the preamble. The proposed reporting requirement would affect the 48 States (including Washington, DC) that deliver HCBS under section 1915(c), 1915(i), 1915(j), and 1915(k) authorities. We estimate both a one-time and ongoing burden to implement these requirements at the State level.

As proposed at § 441.311(c), the data collection would include reporting every other year on all measures in the HCBS Quality Measure Set that are identified by the Secretary.[261] For certain measures which are based on data already collected by us, the State can elect to have the Secretary report on their behalf.

Under proposed § 441.312(c)(1)(iii), States would also be required to establish performance targets, subject to our review and approval, for each of the measures in the HCBS Quality Measure Set that are identified as mandatory for States to report or are identified as measures for which we will report on behalf of States, as well as to describe the quality improvement strategies that they will pursue to achieve the performance targets for those measures.

The following proposed changes will be submitted to OMB for their approval after this proposed rule is finalized and our survey instrument has been developed. The survey instrument and burden will be made available to the public for their review under the standard non-rule PRA process which includes the publication of 60- and 30-day **Federal Register** notices. In the meantime, we are setting out our preliminary burden figures (see below) as a means of scoring the impact of this rule's proposed changes. The availability of the survey instrument and more definitive burden estimates will be announced in both **Federal Register** notices. The CMS ID number for that collection of information request is CMS–10854 (OMB control number 0938–TBD). Since this would be a new collection of information request, the OMB control number has yet to be determined (TBD) but will be issued by OMB upon their approval of the new collection of information request.

i. One Time HCBS Quality Measure Set Requirements: States (§ 441.311(c))

This one-time burden analysis assumes that States must newly adopt one of the ''experience of care'' surveys cited in the HCBS Quality Measure Set: The Consumer Assessment of Healthcare Providers and Systems Home and Community-Based (HCBS CAHPS®) Survey, National Core Indicators®-Intellectual and Developmental Disabilities (NCI®–IDD), National Core Indicators-Aging and Disability (NCI–AD)™, or Personal Outcome Measures (POM)® to fully meet the HCBS Quality Measures Set mandatory requirements. Currently most States use at least one of these surveys; however, States may need to use multiple ''experience of care'' surveys, depending on the populations served by the States' HCBS program and the particular survey instruments that States select to use, to ensure that all major population groups are assessed using the measures in the HCBS Quality Measure Set.

The estimate of one-time burden related to the effort associated with the proposed requirements is for the first year of reporting. It assumes that the Secretary will initially require 25 of the 97 measures currently included in the HCBS Quality Measure Set. The estimate disregards costs associated with the voluntary reporting of measures in the HCBS Quality Measure Set that are not yet mandatory, and voluntary stratification of measures ahead of the phase-in schedule, discussed later in this section.

Additionally, the Secretary will require stratification by demographic characteristics of 25 percent of the measures in the HCBS Quality Measure Set for which the Secretary has specified that reporting should be stratified 3 years after the effective date of these regulations, 50 percent of such measures by 5 years after the effective date of these regulations, and 100 percent of measures by 7 years after the effective date of these regulations. The burden associated with stratifying data is considered in the ongoing cost estimate only. We anticipate that certain costs will decline after the first year of reporting, but that some of the reduction will be supplanted with costs associated with stratifying data.

With regard to the one-time requirements at § 441.311(c) for reporting on the initial mandatory elements of the HCBS Quality Measure Set, we estimate that would take: 540 hours at $108.68/hr for administrative services managers to conduct project planning, administer and oversee survey administration, compile measures, establish and describe performance targets, describe quality improvement strategies, and produce a report; 40 hours at $95.62/hr for a statistician to determine survey sampling methodology; 500 hours at $62.20/hr for survey researcher(s) to be trained in survey administration and to administer an in-person survey; 200 hours at $34.56/hr for a data entry worker to input the data; 60 hours at $92.92/hr for a computer programmer to synthesize the data; and 5 hours at $204.82/hr for a chief executive to verify, certify, and approve the report. In aggregate, we estimate a one-time burden of 64,560 hours (48 States × 1,345 hr) at a cost of $5,141,918 (48 States × [(540 hr × $108.68/hr) + (40 hr × $95.62/hr) + (500 hr × $62.20/hr) + (200 hr × $34.56/hr) + (60 hr × $92.92/hr) + (5 hr × $204.82/

[261] Available at *https://www.medicaid.gov/federal-policy-guidance/downloads/smd22003.pdf.*

hr)]) Taking into account the Federal contribution to Medicaid administration, the estimated State share of this cost would be $2,570,959 ($5,141,918 × 0.50).

TABLE 27—SUMMARY OF THE ONE-TIME BURDEN FOR STATES FOR THE HCBS QUALITY MEASURE SET REQUIREMENTS AT § 441.311(c)

Requirement	Number of respondents	Total responses	Frequency	Time per response (hr)	Total time (hr)	Wage ($/hr)	Total cost ($)	State share ($)
Conduct project planning, administer and oversee survey administration, compile measures, establish and describe performance targets, describe quality improvement strategies, and produce a report.	48	48	Once	5200	25,920	108.68	2,816,986	1,408,493
Determine survey sampling methodology	48	48	Once	40	1,920	95.62	183,590	91,795
Receive training in survey administration and administer an in-person survey.	48	48	Once	500	24,000	62.20	1,492,800	746,400
Input data	48	48	Once	200	9,600	34.56	346,944	173,472
Synthesize data	48	48	Once	60	2,880	92.92	267,610	133,805
Verify, certify, and approve the report	48	48	Once	5	240	204.82	49,157	24,578
Total	48	288	Once	Varies	64,560	Varies	5,141,918	2,570,959

ii. Ongoing HCBS Quality Measure Set Requirements: States (§ 441.311(c))

With regard to the ongoing burden of fulfilling proposed requirements at § 441.311(c), every other year, for reporting on mandatory elements of the HCBS Quality Measure Set, including data stratification by demographic characteristics, we estimate it would take: 520 hours at $108.68/hr for administrative services managers to conduct project planning, administer and oversee survey administration, compile measures, update performance targets and quality improvement strategy description, and produce a report; 80 hours at $95.62/hr for a statistician to determine survey sampling methodology; 1,250 hours at $62.20/hr for survey researcher(s) to be trained in survey administration and to administer an in-person survey; 500 hours at $34.56/hr for a data entry worker to input the data; 100 hours at $92.92/hr for a computer programmer to synthesize the data; and 5 hours at $204.82/hr for a chief executive to verify, certify, and approve a State data submission to us. In aggregate, we estimate an ongoing burden of 117,840 hours (48 States × 2,455 hr) at a cost of $8,136,446 (48 States × [(520 hr × $108.68/hr) + (80 hr × $95.62/hr) + (1,250 hr × $62.20/hr) + (500 hr × $34.56/hr) + (100 hr × $92.92/hr) + (5 hr × $204.82/hr)]). Given that reporting is every other year, the annual burden would be 58,920 hours (117,840 hr/2 years) and $4,068,223 ($8,136,446/2 years). Taking into account the Federal contribution to Medicaid administration, the estimated State share of this cost would be $2,034,112 ($4,068,223 × 0.50).

TABLE 28—SUMMARY OF THE ONGOING BURDEN FOR STATES FOR THE HCBS QUALITY MEASURE SET REQUIREMENTS AT § 441.311(c)

Requirement	Number of respondents	Total responses	Frequency	Time per response (hr)	Total time (hr)	Wage ($/hr)	Total cost ($)	State share ($)
Conduct project planning, administer and oversee survey administration, compile measures, update performance targets and quality improvement strategy description, and produce a report.	48	48	Every other year.	520	24,960	108.68	2,712,653	1,356,326
Determine survey sampling methodology	48	48	Every other year.	80	3,840	95.62	367,181	183,590
Receive training in survey administration and administer an in-person survey.	48	48	Every other year.	1,250	60,000	62.20	3,732,000	1,866,000
Input data	48	48	Every other year.	500	24,000	34.56	867,360	433,680
Synthesize data	48	48	Every other year.	100	4,800	92.92	446,016	223,008
Verify, certify, and approve the report	48	48	Every other year.	5	240	204.82	49,157	24,578
Total	48	576	Every other year.	Varies	235,680	Varies	8,174,366	4,087,183

b. HCBS Quality Measure Set Requirements: Beneficiary Experience Survey (§ 441.311(c))

State adoption of existing beneficiary experience surveys, contained in the HCBS Quality Measure Set, to fulfill the proposed mandatory reporting requirements would include a burden on beneficiaries. As proposed in the previous section, a State must newly adopt one of the ''experience of care'' surveys cited in the HCBS Quality Measure Set: The Consumer Assessment of Healthcare Providers and Systems Home and Community Based (HCBS CAHPS®) Survey, National Core Indicators® Intellectual and Developmental Disabilities (NCI® IDD), National Core Indicators Aging and Disability (NCI AD)™, or Personal Outcome Measures (POM)®.

With regard to beneficiary burden, we estimate it would take 45 minutes (0.75 hr) at $20.71/hr for a Medicaid beneficiary to complete a survey every other year that will be used to derive one or more of the measures in the

HCBS Quality Measure Set. At 1,000 beneficiaries/State and 48 States, we estimate an aggregate burden of 36,000 hours (1,000 beneficiary responses/State × 48 States × 0.75 hr/survey) at a cost of $ 745,560 (36,000 hr × $20.71/hr). Given that survey is every other year, the annual burden would be 18,000 hours (36,000 hr/2 years) and $372,780 ($745,560/2 years).

TABLE 29—SUMMARY OF BENEFICIARY EXPERIENCE SURVEY BURDEN FOR THE HCBS QUALITY MEASURE SET REQUIREMENTS AT § 441.311(c)

Requirement	Number of respondents	Total responses	Frequency	Time per response (hr)	Total time (hr)	Wage ($/hr)	Total cost ($)	State share ($)
Complete beneficiary experience survey	48,000	24,000	Annually	0.75	18,000	20.71	372,780	n/a
Total	48,000	48,000	Every other Year.	0.75	18,000	20.71	745,560	n/a

10. ICRs Regarding Website Transparency (§ 441.313; Cross-Referenced to §§ 441.486, 441.595, and 441.750, as Well as Part 438)

The proposed rule adds a new section, at § 441.313, titled, ''website Transparency, to promote public transparency related to the administration of Medicaid-covered HCBS under section 1915(c) of the Act.'' Specifically, at § 441.313(a), we propose to require States to operate a website that meets the availability and accessibility requirements at § 435.905(b) and that provides the data and information that States are required to report under the newly proposed reporting section at § 441.311. At § 441.313(a)(1), we propose to require that the data and information that States are required to report under § 441.311 be provided on one website, either directly or by linking to the web pages of the managed care organization, prepaid ambulatory health plan, prepaid inpatient health plan, or primary care case management entity that is authorized to provide services. At § 441.313(a)(2), we propose to require that the web page include clear and easy to understand labels on documents and links.

At § 441.313(a)(3), we propose to require that States verify the accurate function of the website and the timeliness of the information and links at least quarterly. At § 441.313(c), we propose to apply these requirements to services delivered under FFS or managed care delivery systems. At § 441.313(a)(4), we propose to require that States explain that assistance in accessing the required information on the website is available at no cost and include information on the availability of oral interpretation in all languages and written translation available in each prevalent non-English language, how to request auxiliary aids and services, and a toll-free and TTY/TDY telephone number. Further, we propose to apply the proposed requirements at § 441.313 to sections 1915(j), (k), and (i) State plan services by cross-referencing at §§ 441.486, 441.595, and 441.750, respectively.

The following proposed changes will be submitted to OMB for their approval after this proposed rule is finalized and our survey instrument has been developed. The survey instrument and burden will be made available to the public for their review under the standard non-rule PRA process which includes the publication of 60- and 30-day **Federal Register** notices. In the meantime, we are setting out our preliminary burden figures (see below) as a means of scoring the impact of this rule's proposed changes. The availability of the survey instrument and more definitive burden estimates will be announced in both **Federal Register** notices. The CMS ID number for that collection of information request is CMS–10854 (OMB control number 0938–TBD). Since this would be a new collection of information request, the OMB control number has yet to be determined (TBD) but will be issued by OMB upon their approval of the new collection of information request.

The burden associated with the website transparency requirements proposed at § 441.313 will affect the 48 States (including Washington, DC) that deliver HCBS under sections 1915(c), (i), (j), or (k) authorities. We are requiring at § 441.313(c) to apply the website transparency requirements to services delivered under FFS or managed care delivery systems, and we propose to provide States with the option to meet the requirements at § 441.313 by linking to the web pages of the managed care organization, prepaid ambulatory health plan, prepaid inpatient health plan, or primary care case management entity that are authorized to provide services. However, we are not requiring managed care entities to report the data and information required under § 441.311 on their website. As such, we estimate that there is no additional burden for managed care entities associated with the requirements to link to the web pages of the managed care organization, prepaid ambulatory health plan, prepaid inpatient health plan, or primary care case management entity that are authorized to provide services for § 441.313. Further, the burden associated with the requirements for managed care entities to report the data and information required under § 441.311 is estimated in the ICRs Regarding Compliance Reporting (§ 441.311(b)).

If a State opts to comply with the requirements at § 441.313 by linking to the web pages of the managed care organization, prepaid ambulatory health plan, prepaid inpatient health plan, or primary care case management entity that are authorized to provide services, the State would incur a burden. However, such burden would be less than the burden associated with posting the information required under § 441.311 on their own website. We are unable to estimate the number of States that may opt to comply with the requirements at § 441.313 by linking to the web pages of the managed care organization, prepaid ambulatory health plan, prepaid inpatient health plan, or primary care case management entity that are authorized to provide services. As a result, we do not take into account the option in our burden estimate and conservatively assume that all States subject to the requirements at § 441.313 by posting the information required under § 441.311 on their own website.

We estimate both a one-time and ongoing burden to implement these requirements at the State level.

a. One Time Website Transparency Requirements: States (§ 441.313)

The burden associated with the website transparency requirements proposed at § 441.313 will affect the 48 States (including Washington, DC) that deliver HCBS under sections 1915(c), (i), (j), or (k) authorities. We estimate

both a one-time and ongoing burden to implement these requirements at the State level. In developing our burden estimate, we assumed that States would provide the data and information that States are required to report under newly proposed § 441.311 through an existing website, rather than develop a new website to meet this requirement.

With regard to the one-time burden, based on the website transparency requirements, we estimate it would take: 24 hours at $108.68/hr for an administrative services manager to determine the content of the website; 80 hours at $92.92/hr for a computer programmer or contractor to develop the website; 3 hours at $110.82/hr for a general and operations manager to review and approve the website; and 2 hours at $204.82/hr for a chief executive to review and approve the website. In aggregate, we estimate a one-time burden of 5,232 hours (48 States × 109 hr) at a cost of $517,633 (48 States × [(24 hr × $108.68/hr) + (80 hr × $92.92/hr) + (3 hr × $110.82/hr) + (2 hr × $204.82/hr)]). Taking into account the Federal contribution to Medicaid administration, the estimated State share of this cost would be $258,817 ($517,633 × 0.50) per year.

TABLE 30—SUMMARY OF THE ONE-TIME BURDEN FOR STATES FOR THE WEBSITE TRANSPARENCY REQUIREMENTS AT § 441.313

Requirement	Number of respondents	Total responses	Frequency	Time per response (hr)	Total time (hr)	Wage ($/hr)	Total cost ($)	State share ($)/year
Determine content of website	48	48	Once	24	1,152	108.68	125,199	62,600
Develop website	48	48	Once	80	3,840	92.92	356,813	178,406
Review and approve the website at the management level.	48	48	Once	3	144	110.82	15,958	7,979
Review and approve the website at the executive level.	48	48	Once	2	96	204.82	19,663	9,831
Total	48	192	Once	Varies	5,232	Varies	517,633	258,816

b. Ongoing Website Transparency Requirements: States (§ 441.313)

With regard to the State on-going burden related to the website transparency requirement, per quarter we estimate it would take: 8 hours at $108.68/hr for an administrative services manager to provide updated data and information for posting and to verify the accuracy of the website; 20 hours at $92.92/hr for a computer programmer or contractor to update the website; 3 hours at $110.82/hr for a general and operations manager to review and approve the website; and 2 hours at $204.82/hr for a chief executive to review and approve the website. In aggregate, we estimate an ongoing annual burden of 6,336 hours (33 hr × 48 States × 4 quarters) at a cost of $666,228 (48 States × 4 quarters × [(8 hr × $108.68/hr) + (20 hr × $92.92/hr) + (3 hr × $110.82/hr) + (2 hr × $204.82/hr)]). Taking into account the Federal contribution to Medicaid administration, the estimated State share of this cost would be $333,114 ($666,228 × 0.50) per year.

TABLE 31—SUMMARY OF THE ONGOING BURDEN FOR STATES FOR THE WEBSITE TRANSPARENCY REQUIREMENTS AT § 441.313

Requirement	Number of respondents	Total responses	Frequency	Time per response (hr)	Total time (hr)	Wage ($/hr)	Total cost ($)	State share ($)
Provide updated data and information for posting and verify the accuracy of the website.	48	192	Quarterly	8	1,536	108.68	166,932	83,466
Update website	48	192	Quarterly	20	3,840	92.92	356,813	178,406
Review and approve website at the management level.	48	192	Quarterly	3	576	110.82	63,832	31,916
Review and approve website at the executive level	48	192	Quarterly	2	384	204.82	78,651	39,325
Total	48	768	Quarterly	Varies	6,336	Varies	666,228	333,114

11. ICRs Regarding Payment Rate Transparency (§ 447.203)

The following proposed changes will be submitted to OMB for review under control number 0938–1134 (CMS–10391).

This proposed rule would update documentation requirements in § 447.203. To develop the burden estimates associated with these changes, we account for the removal of existing information collection requirements in current § 447.203(b), and the introduction of new requirements at proposed 447.203(b) and (c). As described later in this section, we estimate the impact of the proposed revisions to § 447.203 would result in a net burden reduction. We do not anticipate any additional information collection burden from the conforming edits proposed in § 447.204, as the conforming edits merely alter the items submitted as part of an existing submission requirement, and the burden of producing those items is reflected in the estimates related to § 447.203, including instances where we propose to move language from § 447.204 to § 447.203.

a. Removal of Access Monitoring Review Plan: States (§ 447.203(b)(1) Through (8))

The burden reduction associated with the removal of § 447.203(b)(1) through (8) consists of the removal of time and effort necessary to develop and publish AMRPs, perform ongoing monitoring, and corrective action plans.

Current § 447.203(b)(1) and (2) describes the minimum factors that States must consider when developing an AMRP. Specifically, the AMRP must include: input from both Medicaid beneficiaries and Medicaid providers, an analysis of Medicaid payment data,

and a description of the specific measures the State will use to analyze access to care. Current § 447.203(b)(3) requires that States include aggregate percentage comparisons of Medicaid payment rates to other public (including, as practical, Medicaid managed care rates or Medicare rates) and private health coverage rates within geographic areas of the State. Current § 447.203(b)(4) describes the minimum content that must be included in the monitoring plan. States are required to describe: measures the State uses to analyze access to care issues, how the measures relate to the overarching framework, access issues that are discovered as a result of the review, and the State Medicaid agency's recommendations on the sufficiency of access to care based on the review. Current § 447.203(b)(5) describes the timeframe for States to develop the AMRP and complete the data review for the following categories of services: primary care, physician specialist services, behavioral health, pre- and post-natal obstetric services including labor and delivery, home health, any services for which the State has submitted a SPA to reduce or restructure provider payments which changes could result in diminished access, and additional services as determined necessary by the State or CMS based on complaints or as selected by the State. While the initial AMRPs have been completed, the plan must be updated at least every 3 years, but no later than October 1 of the update year. Current § 447.203(b)(6)(i) requires that any time a State submits a SPA to reduce provider payment rates or restructure provider payments in a way that could diminish access, the State must submit an AMRP associated with the services affected by the payment rate reduction or payment restructuring that has been completed within the prior 12 months.

Section 447.203(b)(6)(ii) requires that States have procedures within the AMRP to monitor continued access after implementation of a SPA that reduces or restructures payment rates. The monitoring procedures must be in place for a period of at least 3 years following the effective date of the SPA. However, States were already required to submit information on compliance with section 1902(a)(30)(A) of the Act prior to the 2015 final rule with comment period. Therefore, removal of § 447.203(b)(6)(ii) will result in a burden reduction.

Finally, we note that this section references the proposed rescission of the current AMRP process contained in § 447.203(b)(1) to § 447.203(b)(8). However, the requirements of paragraph (b)(7) are reflected in proposed paragraph (b)(4), and the requirements of paragraph (b)(8) are reflected in proposed paragraph (c)(5). As such, there is not a change in impact related to the rescission of these specific aspects of the AMRP process, should our proposals be finalized, and are not reflected in this section.

In our currently approved information collection request, we estimated that the requirements to develop and make the AMRPs publicly available for the specific categories of Medicaid services will affect each of the 50 State Medicaid programs and the District of Columbia (51 total respondents). We will use that estimate here as well, although we note that the figure does not represent solely those States, but may include territories not exempt under waivers, and exclude States not subject due to reliance entirely on managed care (with no beneficiaries receiving any benefits through FFS delivery), and these figures fluctuate. As such, for consistency, we will maintain the estimate of 51 respondents subject to this proposed rule. We further note that the one-time cost estimates have already been met for AMRPs, and the ongoing monitoring requirements are every 3 years. As such, the estimates in this section for burden reduction are for 17 respondents, one-third of the 51 affected respondents, to provide an annual estimate of the reduced burden.

We estimated that every 3 years, it would take: 80 hours at $54.26/hr for a research analyst to gather data, 80 hours at $100.80/hr for an information analyst to analyze the data, 100 hours at $96.66/hr for a management analyst to develop the content of the AMRP, 40 hours at $77.28/hr for a business operations specialist to publish the AMRP, and 10 hours at $110.82/hr for managerial staff to review and approve the AMRP. In aggregate, and as shown in Table 35, we estimate the reduced annual burden of the rescission of the ongoing AMRP requirements would be minus 5,270 hours (17 States × 310 hr) and minus $446,593 (17 States × [(80 hr × $54.26/hr) + (80 hr × $100.80/hr) + (100 hr × $96.66/hr) + (40 hr × $77.28/hr) + (10 hr × $110.82/hr)]). Taking into account the 50 percent Federal contribution for administrative expenditures, the rescission represents a saving to States of minus $223,297 ($446,593 × 0.50).

The currently approved ongoing burden associated with the requirements under § 447.203(b)(6)(ii) is the time and effort it takes each of the State Medicaid programs to monitor continued access following the implementation of a SPA that reduces or restructures payment rates. In our currently approved information collection request, we estimate that in each SPA submission cycle, 22 States would submit SPAs to implement rate changes or restructure provider payments based on the number of submissions received in FY 2010. Using our currently approved burden estimates we estimate a reduction of: 40 hours at $96.66/hr for a management analyst to develop the monitoring procedures, 24 hours at $96.66/hr for a management analyst to periodically review the monitoring results, and 3 hours at $110.82/hr for a general and operations manager to review and approve the monitoring procedures. In aggregate, we estimate burden reduction of minus 1,474 hours (22 Respondents × 67 hr) and minus $143,411 (22 States × [(40 hr × $96.66/hr) + (24 hr × $96.66/hr) + (3 hr × $110.82/hr)]). Accounting for the 50 percent Federal administrative match, the total State cost reduction is adjusted to $71,706 ($143,411 × 0.50).

TABLE 32—SUMMARY OF ANNUAL BURDEN REDUCTION ASSOCIATED WITH REMOVAL OF ACCESS MONITORING REVIEW PLAN REQUIREMENTS

[§ 447.203(b)(1) through (8)]

Requirement	Number of respondents	Total responses	Frequency	Time per response (hr)	Total time (hr)	Wage ($/hr)	Total cost ($)	State share ($)
Rescission of § 447.203(b)(1) through (b)(6)(i).	17	17	Triennial (figures are annualized).	(310)	(5,270)	Varies	(446,593)	(223,297)
Rescission of § 447.203(b)(6)(ii)	22	22	Varies (figures are annualized).	(67)	(1,474)	Varies	(143,411)	(71,706)
Total	39	39	Varies	Varies	(6,744)	Varies	(590,004)	(295,003)

b. Payment Rate Transparency (§ 447.203(b)(1) Through (5))

We are proposing to replace the AMRP requirements with a new payment rate transparency requirement at § 447.203(b)(1) through (5). The burden associated with the proposed payment rate transparency requirement consists of the time and effort to develop and publish a Medicaid FFS provider payment rate information and analysis.

Proposed § 447.203(b)(1) specifies that all FFS Medicaid payments must be published on a publicly accessible website that is maintained by the State. Proposed § 447.203(b)(2) specifies the service types that are subject to the proposed payment analysis, which include: primary care services; obstetrical and gynecological services; outpatient behavioral health services; and certain HCBS. Proposed § 447.203(b)(3) describes the required components of the payment analysis to include, for services in proposed § 447.203(b)(2)(i) through (iii), a percentage comparison of Medicaid payment rates to the most recently published Medicare payment rates effective for the time period for each of the service categories specified in paragraph (b)(2). We also specify that the payment analysis must include percentage comparisons made on the basis of Medicaid base payments. For HCBS described in proposed § 447.203(b)(2)(iv), we propose to require a State-based comparison of average hourly payment rates. Proposed § 447.203(b)(4) details the payment analysis timeframe, with the first payment analysis required to be published by the State agency by January 1, 2026, and updated every 2 years by January 1. Proposed § 447.203(b)(5) describes our mechanism for ensuring compliance and that we may take compliance action against a State that fails to meet the requirements of the payment rate transparency, comparative payment rate analysis, and payment rate disclosure provisions in preceding proposed paragraphs in § 447.203(b) including a deferral or disallowance of certain of the State's administrative expenditures following the procedures described at part 430, subpart C.

We estimate that the proposed requirements to complete and make publicly available all FFS Medicaid payments and the comparative payment rate analysis and payment rate disclosures under § 447.203(b)(1) through (5) for the specific categories of Medicaid services would affect 51 total respondents, based on the estimate in the prior section regarding the variation in States and territories subject to these requirements. We propose to require applicable States and territories to publish all FFS Medicaid payments initially by January 1, 2026, while future updates to the payment rate transparency information would depend on when a State submits a SPA updating provider payments and we have approved that SPA. As such, we assume 51 one-time respondents for the initial rates publication. Because the comparative payment rate analysis and payment rate disclosure requirement is biennial, we assume 26 annual respondents in any given year, and we will assume this figure would account for the updates made following a rate reduction SPA or rate restructuring SPA approval. The proposed comparative payment rate analysis would be similar to the current requirement at § 447.203(b)(3) that requires AMRPs to include a comparative payment rate analysis against public or private payers. The inclusion of levels of provider payment available from other payers is also one of five required components of the AMRP as specified by current § 447.203(b)(1). To estimate the burden associated with our proposed comparative payment rate analysis and payment rate disclosure provisions, we assume this work would require approximately 25 percent of the ongoing labor hour burden that we previously estimated to be required by the entire AMRP, to account for the service categories subject to the comparative payment rate analysis and payment rate disclosure in proposed § 447.203(b)(2) as decreased from the full body of AMRP service requirements. We invite comment on these estimated proportions.

With regard to the developing and publishing the payment rate transparency data at proposed § 447.203(b)(1), we estimate a low one-time and ongoing burden due to the data being available, and the main work required to meet the proposed requirement would be formatting and web publication. As such, we estimate it would initially take: 5 hours at $54.26/hr for a research assistant to gather the data, 5 hours at $77.28/hr for a business operations specialist to publish, and 1 hour at $110.82/hr for a general and operations manager to review and approve the rate transparency data. In aggregate, we estimate a one-time burden of 561 hours (51 Respondents × 11 hr) at a cost of $39,195 (51 Respondents × [(5 hr × $54.26/hr) + (5 hr × $77.28/hr) + (1 hr × $110.82/hr)]). Taking into account the Federal administrative match of 50 percent, the requirement will cost States $19,597 ($39,195 × 0.50).

For the ongoing cost to update assumed to take place every 2 years (although we are proposing that updates would only be required as necessary to keep the data current, with any update made no later than 1 month following the date of CMS approval of the SPA or similar amendment providing for the change), we estimate an annualized impact on 26 respondents (51 respondents every 2 years) of: 2 hours at $54.26/hr for a research assistant to update the data, 1 hour at $77.28/hr for a business operations specialist to publish the updates, and 1 hour at $110.82/hr for a general and operations manager to review and approve the rate transparency update. In aggregate, we estimate an annualized burden of 104 hours (26 Respondents × 4 hr) at a cost of $7,712 (26 Respondents × [(2 hr × $54.26/hr) + (1 hr × $77.28/hr) + (1 hr × $110.82/hr)]). Taking into account the Federal administrative match of 50 percent, the requirement will cost States $3,856 ($7,712 × 0.50).

With regard to developing and publishing the comparative payment rate analysis and payment rate disclosure at proposed § 447.203(b)(2), we estimate it would take: 20 hours at $54.26/hr for a research assistant to gather the data, 20 hours at $100.80/hr for an information analyst to analyze the data, 25 hours at $96.66/hr for a management analyst to design the comparative payment rate analysis, 11 hours at $77.28/hr for a business operations specialist to publish the comparative payment rate analysis and payment rate disclosure, and 3 hours at $110.82/hr for a general and operations manager to review and approve the comparative payment rate analysis and payment rate disclosure. In aggregate, we estimate an annualized burden, based on 51 respondents every 2 years, of 2,054 (26 Respondents × 79 hr) at a cost of $174,206 (26 States × [(20 hr × $54.26/hr) + (20 hr × $100.80/hr) + (25 hr × $96.66/hr) + (11 hr × $77.28/hr) + (3 hr × $110.82/hr)]). We then adjust the total cost to $87,103 ($174,206 × 0.50) to account for the 50 percent Federal administrative match. We have summarized the total burdens in Table 33.

TABLE 33—SUMMARY OF BURDEN ASSOCIATED WITH PROPOSED PAYMENT RATE TRANSPARENCY REQUIREMENTS
[Proposed § 447.203(b)(1) through (5)]

Requirement	Number of respondents	Total responses	Frequency	Time per response (hr)	Total time (hr)	Wage ($/hr)	Total cost ($)	State share ($)
§ 447.203(b)(1) Rate Transparency	51	51	One-time	11	561	Varies	39,195	19,597
§ 447.203(b)(1) Rate Transparency	26	26	Biannual (figures are annualized).	4	104	Varies	7,712	3,856
§ 447.203(b)(2) and (3) Rate Analysis	26	26	Biannual (figures are annualized).	79	2,054	Varies	174,206	87,103
Total	51	103	Varies	Varies	2,719	Varies	221,113	110,557

c. Medicaid Payment Rate Interested Parties' Advisory Group (§ 447.203(b)(6))

The burden associated with the recordkeeping requirements proposed § 447.203(b)(6), specifically the online publication associated with the reporting and recommendations of the interested parties advisory group, would consist of the time and effort for all 50 States and the District of Columbia to:

- Appoint members to the interested parties' advisory group.
- Provide the group members with materials necessary to:

++ Review current and proposed rates.

++ Hold meetings.

++ Provide a written recommendation to the State.

- Publish the group's recommendations to a website maintained by the single State agency.

The proposed requirements would require varying levels of efforts for States depending on the existence of groups that may fulfil the requirements of this group. However, because it is unknown how many States would be able to leverage existing practices, and to what extent, this estimate does not account for those differences.

We estimate that it would take 40 hours at $131.34/hr for a human resources manager to recruit interested parties and provide the necessary materials for the group to meet. In aggregate, we estimate a one-time burden of 2,040 hours (51 Respondents × 40 hr) at a cost of $267,934 (2,040 hr × $131.34/hr). Taking into account the 50 percent administrative match, the total one-time State cost is estimated to be $133,967 ($267,934 × 0.50).

We believe the ongoing work to maintain the needs of this group would take a human resources manager 5 hours at $131.34/hr annually. Additionally, we estimate it would take 4 hours for the biennial requirement, or 2 hours annually at $110.82/hr for an operations manager to review and prepare the recommendation for publication. In aggregate, we estimate an ongoing annualized burden of 182 hours (26 Respondents × 7 hr) at a cost of $22,837 (26 Respondents × [(5 hr × $131.34/hr) + (2 hr × $110.82/hr)]). Accounting for the 50 percent Federal administrative match, the total State cost is adjusted to $11,418 ($22,837 × 0.50). We have summarized the total burdens in Table 34.

TABLE 34—SUMMARY OF BURDEN FOR MEDICAID PAYMENT RATE INTERESTED PARTIES' ADVISORY GROUP

Requirement	Number of respondents	Total responses	Frequency	Time per response (hr)	Total time (hr)	Wage ($/hr)	Total cost ($)	State share ($)
§ 447.203(b)(6) (Establish advisory group)	51	51	One-time	40	2,040	131.34	267,934	133,967
§ 447.203(b)(6) (Support and publish recommendation).	51	26	Biennial (figures are annualized).	7	182	Varies	22,837	11,418
Total	51	77	Varies	Varies	2,222	Varies	290,771	145,386

d. State Analysis Procedures for Payment Rate Reductions or Payment Restructuring (§ 447.203(c))

The proposed State analysis procedures for payment rate reductions and payment restructurings at § 447.203(c)(1) through (3) within this proposed rule effectively would replace payment rate reduction or payment restructuring procedures in current § 447.203(b)(6). As noted, the burden reduction associated with the removal of § 447.203(b)(6)(i) has already been accounted for in the recurring burden reduction estimate shown in Table 36 for the removal of the AMRP requirements, and the burden reduction associated with the removal of monitoring requirements at current § 447.203(b)(6)(ii) has been accounted for in Table 37. Our proposed replacement procedures at § 447.203(c)(1) through (3) would introduce new requirements as follows.

i. Initial State Analysis for Rate Reduction or Restructuring (§ 447.203(c)(1))

Proposed § 447.203(c)(1) would require that for States proposing to reduce or restructure provider payment rates, the State must document that their program and proposal meet all of the following requirements: (i) Medicaid rates in the aggregate for the service category following the proposed reduction(s) or restructurings are at or above 80 percent of most recent Medicare prices or rates for the same or a comparable set of services; (ii) Proposed reductions or restructurings result in no more than a 4 percent reduction of overall spending for each service category affected by a proposed reduction or restructuring in a single State fiscal year; and (iii) Public process yields no significant access concerns or the State can reasonably respond to concerns.

Proposed § 447.203(c)(1) would apply to all States that submit a SPA that proposes to reduce or restructure provider payment rates. We limited our estimates for new information collection burden to the requirements at § 447.203(c)(1)(i) through (ii). Our estimates assume States will build off the comparative analysis required by proposed § 447.203(b)(2) through (4) to complete the requirements proposed by § 447.203(c)(1)(i), which will limit the additional information collection burden. We also assume no additional

information collection burden posed by the public review process required by proposed § 447.203(c)(1)(iii), as this burden is encapsulated by current public process requirements at § 447.204.

The requirements of proposed § 447.203(c) apply to all 50 States and the District of Columbia, as well as US territories. We will again use the estimate of 50 utilized in preceding sections, which we note may include territories not exempt under waivers, and exclude States not subject due to reliance entirely on managed care (with no beneficiaries receiving any benefits through FFS delivery), and these figures fluctuate. As such, for consistency, we will maintain the estimate of 51 respondents subject to this proposed rule. While we cannot predict how many States will submit a rate reduction SPA or rate restructuring SPA in a given year, the figures from 2019 provide the best recent estimate, as the years during the COVID pandemic do not reflect typical behavior. In 2019, we approved rate reduction and rate restructuring SPAs from 17 unique State respondents. Therefore, to estimate the annualized number of respondents subject to this information collection burden, we will utilize a count of 17 respondents.

With regard to the burden associated with completing the required State analysis for proposed rate reductions or restructurings at § 447.203(c)(1), we estimate that it would take: 20 hours at $96.66/hr for a management analyst to structure the rate reduction or restructuring analysis, 25 hours at $100.80/hr for an information analyst to complete the rate reduction or restructuring analysis, and 3 hours at $110.82/hr for a general and operations manager to review and approve the rate reduction or restructuring analysis. In aggregate, we estimate a burden of 816 hours (17 States × 48 hr) at a cost of $81,356 (17 States × [(20 hr × $96.66/hr) + (25 hr × $100.80/hr) + (3 hr × $110.82/hr)]). Accounting for the 50 percent Federal administrative reimbursement, this adjusts to a total State cost of $40,678 ($81,356 × 0.50). We are soliciting public comment on these estimates as well as relevant State data to further refine the burden and time estimates.

TABLE 35—BURDEN ASSOCIATED WITH TIER 1 STATE ANALYSIS PROCEDURES FOR RATE REDUCTIONS OR RESTRUCTURINGS

[Proposed § 447.203(c)(1)]

Requirement	Number of respondents	Total responses	Frequency	Time per response (hr)	Total time (hr)	Wage ($/hr)	Total cost ($)	State share ($)
§ 447.203(c)(1)	17	17	Annual	48	816	Varies	81,356	40,678
Total	17	17	Annual	48	816	Varies	81,356	40,678

ii. Additional State Rate Analysis (§ 447.203(c)(2))

Proposed § 447.203(c)(2) describes requirements for payment proposals that do not meet the requirements in paragraph (c)(1), requiring the State to provide the nature of the change and policy purpose, the rates compared to Medicare and/or other payers pre- and post-reduction or restructuring, counts/trends of actively participating providers by geographic areas, counts of FFS Medicaid beneficiaries residing in geographic areas/characteristics of the beneficiary population, service utilization trends, access to care complaints from beneficiaries, providers, and other interested parties, and the State's response to access to care complaints.

The information collection requirements proposed at § 447.203(c)(2) applies to those States that submit rate reduction or restructuring SPAs that do not meet one or more of the criteria proposed by § 447.203(c)(1). Using 2019 rate reduction and restructuring SPA figures, we estimate that 17 States will submit rate reduction or restructuring SPAs per year. Then, a 2019 Urban Institute analysis [262] indicates that 22 States (or 43 percent) have rates that meet the 80 percent fee ratio threshold proposed in § 447.203(c)(1)(i) across all services. Although our proposal does not include all services, using this all services amount is our best method to estimate how many States may fall below on any given service without knowing which. Because we cannot predict the amount a State may propose to reduce, once or cumulatively for the SFY, and because failure of any one criterion in § 447.203(c)(1) would require additional analysis under § 447.203(c)(2), we will use that percentage to assess how many States would need to perform additional analysis. Using this percentage, we estimate that 7 (43 percent × 17) of the estimated 17 unique State respondents may submit rate reduction or restructuring SPAs meet that criteria for the streamlined analysis process under proposed § 447.203(c)(1). Therefore, we assume that 10 out of 17 unique annual State respondents who submit rate reduction or restructuring SPAs would also need to perform the additional analysis § 447.203(c)(2).

The required components of the review and analysis in proposed § 447.203(c)(2) are similar to the AMRP requirements found at current § 447.203(b)(1). However, due to the anticipated development and release of a template for States to facilitate completion of the required analysis, as well as the lack of a requirement to publish the analysis, we anticipate a moderately reduced burden associated with proposed § 447.203(c)(2) when compared to the burden estimated for the AMRPs.

With regard to our proposed requirements, we estimate that it would take: 64 hours at $54.26/hr for a social science research assistant to gather data, 64 hours at $100.80/hr for a computer and information analyst to analyze data, 80 hours at $96.66/hr for a management analyst to structure the analyses and organize output, and 8 hours at $110.82/hr for a general and operations manager to review and approve the rate reduction or restructuring analysis. In aggregate, we estimate a burden of 2,160 hours (10 States × 216 hr) at a cost of $185,432 (10 States × [(64 hr × $54.26/hr) + (64 hr × $100.80/hr) + (80 hr × $96.66/hr) + (8 hr × $110.82/hr)]). The total cost is adjusted down to $92,716 ($185,432 × 0.50) for States after accounting for the 50 percent Federal administrative match. We are soliciting public comment on these estimates as well as relevant State data to further refine the burden and time estimates.

We do not assume any additional information collection imposed by the

[262] Zuckerman, S. et al. ''Medicaid Physician Fees Remained Substantially Below Fees Paid By Medicare in 2019.'', *Health Affairs,* Volume 40, Number 2, February 2021, p. 343–348, *https://www.healthaffairs.org/doi/10.1377/hlthaff.2020.00611,* accessed August 31, 2022.

compliance procedures proposed by § 447.203(c)(3).

Table 41 shows our estimated combined annualized burden for § 447.203(c), which includes 17 States for § 447.203(c)(1) and 10 States for § 447.203(c)(2). In total, we estimate an annualized burden of 4,992 (1,104 hours + 2,160 hours) hours at a cost of $443,848 ($110,070 + $74,172). This cost to States is then adjusted to $221,924 after the 50 percent Federal administrative reimbursement is applied.

TABLE 36—SUMMARY OF BURDEN ASSOCIATED WITH STATE ANALYSIS PROCEDURES FOR RATE REDUCTIONS OR RESTRUCTURINGS

[Proposed § 447.203(c)]

Requirement	Number of respondents	Total responses	Frequency	Time per response (hr)	Total time (hr)	Wage ($/hr)	Total cost ($)	State share ($)
§ 447.203(c)(1) (initial State analysis)	17	17	Annual	48	816	Varies	81,356	40,678
§ 447.203(c)(2) (additional State analysis)	12	12	Annual	216	2,160	Varies	185,432	92,716
Total	17	29	Annual	264	2,976	Varies	266,788	133,394

D. Proposed Burden Estimate Summary

TABLE 37—SUMMARY OF PROPOSED ANNUAL BURDEN ESTIMATES

Regulation section(s) in Title 42 of the CFR	OMB Control Number (CMS ID Number)	Number of respondents	Number of responses	Time per response (hr)	Total time (hr)	Hourly labor Rate ($/hr)	Total labor cost ($)	State share ($)	Total beneficiary cost ($)
§ 431.12 (Table 2) (MACs & BAGs)	OMB 0938–TBD (CMS–10845).	51 States.	153	Varies ...	17,340	Varies ...	1,581,591	790,795	n/a
§ 441.301(c)(3)—One-time burden to States (Table 3) (Person-Centered Service Plans).	OMB 0938–TBD (CMS–10854).	48 States.	144	Varies ...	528	Varies ...	62,203	31,102	n/a
§ 441.301(c)(3)—One-time burden to Managed Care Entities (Table 4) (Person-Centered Service Plans).	OMB 0938–TBD (CMS–10854).	161 MCEs.	322	Varies ...	966	Varies ...	120,463	n/a	n/a
§ 441.301(c)(7)—One-time burden to States (Table 5) (Grievance Systems).	OMB 0938–TBD (CMS–10854).	48 States.	240	Varies ...	24,960	Varies ...	2,481,926	1,240,964	n/a
§ 441.301(c)(7)—Ongoing burden to States (Table 6) (Grievance Systems).	OMB 0938–TBD (CMS–10854).	48 States.	58,558	Varies ...	16,206	Varies ...	1,081,374	540,687	n/a
§ 441.302(a)(6)—One-time burden to States (Table 7) (Incident Management System).	OMB 0938–TBD (CMS–10854).	48 States.	384	Varies ...	19,872	Varies ...	124,874,125	62,437,063	n/a
§ 441.302(a)(6)—Ongoing burden to States (Table 8) (Incident Management System).	OMB 0938–TBD (CMS–10854).	48 States.	283,638	Varies ...	15,177	Varies ...	24,732,634	12,366,317	n/a
§ 441.302(a)(6)—Ongoing burden to Service Providers (Table 9) (Incident Management System).	OMB 0938–TBD (CMS–10854).	15,742 providers.	28,345	1	28,345	110.82 ..	3,141,193	n/a	n/a
§ 441.302(a)(6)—One-time burden to Managed Care Entities (Table 10) (Incident Management System).	OMB 0938–TBD (CMS–10854).	161 MCEs.	805	Varies ...	26,726	Varies ...	2,576,084	n/a	n/a
§ 441.302(a)(6)—Ongoing burden to Managed Care Entities (Table 11) (Incident Management System).	OMB 0938–TBD (CMS–10854).	161 MCEs.	7,286	Varies ...	5,476	Varies ...	503,633	n/a	n/a
§ 441.302(k)—One-time burden to States (Table 12) (HCBS Payment Adequacy).	OMB 0938–TBD (CMS–10854).	48 States.	288	Varies ...	9,792	Varies ...	916,693	458,347	n/a
§ 441.302(k)—Ongoing burden to States (Table 13) (HCBS Payment Adequacy).	OMB 0938–TBD (CMS–10854).	48 States.	144	Varies ...	432	Varies ...	47,231	23,616	n/a
§ 441.302(k)—One-time burden to service providers (Table 14) (HCBS Payment Adequacy).	OMB 0938–TBD (CMS–10854).	11,555 Providers.	34,665	Varies ...	959,065	Varies ...	81,897,911	n/a	n/a
§ 441.302(k)—Ongoing burden to service providers (Table 15) (HCBS Payment Adequacy).	OMB 0938–TBD (CMS–10854).	11,555 Providers.	34,665	Varies ...	242,655	Varies ...	21,553,542	n/a	n/a
§ 441.302(k)—One-time burden to managed care entities (Table 16) (HCBS Payment Adequacy).	OMB 0938–TBD (CMS–10854).	161 MCEs.	644	Varies ...	15,778	Varies ...	1,486,877	n/a	n/a
§ 441.302(k)—Ongoing burden to managed care entities (Table 17) (HCBS Payment Adequacy).	OMB 0938–TBD (CMS–10854).	161 MCEs.	322	Varies ...	1,288	Varies ...	155,713	n/a	n/a
§ 441.303(f)(6), § 441.311(d)(1)—One-Time burden to States (Table 18) (Supporting Documentation for HCBS Access).	OMB 0938–TBD (CMS–10854).	39 States.	156	Varies ...	1,599	Varies ...	169,236	84,618	n/a

TABLE 37—SUMMARY OF PROPOSED ANNUAL BURDEN ESTIMATES—Continued

Regulation section(s) in Title 42 of the CFR	OMB Control Number (CMS ID Number)	Number of respondents	Number of responses	Time per response (hr)	Total time (hr)	Hourly labor Rate ($/hr)	Total labor cost ($)	State share ($)	Total beneficiary cost ($)
§ 441.303(f)(6), § 441.311(d)(1)—Ongoing burden to States (Table 19) (Supporting Documentation for HCBS Access).	OMB 0938–TBD (CMS–10854).	39 States.	156	Varies ...	585	Varies ...	67,639	33,820	n/a
§ 441.311(d)(2)(i) One-Time burden to States (Table 20) (Additional HCBS Access Reporting).	OMB 0938–TBD (CMS–10854).	48 States.	240	Varies ...	6,000	Varies ...	591,154	295,577	n/a
§ 441.311(d)(2)(i) Ongoing burden to States (Table 21) (Additional HCBS Access Reporting).	OMB 0938–TBD (CMS–10854).	48 States.	240	Varies ...	2,160	Varies ...	222,888	111,444	n/a
§ 441.311(d)(2)(i) One-Time burden to managed care entities (Table 22) (Additional HCBS Access Reporting).	OMB 0938–TBD (CMS–10854).	161 MCEs.	644	Varies ...	9, 177	Varies ...	918,479	n/a	n/a
§ 441.311(d)(2)(i) Ongoing burden to managed care entities (Table 23) (Additional HCBS Access Reporting).	OMB 0938–TBD (CMS–10854).	161 MCEs.	644	Varies ...	5,474	Varies ...	558,303	n/a	n/a
§ 441.311(b)(1) Ongoing burden to States (Table 24) (Incident Management System Assessment) [a].	OMB 0938–1362 (CMS–10692).	48 States.	96	Varies ...	96	Varies ...	7,976	3,988	n/a
Removal of Current Form 372(S) Ongoing Reporting Information Collection (Table 25).	OMB 0938–0272 (CMS–372(S)).	48 States.	253	(44)	(11,132)	75.32	(860,281)	(430,140)	n/a
Form 372(S) Reporting Requirement to include Proposed § 441.311(b)(2)–(4) (Table 26).	OMB 0938–TBD (CMS–10854).	48 States.	144	Varies ...	2,640	Varies ...	221,093	110,546	n/a
§ 441.311(c) One-time burden to States (Table 27) (HCBS Quality Measure Set).	OMB 0938–TBD (CMS–10854).	48 States.	288	Varies ...	64,560	Varies ...	5,141,918	2,570,959	n/a
§ 441.311(c) Ongoing burden to States (Table 28) (HCBS Quality Measure Set) [b].	OMB 0938–TBD (CMS–10854).	24 States.	288	Varies ...	117,840	Varies ...	4,087,183	2,043,592	n/a
§ 441.311(c) Ongoing burden to beneficiaries (Table 29) (HCBS Quality Measure Set).	OMB 0938–TBD (CMS–10854).	48,000 beneficiaries.	24,000	0.75	18,000	20.71	n/a	n/a	372,780
§ 441.313 One-time burden to States (Table 30) (Website Transparency).	OMB 0938–TBD (CMS–10854).	48 States.	192	Varies ...	5,232	Varies ...	517,633	258,816	n/a
§ 441.313 Ongoing burden to States (Table 31) (Website Transparency) [d].	OMB 0938–TBD (CMS–10854).	48 States.	768	Varies ...	6,336	Varies ...	666,228	333,114	n/a
Removal of § 447.203(b)(1)–(6)(i)) (Table 32) (Removal of AMRP).	OMB 0938–1134 (CMS–10391).	51 States and Territories.	17	(310)	(5,270)	Varies ...	(446,593)	(223,297)	n/a
Removal of § 447.203(b)(6)(ii) (Table 32) (Removal of AMRP).	OMB 0938–1134 (CMS–10391).	51 States and Territories.	22	(67)	(1,474)	Varies ...	(143,411)	(71,706)	n/a
§ 447.203(b)(1) (Table 33) (Rate transparency).	OMB 0938–1134 (CMS–10391).	51 States and Territories.	26	4	104	Varies ...	7,712	3,856	n/a
§ 447.203(b)(2) (Table 33) (Rate analysis).	OMB 0938–1134 (CMS–10391).	51 States and Territories.	26	79	2,054	Varies ...	174,206	87,103	n/a
§ 447.203(b)(6) (Table 34) (advisory group).	OMB 0938–1134 (CMS–10391).	51 States and Territories.	26	7	182	Varies ...	22,837	11,418	n/a
§ 447.203(c)(1) (Table 35) (initial State analysis).	OMB 0938–1134 (CMS–10391).	51 States and Territories.	17	48	816	Varies ...	81,356	40,678	n/a

TABLE 37—SUMMARY OF PROPOSED ANNUAL BURDEN ESTIMATES—Continued

Regulation section(s) in Title 42 of the CFR	OMB Control Number (CMS ID Number)	Number of respondents	Number of responses	Time per response (hr)	Total time (hr)	Hourly labor Rate ($/hr)	Total labor cost ($)	State share ($)	Total beneficiary cost ($)
§ 447.203(c)(2) (Table 36) (additional State analysis).	OMB 0938–1134 (CMS–10391).	51 States and Territories.	12	216	2,160	Varies ...	185,432	92,716	n/a
Total	.....	Varies ...	478,858	Varies ...	1,600,122	Varies ...	279,404,181	82,205,315	504,180

[a] The reporting requirement is every other year. Therefore, the on-going burden reflected in this table is half of the on-going burden per State reflected in Table 24.
[b] The reporting requirement is every other year. Therefore, the on-going burden reflected in this table is half of the on-going burden per State reflected in Table 32.
[c] The reporting requirement is every other year. Therefore, the on-going burden reflected in this table is half of the on-going burden per discussed above.
[d] The reporting requirement is quarterly. Therefore, the on-going burden reflected in this table is four times the on-going burden discussed above.

E. Submission of PRA-Related Comments

We have submitted a copy of this proposed rule to OMB for its review of the rule's information collection requirements. The requirements are not effective until they have been approved by OMB.

To obtain copies of the supporting statement and any related forms for the proposed collections discussed above, please visit the CMS website at *www.cms.hhs.gov/PaperworkReductionActof1995,* or call the Reports Clearance Office at 410–786–1326.

We invite public comments on these potential information collection requirements. If you wish to comment, please submit your comments electronically as specified in the **DATES** and **ADDRESSES** section of this proposed rule and identify the rule (CMS–2442–P), the ICR's CFR citation, and OMB control number.

IV. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

V. Regulatory Impact Analysis

A. Statement of Need

1. Medicaid Advisory Committee

The changes to § 431.12 are intended to provide beneficiaries a greater voice in State Medicaid programs. In making policy and program decisions, it is vital for States to incorporate the perspective and experience of those served by the Medicaid program. States are currently required to operate a MCAC, made up of health professionals, consumers, and State representatives to ''advise the Medicaid agency about health and medical care services.'' This rule establishes new requirements for a MAC in place of the MCAC, with additional membership requirements to include a broader group of interested parties, to advise the State Medicaid agency on matters related to the effective administration of the Medicaid program. We seek to expand the viewpoints represented on the MAC, to provider States with richer feedback on Medicaid program and policy issues. States are already required to set up and use MCACs. The proposed changes will result in the State also setting up a smaller group, the BAG which will likely have a cost implication. The additional cost will depend on whether or not States already have a beneficiary committee—we know that many States already do. This smaller group which feeds into the larger MCAC will benefit the Medicaid program by creating a forum for beneficiaries to weigh in on key topics and share their unique views as Medicaid program participants. The new provisions of § 431.12 also enhance transparency and accountability through public reporting requirements related to the operation and activities of the MAC and BAG, and guidelines for operation of both bodies.

2. Home and Community-Based Services (HCBS)

The proposed changes at part 441, subpart G, seek to amend and add new Federal requirements, which are intended to improve access to care, quality of care, and health outcomes, and strengthen necessary safeguards that are in place to ensure health and welfare, and promote health equity for people receiving Medicaid-covered HCBS. The provisions in this proposed rule are intended to achieve a more consistent and coordinated approach to the administration of policies and procedures across Medicaid HCBS programs in accordance with section 2402(a) of the Affordable Care Act, and is made applicable to part 441, subparts J, K, and M, as well as part 438 to achieve these goals.

Specifically, the proposed rule seeks to: strengthen person-centered services planning and incident management systems in HCBS; require minimum percentages of Medicaid payments for certain HCBS to be spent on compensation for the direct care workforce; require States to establish grievance systems in FFS HCBS programs; report on waiver waiting lists in section 1915(c) waiver programs, service delivery timeframes for certain HCBS, and a standardized set of HCBS quality measures; and promote public transparency related to the administration of Medicaid-covered HCBS through public reporting on measures related to incident management systems, critical incidents, person-centered planning, quality, access, and payment adequacy.

In 2014, we released guidance [263] for section 1915(c) waiver programs, which described a process in which States were to report on State-developed performance measures to demonstrate that they meet the six assurances that are required for section 1915(c) waiver programs. Those six assurances include the following:

1. *Level of Care:* The State demonstrates that it implements the processes and instrument(s) specified in its approved waiver for evaluating/reevaluating an applicant's/waiver participant's level of care consistent with care provided in a hospital, nursing facility, or Intermediate Care Facilities for Individuals with Intellectual Disabilities.

2. *Service Plan:* The State demonstrates it has designed and

[263] *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/3-cmcs-quality-memo-narrative_0_71.pdf.*

implemented an effective system for reviewing the adequacy of service plans for waiver participants.

3. *Qualified Providers:* The State demonstrates that it has designed and implemented an adequate system for assuring that all waiver services are provided by qualified providers.

4. *Health and Welfare:* The State demonstrates it has designed and implemented an effective system for assuring waiver participant health and welfare.

5. *Financial Accountability:* The State demonstrates that it has designed and implemented an adequate system for insuring financial accountability of the waiver program.

6. *Administrative Authority:* The Medicaid Agency retains ultimate administrative authority and responsibility for the operation of the waiver program by exercising oversight of the performance of waiver functions by other State and local/regional non-State agencies (if appropriate) and contracted entities.

Despite these assurances, there is evidence that State HCBS systems still need to be strengthened and that there are gaps in existing reporting requirements. We believe that this proposed rule is necessary to address these concerns and strengthen HCBS systems. The requirements in this proposed rule are intended to supersede and fully replace the reporting and performance expectations described in the 2014 guidance for section 1915(c) waiver programs. They are also intended to promote consistency and alignment across HCBS programs, as well as delivery systems, by applying the requirements (where applicable) to sections 1915(i), (j), and (k) authorities State plan benefits and to both FFS and managed care delivery systems.

3. Fee-for-Service (FFS)

Provisions under § 447.203 from this proposed rule would impact States' required documentation of compliance with section 1902(a)(30)(A) of the Act to ''assure that payments are . . . sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area.'' We have received comments from State agencies that the existing AMRP requirement first established by the 2015 final rule with comment period imposes excessive administrative burden for its corresponding value in demonstrating compliance with section 1902(a)(30)(A) of the Act.

This proposed rule would replace the existing AMRP requirement with a more limited payment rate transparency requirement under proposed § 447.203(b), while requiring a more detailed access impact analysis (as described at proposed § 447.203(c)(2)) when a State proposes provider rate reductions or restructurings that exceed certain thresholds for a streamlined analysis process under proposed § 447.203(c)(1). By limiting the data collection and publication requirements imposed on all States, while targeting certain provider rate reductions or restructuring proposals for a more detailed analysis, this proposed rule would provide administrative burden relief to States while maintaining a transparent and data-driven process to assure State compliance with section 1902(a)(30)(A) of the Act.

B. Overall Impact

We have examined the impacts of this rule as required by E.O. 12866 on Regulatory Planning and Review (September 30, 1993), E.O. 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), E.O. 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2))

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Section 3(f) of Executive Order 12866 as amended by Executive Order 14094 defines a ''significant regulatory action'' as an action that is likely to result in a rule: (1) having an annual effect on the economy of $200 million or more in any 1 year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments or communities; (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising legal or policy issues for which centralized review would meaningfully further the President's priorities, or the principles set forth in the Executive Order.

A regulatory impact analysis (RIA) must be prepared for major rules. Accordingly, this proposed rule is not a ''significant'' rule under section 3(f)(1) of the Executive Order, as the aggregate amount of benefits and costs will not meet the $200 million threshold in any 1 year.

Based on our estimates using a ''no action'' baseline in accordance with OMB Circular A–4, (available at *https://www.whitehouse.gov/wpcontent/uploads/legacy_drupal_files/omb/circulars/A4/a-4.pdf*), OMB's Office of Information and Regulatory Affairs has determined that this rulemaking is ''significant'' according to section 3(f)(4), raising legal or policy issues for which centralized review would meaningfully further the President's priorities, or the principles set forth in Executive Order 12866. Therefore, OMB has reviewed these proposed regulations, and the Departments have provided the following assessment of their impact.

C. Detailed Economic Analysis

As mentioned in the prior section, and in accordance with OMB Circular A–4, the following estimates were determined using a ''no action'' baseline. That is, our analytical baseline for impact is a direct comparison between the proposed provisions and not proposing them at all.

1. Benefits

a. Medicaid Advisory Committees (MAC)

We believe the changes to § 431.12 would benefit State Medicaid programs and those they serve by ensuring that beneficiaries have a significant role in advising States on the experience of receiving health care and services through Medicaid. These benefits cannot be quantified. However, the BAG and a more diverse and transparent MAC will provide opportunities for richer interested parties feedback and expertise to positively impact State decision making on Medicaid program and policy chances. For example, beneficiary feedback on accessing health care services and the quality of those services can inform decisions on provider networks and networks adequacy requirements. Issues that States need to address, like cultural competency of providers, language accessibility, health equity, and disparities and biases in the Medicaid program, can be revealed through beneficiary experiences. The MAC falls into the Public Administration 921 Executive, Legislative, and Other General Government Support.

b. Person-Centered Service Plans, Grievance Systems, Incident Management Systems

The proposed changes benefit Medicaid beneficiaries and States by requiring States to demonstrate through reporting requirements that they provide safeguards to assure eligibility for Medicaid-covered care and services is determined and provided in a manner that is in the Medicaid beneficiaries' best interest, although these potential benefits cannot be monetarily quantified at this time. The proposed changes would provide further safeguards that ensure health and welfare by strengthening the person-centered service plan requirements, establishing grievance systems, amending requirements for incident management systems, and establishing new reporting requirements for States, and contracted managed care entities identified by the North American Industry Classification System (NAICS) industry code (Direct Health and Medical Insurance Carriers (524114).

These changes would benefit individuals on HCBS waiver wait lists, and individuals who receive homemaker, home health aide, and personal care services, under the amended and proposed regulations found at §§ 441.301(c), 441.302(a)(6), 441.302(h), 441.303(f), 441.311, and cross-referenced in §§ 441.464, 441.555(b)(2)(iv), 441.570, and 441.745(a)(1)(iii). These potential benefits cannot be monetarily quantified at this time.

c. Home and Community-Based Services (HCBS) Payment Adequacy

The proposed rule adds new requirements at §§ 441.302(k) and 441.311 (cross-referenced at §§ 441.464(f) and 441.745(a)(1)(vi)) that require States to demonstrate through reporting that payments to providers are sufficient to provide access to care that is at least comparable to that of the general population in the same geographic location, in accordance with section 1902(a)(30(A) of the Act. This proposed rule seeks to address access to care that is being affected by direct care workforce shortages.

Through this proposed rule, which establishes certain minimum thresholds for compensation for direct care workers, we can better ensure payment adequacy to a provider population experiencing worker shortages that impact beneficiary access. States will be required to report annually to us on the percent of payments for certain HCBS that are spent on compensation for direct care workers and will be required to separately report on payments for services that are self-directed. States may benefit from reporting in the aggregate for each service subject to the requirement across HCBS programs and delivery systems, which minimizes administrative burden while providing us better oversight of compensation of the direct care workforce, although these potential benefits cannot be monetarily quantified at this time due to the variety of State data collection approaches.

d. Home and Community-Based Services (HCBS) Quality Measure Set Reporting

As described in section II.B.8. of this proposed rule, on July 21, 2022, we issued State Medicaid Director Letter (SMDL) # 22–003 [264] to release the first official version of the HCBS Quality Measure Set. This proposed rule provides definitions and sets forth requirements proposed at § 441.312 that expand on the HCBS Quality Measure Set described in the SMDL. By expanding and codifying aspects of the SMDL, we can better drive improvement in quality of care and health outcomes for beneficiaries receiving HCBS. States will also benefit from the clarity afforded by this proposed rule, and from the assurance that other States they may be looking to for comparison are adhering to the same requirements. The clarity and assurance, at this time, cannot be measured.

e. Fee-for-Service (FFS) Payment Transparency

The proposed changes to § 447.203 would update requirements placed on States to document access to care and service payment rates. The proposed updates create a systematic framework through which we can ensure compliance with section 1902(a)(30)(A) of the Act, while reducing existing burden on States and maximizing the value of their efforts, as described in section III.C.11.a of this rule.

The proposed payment rate transparency provisions at § 447.203(b) create a process that would facilitate transparent oversight by us and other interested parties. By requiring States to calculate Medicaid payment rates as a percent of corresponding Medicare payment rates, this provision offers a uniform benchmark through which us and interested parties can assess payment rate sufficiency. When compared to the existing AMRP requirement, the rate analysis proposed by § 447.203(b) should improve the utility of the reporting, while reducing the associated administrative burden, as reflected in the Burden Estimate Summary Table 37. Proposed updates at § 447.203(c) specify required documentation and analysis when States propose to reduce or restructure provider payment rates. By establishing thresholds at § 447.203(c)(1), this proposed rule would generally limit the more extensive access review prescribed by § 447.203(c)(2) to those SPAs that we believe more likely to cause access concerns. In doing so, these proposed updates reduce the State administrative burden imposed by existing documentation requirements for proposed rate reductions or restructurings, without impeding our ability to ensure proposed rate reduction and restructuring SPAs comply with section 1902(a)(30)(A) of the Act. These burden reductions are reflected in the Collection of Information section of this rule.

When considering the benefits of these regulatory updates, we considered the possibility that the improved transparency required by § 447.203(b) could create upward pressure on provider payment rates, and that the tiered nature of documentation requirements set by § 447.203(c) could create an incentive for States to moderate proposed payment reductions or restructurings that were near the proposed thresholds that would trigger additional analysis and documentation requirements. If either of these rate impacts were to occur, existing literature implies there could be follow-on benefits to Medicaid beneficiaries, including but not limited to increased physician acceptance rates,[265] increased appointment availability,[266] and even improved self-reported health.[267] However, nothing in this proposed rulemaking would require States to directly adjust payment rates, and we recognize that multiple factors influence State rate-setting proposals, including State budgetary pressures, legislative priorities, and other forces. These competing influences create substantial uncertainty about the specific impact of the proposed provisions at § 447.203 on provider payment rate-setting and beneficiary access. Rather, the specific intent and anticipated outcome of these

[264] *https://www.medicaid.gov/federal-policy-guidance/downloads/smd22003.pdf.*

[265] Holgash, K. and Martha Heberlein, *Health Affairs,* April 10, 2019.

[266] Candon, M., et al. *JAMA Internal Medicine,* January 2018, p. 145–146.

[267] Alexander, D., and Molly Schnell. ''The Impacts of Physician Payments on Patient Access, Use, and Health'', National Bureau of Economic Research, Working Paper 26095, July 2019 (revised August 2020), p. 1–74. *https://www.nber.org/papers/w26095.* Accessed June 16, 2022.

provisions is the creation of a more uniform, transparent, and less burdensome process through which States can conduct required payment rate and access analyses and we can perform our oversight role related to provider payment rate sufficiency.

2. Costs

a. Medicaid Advisory Committee (MAC)

States will incur additional costs (estimated below) in appointing and recruiting members to the MAC and BAG and also developing and publishing bylaws, membership lists, and meeting minutes for the MAC and BAG. All of these costs can be categorized under the NAICS Code 921 (Executive, Legislative, and Other General Government Support) since States are the only entity accounted for in the MAC and BAG. How often these costs occur will vary in how often the State chooses to make changes such as add or replace members of the MAC and BAC or change its bylaws. Additionally, there will be new costs, estimated below, for States related to meeting logistics and administration for the BAG. All of these new costs can also be categorized under the NAICS Code 921 (Executive, Legislative, and Other General Government Support). Since most States are already holding MAC meetings under current regulatory requirements, any new costs related to MAC requirements would likely be minimal. In terms of the BAG meeting costs, we estimate a total annual cost of $532,627 for States. We estimate it will take a business operations specialist 10 hours to plan and execute each BAG meeting, at a total cost of $155,448 ($76.20/hour × 10 hours × 4 meetings/year) × 51 States and the District of Columbia). To satisfy the requirements of § 431.12(i)(4)(i), a public relations specialist will spend an estimated 80 hours/year supporting Medicaid beneficiary MAC and BAG members at a total cost of $287,395 ($70.44/hour × 80 hours) × 51 States and the District of Columbia). A chief executive in State government, as required by § 431.12(i)(4)(iii), will spend a total of 8 hours a year attending BAG meetings, which we estimate will be 2 hours in duration, 4 times a year at a total cost of $48,984 ($120.06/hour × 2 hours/meeting × 4 meetings) × 51 States and the District of Columbia). Each meeting of the BAG will cost States an estimated $200 in meeting costs and telecommunication, at an annual total cost of $40,800 ($200 × 4 meetings) × 51 States and the District of Columbia).

There will also be a per meeting cost to States for financial support for beneficiary members participating in MAC and BAG meetings, as described in § 431.12(i)(4)(ii). We estimate a cost of $75/beneficiary/meeting in the form of transportation vouchers, childcare reimbursement, meals, and/or other financial compensation. Assuming 4 meetings per year (with BAG and MAC meetings co-located and occurring on the same day) and an average of 8 beneficiary members on the BAG and MAC, the cost of financial support for beneficiary members across States is estimated to cost approximately $122,400 annually (($75/beneficiary × 8 beneficiaries × 4 meetings/year) × 51 States and the District of Columbia). This cost will vary depending on the decisions States make around financial support, the number of beneficiary members of the BAG and MAC, and the number of meetings per year. We seek comment on the costs associated with planning, execution, and participation in the MAC and BAG meetings.

TABLE 38—PROJECTED 5-YEAR COSTS FOR PROPOSED UPDATES

Provision	Calendar year (CY)					Total CY 2024–2028 ($ in millions)
	2024 ($ in millions)	2025 ($ in millions)	2026 ($ in millions)	2027 ($ in millions)	2028 ($ in millions)	
§ 431.12 MAC & BAG logistic and admin support	0.533	0.532	0.532	0.532	0.532	2.663
§ 431.12 Financial support to MAC/BAG beneficiary members (cost will range per State)	0.122	0.122	0.122	0.122	0.122	0.612
Total	0.655	0.655	0.655	0.655	0.655	3.275

Costs will vary depending by State depending on how many in person meetings are held and how many Medicaid beneficiaries are selected for the MAC and BAG.

b. Home and Community-Based Services (HCBS)

Costs displayed in Table 38 are inclusive of both one-time and ongoing costs. One-time costs are split evenly over the years leading up to the proposed effective date. For example, if a proposed provision takes effect 3 years after the final rule's publication, the one-time costs would be split evenly across each of the years leading to that effective date. Because costs are projected over 5 years, the total estimated costs exceed the amounts shown in the COI section. The estimates below do not account for higher costs associated with medical care, as the costs are related exclusively to reporting costs. Costs to States, the Federal government, and managed care entities do not account for enrollment fluctuations, as they assume a stable number of States operating HCBS programs and managed care entities delivering services through these programs. Similarly, costs to providers and beneficiaries do not account for enrollment fluctuations. In the COI section, costs are based on a projected range of HCBS providers and beneficiaries. Given this uncertainty, here, we based cost estimates on the mid-point of the respective ranges and kept those assumptions consistent over the course of the 5-year projection. Per OMB guidelines, the projected estimates for future years do not consider ordinary inflation.

Table 39 summarizes the estimated ongoing costs for States, managed care entities (Direct Health and Medical Insurance Carriers (NAICS 524114)), and providers (Services for the Elderly and Persons with Disabilities (NAICS 624120) and Home Health Care Services (NAICS 621610)) from the COI section of the HCBS provisions of the proposed rule projected over 5 years. This comprises the entirety of anticipated quantifiable costs associated with proposed changes to part 441, subpart G. It is also possible that increasing the threshold from 86 percent to 90 percent for compliance reporting at § 441.311(b)(2) through (3) may lead to additional costs to remediate issues pertaining to critical incidents or person-centered planning. However, the various avenues through which States could address these concerns creates substantial uncertainty as to what those costs may be. While we acknowledge the potential for increased costs in a limited number of States that may fall within the gap between the existing and

the proposed compliance thresholds, we do not quantify them here.

TABLE 39—PROJECTED 5-YEAR COSTS FOR PROPOSED UPDATES TO 441 SUBPARTS G, J, K, AND M

Provision	Calendar year (CY)					Total CY 2024–2028 ($ in millions)
	2024 ($ in millions)	2025 ($ in millions)	2026 ($ in millions)	2027 ($ in millions)	2028 ($ in millions)	
Proposed § 441.301(c)(3) (Person-Centered Service Plans)	0.06	0.06	0.06			0.18
Proposed § 441.301(c)(7) (Grievance Systems)	1.24	1.24	0.87	0.87	0.87	5.10
Proposed § 441.302(a)(6) (Incident Management System)	41.15	41.15	41.15	6.78	6.78	137.01
Proposed § 441.302(k) (HCBS Payment Adequacy)	21.08	21.08	21.08	21.08	21.73	106.03
Proposed § 441.303(f)(6), § 441.311(d)(1) (Supporting Documentation for HCBS Access)	0.06	0.06	0.06	0.07	0.07	0.30
Proposed § 441.311(d)(2)(i) (Additional HCBS Access Reporting)	0.50	0.50	0.50	0.78	0.78	3.07
Proposed § 441.311(b)(1) (Incident Management System Assessment)				0.00	0.00	0.01
Removal of Current Form 372(S) Ongoing Reporting Information Collection				(0.84)	(0.84)	(1.68)
Proposed Form 372(S) Reporting Requirement to include Proposed § 441.311(b)(2)–(4)				0.22	0.22	0.44
Proposed § 441.311(c) (HCBS Quality Measure Set)	1.72	1.72	1.72	4.59	4.59	14.34
Proposed § 441.313 (Website Transparency)				1.18	1.18	2.37
Total	65.80	65.80	65.44	34.74	35.39	267.18

The costs displayed in Table 40 are inclusive of costs anticipated to be incurred by State Medicaid agencies, the Federal government, providers, managed care entities, and beneficiaries. Table 40 distributes those costs across these respective entities.

TABLE 40—PROJECTED DISTRIBUTION OF COSTS FOR PROPOSED UPDATES TO 42 CFR 441 SUBPART G, J, K, AND M

Costs associated with updates to § 42 CFR 441 Subparts G, J, K, and M	Calendar year (CY)					Total CY 2024–2028 ($ in millions)
	2024 ($ in millions)	2025 ($ in millions)	2026 ($ in millions)	2027 ($ in millions)	2028 ($ in millions)	
Total Costs associated with updates to 42 CFR 441 subparts G, J, K, and M	65.80	65.80	65.44	34.74	35.39	267.18
State Costs	21.88	21.88	21.69	4.59	4.50	74.54
Federal Costs	21.88	21.88	21.69	4.59	4.50	74.54
HCBS Provider Costs (Services for the Elderly and Persons with Disabilities (NAICS 624120) and Home Health Care Services (NAICS 621610))	20.47	20.47	20.47	23.62	24.69	109.73
Managed Care Entity Costs (Direct Health and Medical Insurance Carriers (NAICS 524114))	1.58	1.58	1.58	1.43	1.19	7.35

c. Fee-for-Service (FFS) Payment Rate Transparency

The costs associated with the payment rate transparency proposals are wholly associated with information collection requirements, and as such those impacts are reflected in the COI section of this rule. For ease of reference, and for projection purposes, we are including those costs here in Table 41.

TABLE 41—PROJECTED 5-YEAR COSTS FOR PROPOSED UPDATES TO 42 CFR 447.203

Provision	Calendar year (CY)					Total CY 2024–2028 ($ in millions)
	2024 ($ in millions)	2025 ($ in millions)	2026 ($ in millions)	2027 ($ in millions)	2028 ($ in millions)	
Removal of current § 447.203 (AMRPs)	−0.601	−0.601	−0.601	−0.601	−0.601	−3
Proposed § 447.203(b)	0.516	0.209	0.209	0.209	0.209	1.353
Proposed § 447.203(c) (SPAs)	0.276	0.276	0.276	0.276	0.276	1.38
Total	0.191	−0.116	−0.116	−0.116	−0.116	−0.267

TABLE 42—NAICS CLASSIFICATION OF SERVICES AND THEIR DISTRIBUTION OF COSTS

Services	NAICS	Percentage of costs (percent)
Managed Care Entities	Direct Health and Medical Insurance Carriers (524114)	100
Home and Community-Based Services (HCBS)	Elderly and Persons with Disabilities (624120)	67
Home and Community-Based Services (HCBS)	Home Health Care Services (621610)	37

TABLE 43—ONE TIME AND ANNUAL COSTS DETAILED

	Costs to states ($)	Costs to beneficiaries ($)	Cost to providers ($)	Cost to managed care entities ($)	One time burden overall total ($)	Annual burden overall total ($)
Regulatory Review	19,587.06	39,174.12		61,833.66	120,594.84	0
§ 431.12 Medical Care Advisory Committee Requirements	790,795					790,795
§ 441.301(c)(3) (Person-Centered Service Plans) (Table 3,4)	31,102			120,463	151,565	
§ 441.301(c)(7) (Grievance Systems) (Table 5)	1,240,964				1,240,964	
§ 441.301(c)(7) (Grievance Systems) (Table 6)	540,687					540,687
§ 441.302(a)(6) (Incident Management System) (Table 7,10)	62,437,000			2,576,084	65,009,084	
§ 441.302(a)(6) (Incident Management System) (Table 8, 9, 10, 11)	12,366,317		3,141,193	503,633		16,011,132
§ 441.302(k) (HCBS Payment Adequacy) (Table 12,14, 16)	458,347		103,451,453	1,486,877	105,396,677	
§ 441.302(k) (HCBS Payment Adequacy) (Table 13,15, 17)	23,616		21,553,542	155,713		21,732,871
§ 441.303(f)(6), § 441.311(d)(1) Supporting Documentation for HCBS Access (Table 18)	84,618				84,618	
§ 441.303(f)(6), § 441.311(d)(1) Supporting Documentation for HCBS Access (Table 19)	33,820					33,820
§ 441.311(d)(2)(i) (HCBS Access Reporting) (Table 20, 22)	295,577			918,479	1,214,056	
§ 441.311(d)(2)(i) (HCBS Access Reporting) (Table 21, 23)	111,444			558,303		669,747
§ 441.311(b)(1) (Incident Management System Assessment) (Table 24)	3,988					3,988
Removal of Current Form 372(S) Ongoing Reporting Information Collection (Table 25)	($430,140))					($430,140)
Form 372(S) Reporting Requirement to include Proposed § 441.311(b)(2)–(4) (Table 26)	110,546					110,546
441.311(c) (Table 27) (HCBS Quality Measure Set)	2,570,959				2,570,959	
441.311(c) (Table 28,29) (HCBS Quality Measure Set)	2,043,592	504,180				2,547,772
§ 441.313 (Table 30) (Website Transparency)	258,816				258,816	
§ 441.313 (Table 31) (Website Transparency)	333,114					333,114
§ 447.203(b)(1) (Table 33) (Rate transparency)	23,453				39,195	7,712
§ 447.203(b)(2) (Table 33) (Rate analysis)	87,103					174,206
§ 447.203(b)(6) (Table 34) (advisory group)	145,386				267,934	22,837
§ 447.203(c)(1) (Table 35) (initial State analysis)	40,678					81,356
§ 447.203(c)(2) (Table 36) (additional State analysis)	92,716					185,432

3. Transfers

Transfers are payments between persons or groups that do not affect the total resources available to society. They are a benefit to recipients and a cost to payers, with zero net effects. Because this rule proposes changes to requirements to State agencies without changes to payments from Federal to State governments, the transfer impact is null, and cost impacts are reflected in the other sections of this rule.

4. Regulatory Review Cost Estimation

If regulations impose administrative costs on private entities, such as the time needed to read and interpret this proposed or final rule, we should estimate the cost associated with regulatory review. There is uncertainty involved with accurately quantifying the number of entities that will review the rule. However, for the purposes of this proposed rule we assume that on average, each of the 51 affected State Medicaid agencies will have one contractor per State review this proposed rule. This average assumes that some State Medicaid agencies may use the same contractor, others may use multiple contractors to address the various provisions within this proposed rule, and some State Medicaid agencies may perform the review in-house. We also assume that each affected managed care entity (estimated in the COI section to be 161 managed care entities) will review the proposed rule. Lastly, we assume that an average of two advocacy or interest group representatives from each State will review this proposed rule. In total, we are estimating that 314 entities (51 State Contractors + 161 Managed Care Entities + 102 Advocacy and Interest Groups) will review this proposed rule. We acknowledge that this assumption may understate or overstate the costs of reviewing this rule. We welcome any comments on the approach in estimating the number of entities which will review this proposed rule.

We also recognize that different types of entities are in many cases affected by mutually exclusive sections of this proposed rule, and therefore for the purposes of our estimate we assume that each reviewer reads approximately 50 percent of the rule. We seek comments on this assumption.

Using the wage information from the Bureau of Labor Statistics, *https://www.bls.gov/oes/current/oes_nat.htm,* we consider medical and health service managers (Code 11–9111), as including the 51 State Contractors, 161 Managed Care Entities and 102 Advocacy and Interest Groups identified in the proposed rule, and we estimate that the cost of reviewing this rule is $115.22 per hour, including fringe benefits and other indirect costs. Assuming an average reading speed of 250 words per minute, we estimate that it would take approximately 3.33 hours for each individual to review half of this proposed rule ([100,000 words × 0.5]/ 250 words per minute/60 minutes per hour). For each entity that reviews the rule, the estimated cost is $384.06 (3.33 hours × $115.22). Therefore, we estimate

that the total one-time cost of reviewing this regulation is $120,594.84 ($384.06 per individual review × 314 reviewers).

D. Alternatives Considered

1. Medicaid Advisory Committee (MAC)

In determining the best way to promote beneficiary and interested parties' voices in State Medicaid program decision making and administration, we considered several ways of revising the MCAC structure and administration. We considered setting minimum benchmarks for each category of all types of MAC members, but we viewed it as too restrictive. We ultimately concluded that only setting minimum benchmarks (at least 25 percent) for beneficiary representation on the MAC and requiring representation from the other MAC categories would give States maximum flexibility in determining the exact composition of their MAC. However, we understand that some States may want us to set specific thresholds for each MAC category rather than determine those categories on their own.

We also considered having not having a separate BAG, but we ultimately determined that requiring States to establish a separate BAG assures that there is a dedicated forum for States to receive beneficiary input outside of the MAC. In the MAC setting, a beneficiary might not feel as comfortable speaking up among other Medicaid program interested parties. The BAG also provides an opportunity for beneficiaries to focus on the issues that are most important to them, and bring those issues to the MAC.

Finally, we also considered setting specific topics for the MAC to provide feedback. However, due to the range of issues specific to each State's Medicaid program, we determined it was most conducive to allow States work with their MAC to identify which topics and priority issues would benefit from interested parties' input.

2. Home and Community-Based Services (HCBS)

a. Person-Centered Service Plans, Grievance Systems, Incident Management Systems

We considered whether to codify the existing 86 percent performance level that was outlined in the 2014 guidance for both person-centered service plans and incident management systems. We did not choose this alternative due to feedback from States and other interested parties of the importance of these requirements, as well as concerns that an 86 percent performance level may not be sufficient to demonstrate that a State has met the requirements.

We considered whether to apply these requirements to section 1905(a) ''medical assistance'' State Plan personal care, home health, and case management services. We decided against this alternative based on State feedback that they do not have the same data collection and reporting capabilities for these services as they do for HCBS delivered under sections 1915(c), (i), (j), and (k) of the Act and because of differences between the requirements of those authorities and section 1905(a) State Plan benefits.

Finally, we considered allowing a good cause exception to the minimum performance level reporting requirements to both the person-centered service plan and the incident management system. We decided against this alternative because the 90 percent performance level is intended to account for various scenarios that might impact a State's ability to achieve these performance levels. Furthermore, there are existing disaster authorities that States could utilize to request a waiver of these requirements in the event of a public health emergency or a disaster.

b. HCBS Payment Adequacy

We considered several alternatives to the proposed rule. We considered whether the requirements relating to the percent of payments going to the direct care workforce should apply to other services, such as adult day health, habilitation, day treatment or other partial hospitalization services, psychosocial rehabilitation services, and clinic services for individuals with mental illness. We decided against this alternative because the proposed services (homemaker, home health aide, and personal care) are those for which the vast majority of payment should be comprised of compensation for direct care workers and for which there would be low facility or other indirect costs. We also did not include other services for which the percentage might be variable due to the diversity of services included or for which worker compensation would be reasonably expected to comprise only a small percentage of the payment.

We considered whether to apply these payment adequacy requirements to section 1905(a) ''medical assistance'' State Plan personal care and home health services, but decided not to, based on State feedback that they do not have the same data collection and reporting capabilities for these services as they do for sections 1915(c), (i), (j), and (k) HCBS.

We considered whether other reporting requirements such as a State assurance or attestation or an alternative frequency of reporting could be used to determine State compliance but determined that the proposed requirement is necessary to demonstrate compliance.

We considered whether to require reporting at the delivery system, HCBS waiver program, or population level but decided against additional levels of reporting because it would increase reporting burden for States without providing additional information necessary for determining whether States meet the requirements at § 441.302(k).

c. Supporting Documentation Requirements

No alternatives were considered.

d. HCBS Quality Measure Set Reporting

We considered giving States the flexibility to choose which measures they would stratify and by what factors but decided against this alternative as discussed in the Mandatory Medicaid and CHIP Core Set Reporting proposed rule (see 87 FR 51313). We believe that consistent measurement of differences in health outcomes between different groups of beneficiaries is essential to identifying areas for intervention and evaluation of those interventions.[268] Consistency could not be achieved if each State made its own decisions about which data, it would stratify and by what factors.

3. Payment Rate Transparency

In developing this proposed rule, we considered multiple alternatives. We considered not proposing this rule and maintaining the status quo under current regulations at § 447.203 and 204. However, as noted throughout the Background and Provisions sections of this rule, since the 2011 proposed rule, we have received concerns from interested parties, including State agencies, about the administrative burden of completing AMRPs and questioning whether they are the most efficient way to determine access to care. These comments expressed particular concern about the AMRPs' value when they are required to accompany a proposed nominal rate reduction or restructuring, or where proposed rate changes are made via application of a previously approved rate methodology. At the same time, and as we have discussed, the Supreme

[268] Schlotthauer AE, Badler A, Cook SC, Perez DJ, Chin MH. Evaluating Interventions to Reduce Health Care Disparities: An RWJF Program. Health Aff (Millwood). 2008;27(2):568–573.

Court's 2015 decision in Armstrong v. Exceptional Child Care, Inc., 135 S. Ct. 1378 (2015) ruled that Medicaid providers and beneficiaries do not have private right of action to challenge State-determined Medicaid payment rates in Federal courts. This decision emphasized a greater importance on our administrative review of SPAs proposing to reduce or restructure payment rates. For both of these reasons, this proposed rule includes proposals that would create an alternative process that both reduces the administrative burden on States and standardizes and strengthens our review of proposed payment rate reductions or payment restructurings to ensure compliance with section 1902(a)(30)(A) of the Act.

We considered, but did not propose, adopting a complaint-driven process or developing a Federal review process for assessing access to care concerns. Although such processes could further our goals of ensuring compliance with the access requirement in section 1902(a)(30)(A) of the Act, we concluded similar effects could be achieved through methods that did not require the significant amount of Federal effort that would be necessary to develop either or both of these processes. Additionally, a complaint-driven process would not necessarily ensure a balanced review of State-proposed payment rate or payment structure changes, and it is possible that a large volume of complaints could be submitted with the intended or unintended effect of hampering State Medicaid program operations. Therefore, the impact of adopting a complaint-driven process or developing a Federal review process for assessing access to care concerns may be negligible given existing processes. Instead, we believe that relying on existing processes that States are already engaged in, such as the ongoing provider and beneficiary feedback channels under paragraph (b)(7) in § 447.203 and the public process requirement for States submitting a SPA that proposed to reduce or restructure Medicaid service payments in § 447.204, would be more effective than creating a new process. While we are relying on existing public feedback channels and processes that States are already engaged in, we are seeking public comment regarding our alternative consideration to propose adopting a complaint driven process or developing a Federal review process for assessing access to care concerns.

We considered finalizing the 2018 proposed rule that would have provided exemptions to the AMRP process for States with high managed care penetration or finalizing the 2019 proposed rule that would have rescinded the AMRP requirements without substantive replacement. As described in the 2018 proposed rule, while we agreed that our experience implementing the AMRP process from the 2015 final rule with comment period raised questions about the benefit of the access analysis when States proposed nominal payment rate reductions or payment restructurings that were unlikely to result in diminished access to care, we did not believe maintaining the AMRP process was the best course of action.[269] Additionally, after proposing to rescind the AMRP requirements through the 2019 proposed rule and issuing a CMCS Informational Bulletin about an agency wide effort to establish a new, comprehensive access strategy, we decided not to rescind the AMRP requirements without another regulation in place to codify the requirements for State compliance with section 1902(a)(30)(A) of the Act given our oversight responsibility. While we have already received and reviewed public comments received on the 2018 proposed rule or the 2019 proposed rule, we are seeking any additional public comments that were not already captured during the comment periods of the 2018 proposed rule or 2019 proposed rule with regard to finalizing these rules as an alternative considered within this proposed rulemaking.

We considered numerous variations of the individual provisions of this proposed rule. We considered, but did not propose, maintaining the benefits outlined in the current § 447.203(b)(5)(ii)(A) through (H) or requiring all mandatory Medicaid benefit categories be included in the comparative payment rate analysis proposed under § 447.203(b)(2). We also considered, but did not propose, including inpatient hospital behavioral health services and covered outpatient drugs including professional dispensing fees as additional categories of services subject to the comparative payment rate analysis proposed under § 447.203(b)(2). We considered, but did not propose, requiring States whose Medicaid payment rates vary by provider type, calculate an average Medicaid payment rate of all providers for each E/M CPT code subject to the comparative payment rate analysis. We also considered, but did not propose, different points of comparison other than Medicare under the comparative payment rate analysis proposed under § 447.203(b)(2) or using a peer payment rate benchmarking approach for benefit categories where Medicaid is the only or primary payer, or there is no comparable Medicare rate under the comparative payment rate analysis proposed under § 447.203(b)(2) and (3). We considered, but did not propose, varying timeframes for the comparative payment rate analysis proposed under § 447.203(b)(2). We also considered not proposing the payment rate transparency aspect of this rule proposed under § 447.203(b)(1), leaving the comparative payment rate analysis to replace the AMRP process as proposed under § 447.203(b)(2). With regard to the proposal in § 447.203(c), we considered, but did not propose, establishing alternative circumstances from those described in the 2017 SMDL for identifying nominal payment rate adjustments, establishing a minimum set of required data for States above 80 percent of the most recent Medicare payment rates after the proposed reduction or restructuring, using measures that are different from the proposed measures that would be reflected in the forthcoming template, allowing States to use their own unstructured data for States that fail to meet all three criteria in § 447.203(c)(1), and CMS producing and publishing the comparative payment rate analysis proposed in § 447.203(b).

We considered, but did not propose, maintaining the benefits outlined in the current § 447.203(b)(5)(ii)(A) through (H) or requiring all mandatory Medicaid benefit categories be included in the comparative payment rate analysis proposed under § 447.203(b)(2). Maintaining the benefits in current § 447.203(b)(5)(ii)(A) through (H) would have simplified the transition from the AMRP process to the payment rate transparency and comparative payment rate analysis requirements, if this proposed rule is finalized. However, our experience implementing the 2015 final rule with comment period, as well as interested parties' and States' feedback about the AMRP process, encouraged us to review and reconsider the current list of benefits subject to the AMRP process under current regulations § 447.203(b)(5)(ii)(A) through (H) to determine where we could decrease the level of effort required from States while still allowing ourselves an opportunity to review for access concerns. During our review of the current list of benefits under § 447.203(b)(5)(ii)(A) through (H), we considered, but did not propose, requiring all mandatory Medicaid benefit categories be included in the comparative payment rate analysis.

[269] 83 FR 12696 at 12697.

However, when considering the existing burden of the AMRP process under current § 447.203)(b), we believed that expanding the list of benefits to include under proposed § 447.203(b) and (c) would not support our goal to develop a new access strategy that aims to balance Federal and State administrative burden with our shared obligation to ensure compliance with section 1902(a)(30)(A) of the Act. As previously noted section II. of this rule, we are seeking public comment on primary care services, obstetrical and gynecological services, outpatient behavioral health services, and personal care, home health aide, and homemaker services provided by individual providers and providers employed by an agency as the proposed categories of services subject to the comparative payment rate analysis requirements in proposed § 447.203(b)(2)(i). Additionally, we are seeking public comment regarding our alternative consideration to propose maintaining the benefits outlined in the current § 447.203(b)(5)(ii)(A) through (H) or propose requiring all mandatory Medicaid benefit categories.

We also considered, but did not propose, including inpatient hospital behavioral health services and covered outpatient drugs including professional dispensing fees as additional categories of services subject to the comparative payment rate analysis proposed under § 447.203(b)(2). As previously described in section II. Of this proposed rule, we did not propose including inpatient behavioral health services as an additional category of service in the comparative payment rate analysis due to existing UPL and CAA payment data requirements for institutional services. The impact of including inpatient behavioral health services in the comparative payment rate analysis would have required duplicative effort by States to report the same information in a different format to us. Additionally, we considered, but did not propose, including covered outpatient drugs (including professional dispensing fees) as an additional category of service in the comparative payment rate analysis due to the complexity of drug pricing policies and use of rebate programs that does not fit into our proposed comparative payment rate analysis methodology that relies on E/M CPT/HCPCS codes to identify the services subject to the analysis.[270] The impact of including covered outpatient drugs (including professional dispensing fees) in the comparative payment rate analysis would have resulted in us proposing an entirely different process, in addition to the comparative payment rate analysis, for States to follow which would create additional burden on States to comply with. However, we are still seeking public comment regarding our decision not to include inpatient behavioral health services and covered outpatient drugs including professional dispensing fees as additional proposed categories of services subject to the comparative payment rate analysis requirements in proposed § 447.203(b)(2).

We considered, but did not propose, requiring States whose Medicaid payment rates vary by provider type to calculate an average Medicaid payment rate of all provider types for each E/M CPT code subject to the comparative payment rate analysis. Rather than proposing States distinguish their Medicaid payment rates by each provider type in the comparative payment rate analysis, we considered proposing States calculate an average Medicaid payment rate of all providers for each E/M CPT code. This consideration would have simplified the comparative payment rate analysis because States would include a single, average Medicaid payment rate amount and only need to separately analyze their Medicaid payment rates for services delivered to pediatric and adult populations, if they varied. However, calculating an average for the Medicaid payment rate has limitations, including sensitivity to extreme values and inconsistent characterizations of the payment rate between Medicaid and Medicare. In this rule, we propose to characterize the Medicare payment rate as the non-facility payment rate listed on the Medicare PFS for the E/M CPT/HCPCS codes subject to the comparative payment rate analysis. If we were to propose the Medicaid payment rate be calculated as an average Medicaid payment rate of all provider types for the same E/M CPT/HCPCS code, then States' calculated average Medicaid payment rate could include a wide variety of provider types, from a single payment rate for physicians to an average of three payment rates for physicians, physician assistants, and nurse practitioners. This wide variation in how the Medicaid payment rate is calculated among States would provide a less meaningful comparative payment rate analysis to Medicare. The extremes and outliers that would be diluted by using an average are not necessarily the same for both Medicaid and Medicare, so even if both sides of the comparison used an average, we would not be able to look more closely at specific large differences between the respective rates. As previously noted in section II. of this proposed rule, we are seeking public comment on the proposed characterization of the Medicaid payment rate, which accounts for variation in payment rates for pediatric and adult populations and distinguishes payment rates by provider type, in the comparative payment rate analysis. Additionally, we are seeking public comment regarding our alternative consideration to propose requiring States whose Medicaid payment rates vary by provider type to calculate an average Medicaid payment rate of all provider types for each E/M CPT code subject to the comparative payment rate analysis.

We considered, but did not propose, requiring States to use a different point of comparison, other than Medicare, for certain services where Medicare is not a consistent or primary payer, such as pediatric dental services or HCBS. The impact of requiring a different point of comparison, other than Medicare, would have carried forward the current regulation requiring States to ''include an analysis of the percentage comparison of Medicaid payment rates to other public (including, as practical, Medicaid managed care rates) and private health insurer payment rates within geographic areas of the State'' in their AMRPs. As previously discussed in this rule, FFS States expressed concerns following the 2015 final rule with comment period that private payer payment rates were proprietary information and not available to them, therefore, the challenges to comply with current regulations would be carried forward into the proposed rule. Therefore, we also considered, but did not propose, using various payment rate benchmarking approaches for benefit categories where Medicaid is the only or primary payer, or there is no comparable Medicare rate. As previously noted in section II. of this proposed rule, we considered benchmarks based on national Medicaid payment averages for certain services included within the LTSS benefit category, benchmarks that use average daily rates for certain HCBS that can be compared to other State Medicaid programs, and benchmarks that use payment data specific to the State's Medicaid program for similarly situated services so that the service payments may be benchmarked to national average. Notwithstanding the previously described limitations of the alternative considered for situations where

[270] *https://www.kff.org/medicaid/issue-brief/pricing-and-payment-for-medicaid-prescription-drugs/.*

differences between Medicaid and Medicare coverage and payment exists, we are seeking public comment regarding our alternative consideration to propose States use a different point of comparison, other than Medicare, for certain services where Medicare is not a consistent or primary payer or States use a payment rate benchmarking approach for benefit categories where Medicaid is the only or primary payer, or there is no comparable Medicare rate. Specifically, we are seeking public comment on the feasibility and burden on States to implement these alternatives considered for the proposed comparative payment rate analysis. For any comparison to other State Medicaid programs or to a national benchmark, we also are seeking public comment on the appropriate role for such a comparison in the context of the statutory requirement to consider beneficiary access relative to the general population in the geographic area.

We considered, but did not propose, various timeframes for the comparative payment rate analysis, including annual (every year), triennial (every 3 years), or quinquennial (every 5 years) updates after the initial effective date of January 1, 2026. As noted in section II. of this proposed rule, we did not propose an annual timeframe as we felt that an annual update requirement was too frequent due to many State's biennial legislative sessions that provide the Medicaid agency with authority it make Medicaid payment rate changes as well as create more or maintain a similar level of administrative burden of the AMRPs. While some States do have annual legislative sessions and may have annual Medicaid payment rate changes, we felt that proposing annual updates solely for the purpose of capturing payment rate changes in States that with annual legislative sessions would be overly burdensome and duplicative for States with biennial legislative sessions who do not have new, updated Medicaid payment rates to update in their comparative payment rate analysis. Therefore, for numerous States with biennial legislative sessions, the resulting analysis would likely not vary significantly from year to year. Additionally, the comparative payment rate analysis proposes to use the most recently published Medicare payment rates and we are cognizant that Medicare payment rate updates often occur on a quarterly basis. While Medicare often increases rates by the market basket inflation amount, as well as through rulemaking, it does not always result in payment increases for providers.[271] [272] We also considered, but did not propose, maintaining the triennial (every 3 years) timeframe currently in regulation, because we thought it necessary to make significant changes to the non-SPA-related reported in § 447.203(b) that would represent a significant departure from the initial AMRP process in the 2015 final rule with comment in the current § 447.203(b)(1) and this new proposed approach did not lend itself to the triennial timeframe of the current AMRP process. Lastly, we considered, but did not propose, the comparative payment rate analysis be published on a quinquennial basis (every 5 years), because this timeframe was too infrequent for the comparative payment rate analysis to provide meaningful, actionable information. As previously noted in section II. of this rule, we are seeking public comment on the proposed timeframe for the initial publication and biennial update requirements of the comparative payment rate analysis as proposed in § 447.203(b)(4). Additionally, we are seeking public comment regarding our alternative consideration to propose an annual, triennial, or quinquennial timeframe for the updating the comparative payment rate analysis after the initial effective date.

We considered, but did not propose, requiring the comparative payment rate analysis be submitted directly to us, as this would not achieve the public transparency goal of the proposed rule. As proposed in § 447.203(b)(3), we are requiring States develop and publish their Medicaid comparative payment rate analysis on the State's website in an accessible and easily understandable format. This proposal is methodologically similar to the current regulation, which requires AMRPs be submitted to us and publicly published by the State and CMS. We found this aspect of the rule to be an effective method of publicly sharing access to care information, as well as ensuring State compliance. As previously noted in section II. of this proposed rule, we are seeking public comment on the proposed requirement for States to publish their Medicaid FFS payment rates for all services and comparative payment rate analysis and payment rate disclosure information on the State's website under the proposed § 447.203(b)(1) and (3), respectively. Additionally, we are seeking public comment regarding our alternative consideration to propose requiring the comparative payment rate analysis be submitted directly to us and not publicly published.

We considered, but did not propose, that we produce and publish the comparative payment rate analysis proposed in § 447.203(b)(2) through (3) whereby we would develop reports for all States demonstrating Medicaid payment rates for all services or a subset for Medicaid services as a percentage of Medicare payment rates. Shifting responsibility for this analysis would remove some burden from States and allow us to do a full cross-comparison of State Medicaid payment rates to Medicare payment rates, while ensuring a consistent rate analysis across States. However, this approach would rely on T–MSIS data, which would increase the lag in available data due to the need for CMS to prepare it, and introduce uncertainty into the results due to ongoing variation in State T–MSIS data quality and completeness. Although our proposed approach still relies on State-supplied data, they are able to perform the comparisons on their own regardless of the readiness and compliance of any other State. Furthermore, we would need to validate its results with States and work through any discrepancies. Ultimately, we determined the increased lag time and uncertainty in results would diminish the utility of the rate analyses proposed in § 447.203(b), if performed by us instead of the States, to support our oversight of State compliance with section 1902(a)(30)(A) of the Act. As previously noted in section II. of this rule, we are seeking public comment on our proposal to require States to develop and publish a comparative payment rate analysis and payment rate disclosure as proposed in § 447.203(b)(2) and (3). Additionally, we are seeking public comment regarding our alternative consideration to propose that we produce and publish the comparative payment rate analysis and payment rate disclosure proposed in § 447.203(b)(2) and (3) for all States.

[271] Although ''market basket'' technically describes the mix of goods and services used in providing health care, this term is also commonly used to denote the input price index (that is, cost category weights and price proxies combined) derived from that market basket. Accordingly, the term ''market basket'' as used in this document refers to the various CMS input price indexes. A CMS market basket is described as a fixed-weight, Laspeyres-type index because it measures the change in price, over time, of the same mix of goods and services purchased in the base period. FAQ—Medicare Market Basket Definitions and General Information, updated May 2022. *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MedicareProgramRatesStats/Downloads/info.pdf* Accessed January 4, 2023.

[272] Medicare Unit Cost Increases Reported as of April 2022. *https://www.cms.gov/files/document/ffs-trends-2021-2023-april-2022.pdf.* Accessed January 4, 2023.

We considered, but did not propose, establishing alternative circumstances from the 2017 SMDL for identifying nominal payment rate adjustments when States propose a rate reduction or restructuring. We previously outlined in SMDL #17–004 several circumstances where Medicaid payment rate reductions generally would not be expected to diminish access: reductions necessary to implement CMS Federal Medicaid payment requirements; reductions that will be implemented as a decrease to all codes within a service category or targeted to certain codes, but for services where the payment rates continue to be at or above Medicare and/or average commercial rates; and reductions that result from changes implemented through the Medicare program, where a State's service payment methodology adheres to the Medicare methodology. This proposed rule would not codify this list of policies that may produce payment rate reductions unlikely to diminish access to Medicaid-covered services. We considered, but did not propose, setting a different percentage for the criteria that State Medicaid rates for each benefit category affected by the reductions or restructurings must, in the aggregate, be at or above 80 percent of the most recent comparable Medicare payment rates after the proposed reduction or restructuring as a threshold. We considered setting the threshold at 100 percent of Medicare to remain consistent with the 2017 SMDL. However, after conducting a literature review, we determined that 80 percent of the most recently published Medicare payment rates is currently the most reliable benchmark of whether a rate reduction or restructuring is likely to diminish access to care. We also considered, but did not propose, setting a different percentage for the criteria that proposed reductions or restructurings result in no more than 4 percent reduction of overall FFS Medicaid expenditures for a benefit category. We considered a variety of percentages, but determined that codifying the 4 percent threshold from the 2017 SMDL and proposed in the 2018 proposed rule [273] was the best option based on our experience implementing this established policy after the publication of the 2017 SMDL. Additionally, we received a significant number of comments in the 2018 proposed rule from State Medicaid agencies that signaled strong support for this percentage threshold as a meaningful threshold for future rate changes.[274] [275] [276] Lastly, we considered, but did not propose, defining what is meant by ''significant'' access concerns received through the public process described in § 447.204 when a State proposes a rate reduction or restructuring. As proposed, we expect State Medicaid agencies to make reasonable determinations about which access concerns are significant when raised through the public process, and as part of our SPA review, may request additional information from the State to better understand any access concerns that have been raised through public processes and whether they are significant. Based on our experience implementing the policies outlined in the 2017 SMDL and a literature review of relevant research about payment rate sufficiency, we proposed criteria for States proposing rate reductions or restructurings that would reduce the SPA submission requirements when those criteria are met. Additionally, each of these thresholds is one of a three-part test where States must meet all three, or else it will trigger a requirement for additional State analysis of the rate reduction or restructuring. As previously noted in section II. of this rule, we are seeking public comment on the streamlined criteria proposed in § 447.203(c)(1). Additionally, we are seeking public comment regarding our alternative consideration to propose establishing alternative circumstances from the 2017 SMDL for identifying nominal payment rate adjustments when States propose a rate reduction or restructuring.

We considered, but did not propose, establishing a minimum set of required data for States above 80 percent of the most recent Medicare payment rates after the proposed reduction or restructuring regardless of the remaining criteria. This requirement would minimize administrative burden on States by not requiring States submit all items in § 447.203(c)(2) and establish a baseline for comparison if future rate reductions or restructurings are proposed that may lower the State's payment rates below 80 percent of the most recent Medicare payment rates. However, we determined that, while we believe 80 percent to be an effective threshold point, we did not want that to serve as the only trigger for additional analysis. As proposed, only States that do not meet all of the proposed requirements in § 447.203(c)(1) will have to submit the required data outlined in § 447.203(c)(2). As previously noted in section II. of this rule, we are seeking public comment on our proposal to require all three criteria described in § 447.203(c)(1)(i) through (iii) for assessing the effect of a proposed payment rate reduction or payment restructuring on access to care. Additionally, we are seeking public comment regarding our alternative consideration to propose establishing alternative circumstances from the 2017 SMDL for identifying nominal payment rate adjustments when States propose a rate reduction or restructuring.

We considered, but did not propose, allowing States to use their own unstructured data, similar to the AMRP process, for States that fail to meet all three criteria in § 447.203(c)(1), thereby eliminating the need for us to develop a template for States proposing rate reductions or restructurings. While this would reduce administrative burden on us and provide States with flexibility in determining relevant data for complying with statutory and regulatory requirements, we received feedback after the 2015 final rule with comment period that States found developing an AMRP from scratch with minimal Federal guidelines a challenging task and other interested parties noted that States had too much discretion in documenting sufficient access to care. Therefore, we proposed developing a template to support State analyses of rate reduction or restructuring SPAs that fail to meet the criteria in § 447.203(c)(1). As noted elsewhere in the preamble, if finalized, we anticipate releasing subregulatory guidance, including a template to support completion of the analysis that would be required under paragraph (c)(2), prior to the beginning date of the *Comparative Payment Rate Analysis and Payment Rate Disclosure Timeframe* proposed in § 447.203(b)(4), which is proposed to begin 2 years after the effective date of the final rule. In the intervening period, we anticipate working directly with States through the SPA review process to ensure compliance with section 1902(a)(30)(A) of the Act. Additionally, we are seeking public comment regarding our alternative consideration to propose allowing States to use their own unstructured data, similar to the AMRP

[273] 83 FR 12696 at 12705.

[274] Connecticut Department of Social Services, Comment Letter on 2018 Proposed Rule (May 21, 2018), *https://downloads.regulations.gov/CMS-2018-0031-0021/attachment_1.pdf.*

[275] California Department of Health Care Services, Comment Letter on 2018 Proposed Rule (May 24, 2018), *https://downloads.regulations.gov/CMS-2018-0031-0090/attachment_1.pdf.*

[276] Florida Agency for Health Care Administration, Comment Letter on 2018 Proposed Rule (May 24, 2018), *https://downloads.regulations.gov/CMS-2018-0031-0083/attachment_1.pdf.*

process, for States that fail to meet all three criteria in § 447.203(c)(1).

After careful consideration, we ultimately determined that the requirements in proposed § 447.203(b) and (c) would strike a more optimal balance between alleviating State and Federal administrative burden, while ensuring a transparent, data-driven, and consistent approach to States' implementation and our oversight of State compliance with the access requirement in section 1902(a)(30)(A) of the Act.

E. Accounting Statement and Table

As required by OMB Circular A–4 (available at *https://www.whitehouse.gov/wp-content/uploads/legacy_drupal_files/omb/circulars/A4/a-4.pdf*), we have prepared an accounting statement in Table 43 showing the classification of the impact associated with the provisions of this proposed rule. Note, Table 43 shown previously in this proposed rule provides a summary of the one-time and annual costs estimates.

TABLE 44—ACCOUNTING TABLE

Category	Estimates	Units		
		Year dollar	Discount rate (%)	Period covered
Regulatory Review Costs:				
Annualized Monetized ($million/year)	.112	2023	7	2024–2028
	.117	2023	3	2024–2028
Costs to States:				
Annualized Monetized ($million/year)	72.12	2023	7	2024–2028
	75.22	2023	3	2024–2028
Costs to Beneficiaries:				
Annualized Monetized ($million/year)	0.47	2023	7	2024–2028
	0.49	2023	3	2024–2028
Costs to Providers:				
Annualized Monetized ($million/year)	102.05	2023	7	2024–2028
	106.44	2023	3	2024–2028
Costs to Managed Care Entities:				
Annualized Monetized ($million/year)	6.84	2023	7	2024–2028
	7.13	2023	3	2024–2028

F. Regulatory Flexibility Act (RFA)

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, we estimate that *almost all* of Home Health Care Services, Services for the Elderly and Persons with Disabilities, and Direct Health and Medical Insurance Carriers are small entities as that term is used in the RFA (include small businesses, nonprofit organizations, and small governmental jurisdictions). The great majority of hospitals and most other health care providers and suppliers are small entities, either by being nonprofit organizations or by meeting the SBA definition of a small business (having revenues of less than $8.0 million to $41.5 million in any 1 year).

For purposes of the RFA, approximately 95 percent of the health care industries impacted are considered small businesses according to the Small Business Administration's size standards with total revenues of $41 million or less in any 1 year.

According to the SBA's website at *http://www.sba.gov/content/small-business-size-standards* HCBS Provider Costs and Managed care Entity fall in the North American Industrial Classification System 621610 Home Health Care Services, 624120 Services for the Elderly and Persons with Disabilities, and 524114 Direct Health and Medical Insurance Carriers.

TABLE 45—HCBS PROVIDERS COSTS AND MANAGED CARE ENTITY SIZE STANDARDS

NAICS (6-digit)	Industry subsector description	SBA size standard/small entity threshold (million)	Total small businesses
621610	Home Health Care Services	$15	20,597
624120	Services for the Elderly and Persons with Disabilities	19	20,740
524114	Direct Health and Medical Insurance Carriers	47	501

Source: 2012 Economic Census. Note, no recent data exist for Enterprise Receipt Size.

Individuals and States are not included in the definition of a small entity. This rule will not have a significant impact measured change in revenue of 3 to 5 percent on a substantial number of small businesses or other small entities. All the industries combined, according to the 2012 Economic Census, earned approximately $46,771,961,000.00. Hence, all the costs combined, amounts to about 1 percent.

Therefore, as its measure of significant economic impact on a substantial number of small entities, HHS uses a change in revenue of more than 3 to 5 percent. We do not believe that this threshold will be reached by the requirements in this proposed rule. Therefore, the Secretary has certified that this proposed will not have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the Act. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. This proposed rule will not have a significant impact on the operations of small rural hospitals since small hospitals are not affected by the proposed rule. Therefore, the Secretary has certified that this proposed rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

G. Unfunded Mandates Reform Act (UMRA)

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2023, that threshold is approximately $177 million. This proposed rule would not impose a mandate that will result in the expenditure by State, local, and Tribal Governments, in the aggregate, or by the private sector, of more than $177 million in any 1 year.

Several of the provisions in the proposed rule address gaps in existing regulations. In these cases, the costs for States to implement those proposals would be minimal. For the remaining areas of the proposed rule, we have sought to minimize burden whenever possible while still achieving the goals of this rulemaking. We further note that, if finalized, States would be able to claim administrative match for the work required to implement the proposals.

H. Federalism

E.O. 13132 establishes certain requirements that an agency must meet when it issues a proposed rule that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. This rule does not impose substantial direct costs on State or local governments, preempt State law, or otherwise have Federalism implications. As mentioned in the previous section of this rule, the costs to States by our estimate do not rise to the level of specified thresholds for significant burden to States. In addition, many proposals amend existing requirements or further requirements that already exist in statute, and as such would not create any new conflict with State law.

I. Conclusion

If the policies in this proposed rule are finalized, it will enable us to implement enhanced access to health care services for Medicaid beneficiaries across FFS, managed care, and HCBS delivery systems.

The analysis in section V. of this proposed rule, together with the rest of this preamble, provides a regulatory impact analysis. In accordance with the provisions of E.O. 12866, this proposed rule was reviewed by the Office of Management and Budget.

Chiquita Brooks-LaSure, Administrator of the Centers for Medicare & Medicaid Services, approved this document on XX XX, 20XX

List of Subjects

42 CFR Part 431

Administrative practice and procedure, Consumer protection, Grant programs—health, Medicaid, Organization and functions (Government agencies), Public assistance programs, Reporting and recordkeeping requirement.

42 CFR Part 438

Administrative practice and procedure, Grant programs—health, Health professions, Medicaid, Older adults, People with Disabilities, Reporting and recordkeeping requirements.

42 CFR Part 441

Administrative practice and procedure, Consumer protection, Grant programs—health, Health professions, Medicaid, Older adults, People with Disabilities, Reporting and recordkeeping requirements

42 CFR Part 447

Accounting, Administrative practice and procedure, Drugs, Grant programs—health, Health facilities, Health professions, Medicaid, Reporting and recordkeeping requirements, and Rural areas.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR Chapter IV as set forth below:

PART 431—STATE ORGANIZATION AND GENERAL ADMINISTRATION

■ 1. The authority citation for part 431 continues to read as follows:

Authority: 42 U.S.C. 1302.

■ 2. Revise § 431.12 to read as follows:

§ 431.12 Medicaid Advisory Committee and Beneficiary Advisory Group.

(a) *Basis and purpose.* This section, based on section 1902(a)(4) of the Act, prescribes State Plan requirements for establishment and ongoing operation of a public Medicaid Advisory Committee (MAC) with a dedicated Beneficiary Advisory Group (BAG) comprised of current and former Medicaid beneficiaries, their family members and caregivers, to advise the State Medicaid agency on matters of concern related to policy development, and matters related to the effective administration of the Medicaid program.

(b) *State plan requirement.* The State Plan must provide for a MAC and a BAG that will advise the Medicaid Agency Director on matters of concern related to policy development and matters related to the effective administration of the Medicaid program.

(c) *Appointment of members.* The agency director, or a higher State authority, must appoint members to the MAC and BAG on a rotating and continuous basis. The State must create a process for recruitment and appointment of members and publish this information on the States website as specified in paragraph (f).

(d) *MAC membership and composition.* The membership of the MAC must be composed of the following percentage and representative categories of interested parties in the State:

(1) Minimum of 25 percent of committee members must be from the BAG.

(2) The remaining committee members must include representation of at least one from each of the following categories:

(A) State or local consumer advocacy groups or other community-based organizations that represent the interests of, or provide direct service, to Medicaid beneficiaries.

(B) Clinical providers or administrators who are familiar with the health and social needs of Medicaid beneficiaries and with the resources available and required for their care. This includes providers or administrators of primary care, specialty care, and long-term care.

(C) Participating Medicaid managed care plans, or the State health plan association representing such plans, as applicable; and

(D) Other State agencies that serve Medicaid beneficiaries (for example, foster care agency, mental health agency, health department, State agencies delegated to conduct eligibility determinations for Medicaid, State Unit on Aging), as ex-officio members.

(e) *Beneficiary Advisory Group.* The State must form and support a BAG, which can be an existing beneficiary group, that is comprised of: Individuals who are currently or have been Medicaid beneficiaries and individuals with direct experience supporting Medicaid beneficiaries (family members or caregivers of those enrolled in Medicaid), to advise and provide input to the State regarding their experience with the Medicaid program, on matters of concern related to policy development and matters related to the effective administration of the Medicaid program.

(1) The MAC members described in paragraph (d)(1) of this section must also be members of the BAG.

(2) The BAG must meet separately from the MAC, on a regular basis, and in advance of each MAC meeting to ensure BAG member preparation for each MAC meeting.

(f) *MAC and BAG administration.* The State agency must create standardized processes and practices for the administration of the MAC and the BAG that are available for public review on the State website. The State agency must—

(1) Develop and publish by posting publicly on its website, bylaws for governance of the MAC and BAG, a current list of MAC and BAG membership, and past meeting minutes of the MAC and BAG meetings, including a list of meeting attendees;

(2) Develop and publish by posting publicly on its website a process for MAC and BAG member recruitment and appointment and selection of MAC and BAG leadership;

(3) Develop, publish by posting publicly on its website, and implement a regular meeting schedule for the MAC and BAG; the MAC and BAG must each meet at least once per quarter and hold off-cycle meetings as needed.

(4) Make at least two MAC meetings per year open to the public and those meetings must include a dedicated time during the meeting for the public to make comments. The public must be adequately notified of the date, location, and time of each public MAC meeting at least 30 calendar days in advance. BAG meetings are not required to be open to the public, unless the State's BAG members decide otherwise. The same requirements would apply to States whose BAG meetings were determined, by its membership, to be open to the public;

(5) Offer a variety of in-person and virtual attendance options including, at a minimum telephone dial-in options at the MAC and BAG meetings for its members. If the MAC or BAG meeting is deemed open to the public, the State must offer at a minimum a telephone dial-in option for members of the public;

(6) Ensure meeting times and locations for MAC and BAG meetings are selected to maximize member attendance and may vary by meeting; and

(7) Facilitate participation of beneficiaries by ensuring that that meetings are accessible to people with disabilities, that reasonable modifications are provided when necessary to ensure access and enable meaningful participation, and communications with individuals with disabilities are as effective as with others, that reasonable steps are taken to provide meaningful access to individuals with Limited English Proficiency, and that meetings comply with the requirements at § 435.905(b) of this chapter and applicable regulations implementing the ADA, section 504 of the Rehabilitation Act, and section 1557 of the Affordable Care Act at 28 CFR part 35 and 45 CFR parts 84 and 92.

(g) *MAC and BAG participation and scope.* The MAC and BAG participants must have the opportunity to participate in and provide recommendations to the State agency on matters related to policy development and matters related to the effective administration of the Medicaid program. At a minimum, the MAC and BAG must determine, in collaboration with the State, which topics to provide advice on related to—

(1) Additions and changes to services;

(2) Coordination of care;

(3) Quality of services;

(4) Eligibility, enrollment, and renewal processes;

(5) Beneficiary and provider communications by State Medicaid agency and Medicaid managed care plans;

(6) Cultural competency, language access, health equity, and disparities and biases in the Medicaid program; or

(7) Other issues that impact the provision or outcomes of health and medical care services in the Medicaid program as by the MAC, BAG, or State.

(h) *State agency staff assistance, participation, and financial help.* The State agency must provide staff to support planning and execution of the MAC and the BAG to include—

(1) Recruitment of MAC and BAG members;

(2) Planning and execution of all MAC and BAG meetings and the production of meeting minutes that include actions taken or anticipated actions by the State in response to interested parties' feedback provided during the meeting. The minutes are to be posted on the State's website within 30 calendar days following each meeting. Additionally, the State must also produce and post on its website an annual report as specified in paragraph (i) of this section; and

(3) The provision of appropriate support and preparation (providing research or other information needed) to the Medicaid beneficiary MAC and BAG members to ensure meaningful participation. These tasks include—

(i) Providing staff whose responsibilities include facilitating MAC and BAG member engagement;

(ii) Providing financial support, if necessary, to facilitate Medicaid beneficiary engagement in the MAC and the BAG.

(iii) Attendance by at least one staff member from the State agency's executive staff at all MAC and BAG meetings.

(i) *Annual report.* The MAC, with support from the State, submit an annual report describing its activities, topics discussed, and recommendations. The State must review the report and include responses to the recommended actions. The State agency must then—

(1) Provide MAC members with final review of the report;

(2) Ensure that the annual report of the MAC includes a section describing the activities, topics discussed, and recommendations of the BAG, as well as the State's responses to the recommendations; and

(3) Post the report to the State's website.

(j) *Federal financial participation.* FFP is available at 50 percent of expenditures for the MAC and BAG activities.

■ 3. Amend § 431.408 by revising paragraph (a)(3)(i) to read as follows:

§ 431.408 State public notice process.

(a) * * *

(3) * * *

(i) The Medicaid Advisory Committee and Beneficiary Advisory Group that operate in accordance with § 431.12 of this subpart; or

* * * * *

PART 438—MANAGED CARE

■ 4. The authority citation for part 438 continues to read as follows:

Authority: 42 U.S.C. 1302.

■ 5. Section 438.72 is added to subpart B to read as follows:

§ 438.72 Additional requirements for long-term services and supports.

(a) [Reserved]

(b) *Services authorized under section 1915(c) waivers and section 1915(i), (j), and (k) State plan authorities.* The State

must comply with the review of the person-centered service plan requirements at § 441.301(c)(1) through (3), the incident management system requirements at § 441.302(a)(6), the payment adequacy requirements at § 441.302(k), the reporting requirements at § 441.311, and the website transparency requirements at § 441.313 for services authorized under section 1915(c) waivers and section 1915(i), (j), and (k) State plan authorities.

PART 441—SERVICES: REQUIREMENTS AND LIMITS APPLICABLE TO SPECIFIC SERVICES

■ 6. The authority citation for part 441 continues to read as follows:

Authority: 42 U.S.C. 1302.

■ 7. Amend § 441.301 by revising paragraphs (c)(1) and (3), and adding paragraph (c)(7) to read as follows:

§ 441.301 Contents of request for a waiver.

* * * * *

(c) * * *

(1) *Person-centered planning process.* The individual, or if applicable, the individual and the individual's authorized representative, will lead the person-centered planning process. When the term ''individual'' is used throughout this section, it includes the individual's authorized representative if applicable. In addition, the person-centered planning process:

* * * * *

(3) *Review of the person-centered service plan*—(i) *Requirement.* The State must ensure that the person-centered service plan is reviewed, and revised, as appropriate, based upon the reassessment of functional need as required by § 441.365(e), at least every 12 months, when the individual's circumstances or needs change significantly, or at the request of the individual.

(ii) *Minimum performance at the State level.* The State must demonstrate, through the reporting requirements at § 441.311(b)(3), that it meets the following minimum performance levels:

(A) Complete a reassessment of functional need at least every 12 months for no less than 90 percent of the individuals continuously enrolled in the waiver for at least 365 days; and

(B) Review and revise, as appropriate, the person-centered service plan, based upon the reassessment of functional need, at least every 12 months for no less than 90 percent of the individuals continuously enrolled in the waiver for at least 365 days.

(iii) *Effective date.* The performance levels described in paragraph (c)(3)(ii) of this section are effective 3 years after the date of enactment of this paragraph; and in the case of the State that implements a managed care delivery system under the authority of sections 1915(a), 1915(b), 1932(a), or 1115(a) of the Act and includes HCBS in the MCO's, PIHP's, or PAHP's contract, the first managed care plan contract rating period that begins on or after 3 years after the date of enactment of this paragraph.

* * * * *

(7) *Grievance system*—(i) *Purpose.* The State must establish a procedure under which a beneficiary may file a grievance related to the State or a provider's compliance with paragraphs (c)(1) through (6) of this section. This requirement does not apply to a managed care delivery system under the authority of sections 1915(a), 1915(b), 1932(a), or 1115(a) of the Act.

(ii) *Definitions.* As used in this section:

Grievance means an expression of dissatisfaction or complaint related to the State's or a provider's compliance with paragraphs (c)(1) through (6), regardless of whether remedial action is requested.

Grievance system means the processes the State implements to handle grievances, as well as the processes to collect and track information about them.

(iii) *General requirements.* (A) The beneficiary or a beneficiary's authorized representative, if applicable, may file a grievance. All references to beneficiary include the role of the beneficiary's representative, if applicable.

(*1*) Another individual or entity may file a grievance on behalf of the beneficiary with the written consent of the beneficiary or authorized representative.

(*2*) A provider cannot file a grievance that would violate the State's conflict of interest guidelines, as required in § 441.540(a)(5).

(B) The State must:

(*1*) Base its grievance processes on written policies and procedures that, at a minimum, meet the conditions set forth in this subsection;

(*2*) Provide beneficiaries reasonable assistance in completing forms and taking other procedural steps related to a grievance. This includes, but is not limited to, ensuring the grievance system is accessible to individuals with disabilities and persons who are limited English proficient, consistent with § 435.905(b) of this chapter, and includes auxiliary aids and services upon request, such as providing interpreter services and toll-free numbers that have adequate TTY/TTD and interpreter capability;

(*3*) Ensure that punitive action is neither threatened nor taken against an individual filing a grievance;

(*4*) Accept grievances and requests for expedited resolution or extension of timeframes from the beneficiary;

(*5*) Provide to the beneficiary the notices and information required under this subsection, including information on their rights under the grievance system and on how to file grievance, and ensure that such information is accessible for individuals with disabilities and individuals who are limited English proficient in accordance with § 435.905(b);

(*6*) Review any grievance resolution with which the beneficiary is dissatisfied; and

(*7*) Provide information about the grievance system to all providers and subcontractors approved to deliver services.

(C) The process for handling grievances must:

(*1*) Allow the beneficiary to file a grievance with the State either orally or in writing.

(*2*) Acknowledge receipt of each grievance.

(*3*) Ensure that the individuals who make decisions on grievances are individuals:

(i) Who were neither involved in any previous level of review or decision-making related to the grievance nor a subordinate of any such individual;

(ii) Who are individuals who have the appropriate clinical and non-clinical expertise, as determined by the State; and

(iii) Who consider all comments, documents, records, and other information submitted by the beneficiary without regard to whether such information was submitted to or considered previously by the State.

(*4*) Provide the beneficiary a reasonable opportunity, face-to-face (including through the use of audio or video technology) and in writing, to present evidence and testimony and make legal and factual arguments related to their grievance. The State must inform the beneficiary of the limited time available for this sufficiently in advance of the resolution timeframe for grievances as specified in paragraphs (c)(7)(v)(B)(*1*) and (*2*) of this section.

(*5*) Provide the beneficiary their case file, including medical records in compliance with 45 CFR 164.510(b), other documents and records, and any new or additional evidence considered, relied upon, or generated by the State related to the grievance. This information must be provided free of charge and sufficiently in advance of the

resolution timeframe for grievance as specified in paragraphs (c)(7)(v)(B)(*1*) and (*2*) of this section.

(*6*) Provide beneficiaries, free of charge, with language services, including written translation and interpreter services in accordance with § 435.905(b), to support their participation in grievance processes and their use of the grievance system.

(iv) *Filing timeframes.* (A) A beneficiary may file a grievance at any time.

(B) The beneficiary may request expedited resolution of a grievance whenever there is a substantial risk that resolution within standard timeframes will adversely affect the beneficiary's health, safety, or welfare, as described in paragraph (c)(7)(v) of this section.

(v) *Resolution and notification*—(A) *Basic rule.* The State must resolve each grievance, and provide notice, as expeditiously as the beneficiary's health, safety, and welfare requires, within State-established timeframes that may not exceed the timeframes specified in this section.

(B) *Specific timeframes*—(*1*) *Standard resolution of grievances.* For standard resolution of a grievance and notice to the affected parties, the timeframe may not exceed 90 calendar days from the day the State receives the grievance. This timeframe may be extended under paragraph (c)(7)(v)(C) of this section.

(*2*) *Expedited resolution of grievances.* For expedited resolution of a grievance and notice to affected parties, the State must establish a timeframe that is no longer than 14 calendar days after the State receives the grievance. This timeframe may be extended under paragraph (c)(7)(v)(C) of this section.

(C) *Extension of timeframes.* (*1*) The States may extend the timeframes from those in paragraph (c)(7)(v)(B) of this section by up to 14 calendar days if—

(*i*) The beneficiary requests the extension; or

(*ii*) The State documents that there is need for additional information and how the delay is in the beneficiary's interest.

(D) *Requirements following extension.* If the State extends the timeframes not at the request of the beneficiary, it must complete all of the following:

(*1*) Make reasonable efforts to give the beneficiary prompt oral notice of the delay.

(*2*) Within 2 calendar days of determining a need for a delay, but no later than the timeframes in paragraph (c)(7)(v)(B) of this section, give the beneficiary written notice of the reason for the decision to extend the timeframe.

(*3*) Resolve the grievance as expeditiously as the beneficiary's health condition requires and no later than the date the extension expires.

(vi) *Format of notice*—(A) *Written notice.* The State must establish a method to notify a beneficiary of the resolution of a grievance and ensure that such methods meet, at a minimum, the standards described at § 435.905(b) of this chapter.

(B) *Oral notice.* For notice of an expedited resolution, the State must also make reasonable efforts to provide oral notice.

(vii) *Recordkeeping.* (A) The State must maintain records of grievances and must review the information as part of its ongoing monitoring procedures.

(B) The record of each grievance must contain, at a minimum, all of the following information:

(*1*) A general description of the reason for the grievance.

(*2*) The date received.

(*3*) The date of each review or, if applicable, review meeting.

(*4*) Resolution of the grievance, as applicable.

(*5*) Date of resolution, if applicable.

(*6*) Name of the beneficiary for whom the grievance was filed.

(C) The record must be accurately maintained in a manner available upon request to CMS.

(viii) *Effective date.* This requirement is effective 2 years after the date of enactment of this paragraph.

■ 8. Amend § 441.302 by—

■ a. Adding paragraph (a)(6);

■ b. Revising paragraph (h);

■ c. Adding new paragraph (k).

The additions and revision read as follows:

§ 441.302 State assurances.

* * * * *

(a) * * *

(6) Assurance that the State operates and maintains an incident management system that identifies, reports, triages, investigates, resolves, tracks, and trends critical incidents.

(i) *Requirements.* The State must:

(A) Define critical incident to include, at a minimum—

(*1*) Verbal, physical, sexual, psychological, or emotional abuse;

(*2*) Neglect;

*(3) E*xploitation including financial exploitation;

(*4*) Misuse or unauthorized use of restrictive interventions or seclusion;

(*5*) A medication error resulting in a telephone call to or a consultation with a poison control center, an emergency department visit, an urgent care visit, a hospitalization, or death; or

(*6*) An unexplained or unanticipated death, including but not limited to a death caused by abuse or neglect.

(B) Use an information system, as defined in 45 CFR 164.304 and compliant with 45 CFR part 164, that, at a minimum—

(*1*) Enables electronic critical incident data collection;

(*2*) Tracking (including of the status and resolution of investigations), and;

(*3*) Trending.

(C) Require providers to report to the State, within State-established timeframes and procedures, any critical incident that occurs during the delivery of services authorized under section 1915(c) of the Act and as specified in the waiver participant's person-centered service plan, or occurs as a result of the failure to deliver services authorized under section 1915(c) of the Act and as specified in the waiver participant's person-centered service plan.

(D) Use claims data, Medicaid fraud control unit data, and data from other State agencies such as Adult Protective Services or Child Protective Services to the extent permissible under applicable State law to identify critical incidents that are unreported by providers and occur during the delivery of services authorized under section 1915(c) of the Act and as specified in the waiver participant's person-centered service plan, or occur as a result of the failure to deliver services authorized under section 1915(c) of the Act and as specified in the waiver participant's person-centered service plan.

(E) Ensure that there is information sharing on the status and resolution of investigations, such as through the use of information sharing agreements, between the State and the entity or entities responsible in the State for investigating critical incidents as defined in § 441.302(a)(6)(i)(A) if the State refers critical incidents to other entities for investigation;

(F) Separately investigate critical incidents if the investigative agency fails to report the resolution of an investigation within State-specified timeframes; and

(G) Demonstrate that it meets the requirements in paragraph (a)(6) of this section through the reporting requirement at § 441.311(b)(1).

(ii) *Minimum performance at the State level.* The State must demonstrate, through the reporting requirements at § 441.311(b)(2), that it meets the following minimum performance levels:

(A) Initiate an investigation, within State-specified timeframes, for no less than 90 percent of critical incidents;

(B) Complete an investigation and determine the resolution of the investigation, within State-specified timeframes, for no less than 90 percent of critical incidents; and

(C) Ensure that corrective action has been completed within State-specified timeframes, for no less than 90 percent of critical incidents that require corrective action.

(iii) *Effective date.* This requirement is effective 3 years after the date of enactment of this paragraph; and in the case of the State that implements a managed care delivery system under the authority of sections 1915(a), 1915(b), 1932(a), or 1115(a) of the Act and includes HCBS in the MCO's, PIHP's, or PAHP's contract, the first managed care plan contract rating period that begins on or after 3 years after the date of enactment of this paragraph.

* * * * *

(h) *Reporting.* Assurance that the agency will provide CMS with information on the waiver's impact, including the data and information as required in § 441.311.

* * * * *

(k) *HCBS payment adequacy.* Assurance that payment rates are adequate to ensure a sufficient direct care workforce to meet the needs of beneficiaries and provide access to services in the amount, duration, and scope specified in the person-centered service plan.

(1) *Definitions.* As used in this section.

(i) *Compensation* means:

(A) Salary, wages, and other remuneration as defined by the Fair Labor Standards Act and implementing regulations (29 U.S.C. 201 *et seq.,* 29 CFR parts 531 and 778);

(B) Benefits (such as health and dental benefits, sick leave, and tuition reimbursement); and

(C) The employer share of payroll taxes for direct care workers delivering services authorized under section 1915(c) of the Act.

(ii) *Direct care worker* means any of the following individuals:

(A) A registered nurse, licensed practical nurse, nurse practitioner, or clinical nurse specialist who provides nursing services to Medicaid-eligible individuals receiving home and community-based services available under this subpart;

(B) A licensed or certified nursing assistant who provides such services under the supervision of a registered nurse, licensed practical nurse, nurse practitioner, or clinical nurse specialist;

(C) A direct support professional;

(D) A personal care attendant;

(E) A home health aide; or

(F) Other individuals who are paid to provide services to address activities of daily living or instrumental activities of daily living, behavioral supports, employment supports, or other services to promote community integration directly to Medicaid-eligible individuals receiving home and community-based services available under this subpart.

(G) A direct care worker may be employed by a Medicaid provider, State agency, or third party; contracted with a Medicaid provider, State agency, or third party; or delivering services under a self-directed service model.

(2) *Requirement.* The State must demonstrate, through the reporting requirements at § 441.311(e), that it meets the minimum performance levels in paragraph (k)(3) of this section for the services at § 440.180(b)(2) through (4) that are delivered by direct care workers and authorized under section 1915(c) of the Act.

(3) *Minimum performance at the State level.* The State must meet the following minimum performance level, calculated as the percentage of total payment for a service represented by total compensation to direct care workers:

(i) At least 80 percent of all payments with respect to services at § 440.180(b)(2) through (4) must be spent on compensation for direct care workers.

(ii) [Reserved]

(4) *Effective date.* This requirement is effective 4 years after the date of enactment of this paragraph; and in the case of the State that implements a managed care delivery system under the authority of sections 1915(a), 1915(b), 1932(a), or 1115(a) of the Act and includes HCBS in the MCO's, PIHP's, or PAHP's contract, the first managed care plan contract rating period that begins on or after 4 years after the date of enactment of this paragraph.

■ 9. Amend § 441.303 by revising paragraph (f)(6) to read as follows:

§ 441.303 Supporting documentation required.

* * * * *

(f) * * *

(6) The State must indicate the number of unduplicated beneficiaries to which it intends to provide waiver services in each year of its program. This number will constitute a limit on the size of the waiver program unless the State requests and the Secretary approves a greater number of waiver participants in a waiver amendment. If the State has a limit on the size of the waiver program and maintains a list of individuals who are waiting to enroll in the waiver program, the State must meet the reporting requirements at § 441.311(d)(1).

* * * * *

■ 10. Section 441.311 is added to subpart G to read as follows:

§ 441.311 Reporting requirements.

(a) *Basis and scope.* Section 1902(a)(6) of the Act requires State Medicaid agencies to make such reports, in such form and containing such information, as the Secretary may from time to time require, and to comply with such provisions as the Secretary may from time to time find necessary to assure the correctness and verification of such reports. Section 1902(a)(19) of the Act requires States to provide safeguards to assure that eligibility for Medicaid-covered care and services will be determined and provided in a manner that is consistent with simplification, simplicity of administration, and in the best interest of Medicaid beneficiaries. This section describes the reporting requirements for States for section 1915(c) waiver programs, under the authority at section 1902(a)(6) and (a)(19) of the Act.

(b) *Compliance reporting*—(1) *Incident management system.* As described in § 441.302(a)(6)—

(i) The State must report, every 24 months, according to the format and specifications provided by CMS, on the results of an incident management system assessment to demonstrate that it meets the requirements in § 441.302(a)(6).

(ii) CMS may reduce the frequency of reporting to up to once every 60 months for States with incident management systems that are determined by CMS to meet the requirements in § 441.302(a)(6).

(2) *Critical incidents,* as defined in § 441.302(a)(6)(i)(A). The State must report to CMS annually on the following, according to the format and specifications provided by CMS:

(i) Number and percent of critical incidents for which an investigation was initiated within State-specified timeframes;

(ii) Number and percent of critical incidents that are investigated and for which the State determines the resolution within State-specified timeframes;

(iii) Number and percent of critical incidents requiring corrective action, as determined by the State, for which the required corrective action has been completed within State-specified timeframes.

(3) *Person-centered planning,* as described in § 441.301(c)(1) through (3).

(i) Percent of beneficiaries continuously enrolled for at least 365 days for whom a reassessment of functional need was completed within the past 12 months. The State may report this metric for a statistically valid random sample of beneficiaries.

(ii) Percent of beneficiaries continuously enrolled for at least 365 days who had a service plan updated as a result of a re-assessment of functional need within the past 12 months. The State may report this metric for a statistically valid random sample of beneficiaries.

(4) The type, amount, and cost of services provided under the State plan.

(c) *Reporting on the Home and Community-Based Services Quality Measure Set,* as described in § 441.312.

(1) *General rules.* The State—

(i) Must report every other year, according to the format and schedule prescribed by the Secretary through the process for developing and updating the measure set described in § 441.312(d), on all measures in the Home and Community-Based Services Quality Measure Set that are identified by the Secretary pursuant to § 441.312(d)(1)(ii) of this subpart.

(ii) May report on all other measures in the Home and Community-Based Services Quality Measure Set that are not described in § 441.312(d)(1)(ii) and (iii) of this subpart.

(iii) Must establish, subject to CMS review and approval, State performance targets for each of the measures in the Home and Community-Based Services Quality Measure Set that are identified by the Secretary pursuant to § 441.312(d)(1)(ii) and (iii) of this subpart and describe the quality improvement strategies that the State will pursue to achieve the performance targets.

(iv) May establish State performance targets for each of the measures in the Home and Community-Based Services Quality Measure Set that are not identified by the Secretary pursuant to § 441.312(d)(1)(ii) and (iii) of this subpart and describe the quality improvement strategies that the State will pursue to achieve the performance targets.

(2) Measures identified per § 441.312(d)(1)(iii) of this subpart will be reported by the Secretary on behalf of the State.

(3) In reporting on Home and Community-Based Services Quality Measure Set measures, the State may, but is not required to:

(i) Report on the measures identified by the Secretary pursuant to § 441.312(c) of this subpart for which reporting will be, but is not yet required (that is, reporting has not yet been phased-in).

(ii) Report on the populations identified by the Secretary pursuant to § 441.312(c) of this subpart for whom reporting will be, but is not yet required.

(d) *Access reporting.* The State must report to CMS annually on the following, according to the format and specifications provided by CMS:

(1) *Waiver waiting lists.* (i) A description of how the State maintains the list of individuals who are waiting to enroll in the waiver program, if the State has a limit on the size of the waiver program, as described in § 441.303(f)(6), and maintains a list of individuals who are waiting to enroll in the waiver program. This description must include, but is not limited to:

(A) Information on whether the State screens individuals on the list for eligibility for the waiver program;

(B) Whether the State periodically re-screens individuals on the list for eligibility; and

(C) The frequency of re-screening, if applicable.

(ii) Number of people on the list of individuals who are waiting to enroll in the waiver program, if applicable.

(iii) Average amount of time that individuals newly enrolled in the waiver program in the past 12 months were on the list of individuals waiting to enroll in the waiver program, if applicable.

(2) *Access to homemaker services, home health aide, and personal care.* (i) Average amount of time from when homemaker services, home health aide services, or personal care services, as listed in § 440.180(b)(2) through (4), are initially approved to when services began, for individuals newly approved to begin receiving services within the past 12 months. The State may report this metric for a statistically valid random sample of beneficiaries.

(ii) Percent of authorized hours for homemaker services, home health aide services, or personal care services, as listed in § 440.180(b)(2) through (4), that are provided within the past 12 months. The State may report this metric for a statistically valid random sample of beneficiaries.

(e) *Payment adequacy.* The State must report to CMS annually on the percent of payments for certain services, as specified in § 441.302(k)(3)(i), that are spent on compensation for direct care workers, at the time and in the form and manner specified by CMS. The State must report separately for each service and, within each service, must separately report services that are self-directed.

(1) *Services.* The State must report on payment adequacy for the services at § 440.180(b)(2) through (4) that are authorized under section 1915(c) of the Act.

(2) [Reserved]

(f) *Effective date.* (1) The reporting requirements at paragraphs (b) through (d) of this section are effective 3 years after the date of enactment of this paragraph; and in the case of a State that implements a managed care delivery system under the authority of sections 1915(a), 1915(b), 1932(a), or 1115(a) of the Act and includes HCBS in the MCO's, PIHP's, or PAHP's contract, the first managed care plan contract rating period that begins on or after 3 years after the date of enactment of this paragraph.

(2) The reporting requirements at paragraph (e) of this section are effective 4 years after the date of enactment of this paragraph; and in the case of a State that implements a managed care delivery system under the authority of sections 1915(a), 1915(b), 1932(a), or 1115(a) of the Act and includes HCBS in the MCO's, PIHP's, or PAHP's contract, the first managed care plan contract rating period that begins on or after 4 years after the date of enactment of this paragraph.

■ 11. Section 441.312 is added to subpart G to read as follows:

§ 441.312 Home and Community-Based Services Quality Measure Set.

(a) *Basis and scope.* Section 1102(a) of the Act provides the Secretary of HHS with authority to make and publish rules and regulations that are necessary for the efficient administration of the Medicaid program. Section 1902(a)(6) of the Act requires State Medicaid agencies to make such reports, in such form and containing such information, as the Secretary may from time to time require, and to comply with such provisions as the Secretary may from time to time find necessary to assure the correctness and verification of such reports. This section describes the Home and Community-Based Services Quality Measure Set, which States are required to use in section 1915(c) waiver programs to promote public transparency related to the administration of Medicaid covered HCBS, under the authority at sections 1102(a) and 1902(a)(6) of the Act.

(b) *Definitions.* As used in this subpart—

Attribution rules means the process States use to assign beneficiaries to a specific health care program or delivery system for the purpose of calculating the measures on the Home and Community-Based Services Quality Measure Set.

Home and Community-Based Services Quality Measure Set means the Home and Community-Based Services Quality Measures for Medicaid established and updated at least every other year by the Secretary through a process that allows for public input and comment,

including through the **Federal Register**, as described in paragraph (d) of this section.

(c) *Responsibilities of the Secretary.* The Secretary shall—

(1) Identify, and update at least every other year, beginning no later than December 31, 2025 and biennially thereafter, the quality measures to be included in the Home and Community-Based Services Quality Measure Set as defined in paragraph (b) of this section.

(2) Consult at least every other year with States and other interested parties identified in paragraph (g) of this section to—

(i) Establish priorities for the development and advancement of the Home and Community-Based Services Quality Measure Set;

(ii) Identify newly developed or other measures which should be added including to address any gaps in the measures included in the Home and Community-Based Services Quality Measure Set;

(iii) Identify measures which should be removed as they no longer strengthen the Home and Community-Based Services Quality Measure Set; and

(iv) Ensure that all measures included in the Home and Community-Based Services Quality Measure Set reflect an evidence-based process including testing, validation, and consensus among interested parties; are meaningful for States; are feasible for State-level, program-level, or provider-level reporting as appropriate.

(3) In consultation with States, develop and update, at least every other year, the HCBS Quality Measure Set using a process that allows for public input and comment as described in paragraph (d) of this section.

(d) *Process for developing and updating the HCBS Quality Measure Set.* The process for developing and updating the HCBS Quality Measure Set will address all of the following:

(1) Identification of all measures in the Home and Community-Based Services Quality Measure Set, including:

(i) Measures newly added and measures removed from the prior version of the Home and Community-Based Services Quality Measure Set;

(ii) The specific measures for which reporting is mandatory;

(iii) The measures for which the Secretary will complete reporting on behalf of States and the measures for which States may elect to have the Secretary report on their behalf; and

(iv) The measures, if any, for which the Secretary will provide States with additional time to report, as well as how much additional time the Secretary will provide, in accordance with paragraph (c) of this section.

(2) Technical information to States on how to collect and calculate the data on the Home and Community-Based Services Quality Measure Set.

(3) Standardized format and reporting schedule for reporting measure data required under this section.

(4) Procedures that State agencies must follow in reporting measure data required under this section.

(5) Identification of the populations for which States must report the measures identified by the Secretary under paragraph (e) of this section, which may include, but is not limited to beneficiaries—

(i) Receiving services through specified delivery systems, such as those enrolled in a managed care plan or receiving services on a fee-for-service basis;

(ii) Who are dually eligible for Medicare and Medicaid, including beneficiaries whose medical assistance is limited to payment of Medicare premiums or cost sharing;

(iii) Who are older adults;

(iv) Who have physical disabilities;

(v) Who have intellectual and development disabilities;

(vi) Who have serious mental illness; and

(vii) Who have other health conditions.

(6) Technical information on attribution rules for determining how States must report on measures for beneficiaries who are included in more than one population, as described in paragraph (d)(5) of this section, during the reporting period.

(7) The subset of measures among the measures in the Home and Community-Based Services Quality Measure Set that must be stratified by race, ethnicity, sex, age, rural/urban status, disability, language, Tribal status, or such other factors as may be specified by the Secretary and informed by consultation every other year with States and interested parties in accordance with paragraph (b)(2) and subsection (g) of this section.

(8) Describe how to establish State performance targets for each of the measures in the Home and Community-Based Services Quality Measure Set.

(e) *Phasing in of certain reporting.* As part of the process that allows for developing and updating the Home and Community-Based Services Quality Measure Set described in paragraph (d) of this section, the Secretary may provide that mandatory State reporting for certain measures and reporting for certain populations of beneficiaries will be phased in over a specified period of time, taking into account the level of complexity required for such State reporting.

(f) *Selection of measures for stratification.* In specifying which measures, and by which factors, States must report stratified measures consistent with paragraph (d)(7) of this section, the Secretary will take into account whether stratification can be accomplished based on valid statistical methods and without risking a violation of beneficiary privacy and, for measures obtained from surveys, whether the original survey instrument collects the variables necessary to stratify the measures, and such other factors as the Secretary determines appropriate; the Secretary will require stratification of 25 percent of the measures in the Home and Community-Based Services Quality Measure Set for which the Secretary has specified that reporting should be stratified by 3 years after the effective date of these regulations, 50 percent of such measures by 5 years after the effective date of these regulations, and 100 percent of measures by 7 years after the effective date of these regulations.

(g) *Consultation with interested parties.* For purposes of paragraph (c)(2) of this section, the Secretary must consult with interested parties as described in this paragraph to include the following:

(1) State Medicaid Agencies and agencies that administer Medicaid-covered home and community-based services.

(2) Health care and home and community-based services professionals, including members of the allied health professions who specialize in the care and treatment of older adults, children and adults with disabilities, and individuals with complex medical needs.

(3) Health care and home and community-based services professionals (including members of the allied health professions), providers, and direct care workers who provide services to older adults, children and adults with disabilities, and individuals with complex medical and behavioral health care needs who live in urban and rural medically underserved communities or who are members of distinct population sub-groups at heightened risk for poor outcomes.

(4) Providers of home and community-based services.

(5) Direct care workers and national organizations representing direct care workers.

(6) Consumers and national organizations representing older adults, children and adults with disabilities,

and individuals with complex medical needs.

(7) National organizations and individuals with expertise in home and community-based services quality measurement.

(8) Voluntary consensus standards setting organizations and other organizations involved in the advancement of evidence-based measures of health care.

(9) Measure development experts.

(10) Such other interested parties as the Secretary may determine appropriate.

■ 12. Section 441.313 is added to subpart G to read as follows:

§ 441.313 website transparency.

(a) The State must operate a website consistent with § 435.905(b) of this chapter that provides the results of the reporting requirements specified at § 441.311. The State must:

(1) Include all content on one web page, either directly or by linking to individual managed care organization, prepaid ambulatory health plan, prepaid inpatient health plan, and primary care case management, as defined in part 438, entity websites;

(2) Include clear and easy to understand labels on documents and links;

(3) Verify no less than quarterly, the accurate function of the website and the timeliness of the information and links; and

(4) Include prominent language on the website explaining that assistance in accessing the required information on the website is available at no cost and include information on the availability of oral interpretation in all languages and written translation available in each non-English language, how to request auxiliary aids and services, and a toll-free and TTY/TDY telephone number.

(b) CMS must report on its website the results of the reporting requirements specified at § 441.311 that the State reports to CMS.

(c) These requirements are effective 3 years after the date of enactment of this paragraph; and in the case of the State that implements a managed care delivery system under the authority of sections 1915(a), 1915(b), 1932(a), and 1115(a) of the Act and includes HCBS in the MCO's, PIHP's, or PAHP's contract, the first managed care plan contract rating period that begins on or after 3 years after the date of enactment of this paragraph.

■ 13. Amend § 441.450 in paragraph (c) by adding, in alphabetical order, the definition of ''Service plan'' to read as follows:

§ 441.450 Basis, scope, and definitions.

* * * * *

(c) * * *

Service plan means the written document that specifies the services and supports (regardless of funding source) that are to be furnished to meet the needs of a participant in the self-directed PAS option and to assist the participant to direct the PAS and to live in the community. The service plan is developed based on the assessment of need using a person-centered and directed process. The service plan supports the participant's engagement in community life and respects the participant's preferences, choices, and abilities. The participant's representative, if any, families, friends, and professionals, as desired or required by the participant, will be involved in the service-planning process. Service plans must meet the requirements of § 441.301(c)(3).

* * * * *

■ 14. Amend § 441.464 by–

■ a. Revising paragraph (d)(2)(v);

■ b. Redesignating current paragraphs (e) and (f) as paragraphs (g) and (h); and

■ c. Adding a new paragraphs (e) and (f).

The revisions and additions read as follows:

§ 441.464 State assurances.

* * * * *

(d) * * *

(2) * * *

(v) Grievance process, as defined in § 441.301(c)(7) when self-directed PAS include services under a section 1915(c) waiver program.

* * * * *

(e) *Incident management system.* The State operates and maintains an incident management system that identifies, reports, triages, investigates, resolves, tracks, and trends critical incidents and adheres to requirements of § 441.302(a)(6).

(f) *Payment rates* are adequate to ensure a sufficient direct care workforce to meet the needs of beneficiaries and provide access to services in the amount, duration, and scope specified in the person-centered service plan, in accordance with § 441.302(k).

* * * * *

■ 15. Amend § 441.474 by adding paragraph (c) to read as follows:

§ 441.474 Quality assurance and improvement plan.

* * * * *

(c) The quality assurance and improvement plan must comply with all components of §§ 441.311 and 441.312 and related reporting requirements relevant to the State's self-directed PAS program.

* * * * *

■ 16. Section 441.486 is added to subpart J to read as follows:

§ 441.486 website transparency.

For States subject to the requirements of subpart J, the State must operate a website consistent with § 441.313.

■ 17. Amend § 441.540 by revising paragraph (c) to read as follows:

§ 441.540 Person-centered service plan.

* * * * *

(c) *Reviewing the person-centered service plan.* The State must ensure that the person-centered service plan is reviewed, and revised, as appropriate, based upon the reassessment of functional need, at least every 12 months, when the individual's circumstances or needs change significantly, and at the request of the individual. States must adhere to the requirements of § 441.301(c)(3).

* * * * *

■ 18. Amend § 441.555 by revising paragraph (b)(2)(iv) to read as follows:

§ 441.555 Support system.

* * * * *

(b) * * *

(2) * * *

(iv) Grievance process, as defined in § 441.301(c)(7).

* * * * *

■ 19. Amend § 441.570 by adding paragraphs (e) and (f) to read as follows:

§ 441.570 State assurances.

* * * * *

(e) An incident management system in accordance with § 441.302(a)(6) is implemented.

(f) Payment rates are adequate to ensure a sufficient direct care workforce to meet the needs of beneficiaries and provide access to services in the amount, duration, and scope specified in the person-centered service plan, in accordance with § 441.302(k).

■ 20. Amend § 441.580 by redesignating paragraph (i) as (j), and adding a new paragraph (i) to read as follows:

§ 441.580 Data collection.

* * * * *

(i) Data and information as required in § 441.311.

* * * * *

■ 21. Amend § 441.585 by adding paragraph (d) to read as follows:

§ 441.585 Quality assurance system.

* * * * *

(d) The State must implement the Home and Community-Based Services Quality Measure Set in accordance with § 441.312.

■ 22. Section 441.595 is added to subpart K to read as follows—

§ 441.595 website transparency.

For States subject to the requirements of subpart K, the State must operate a website consistent with § 441.313.

■ 23. Amend § 441.725 by revising paragraph (c) to read as follows:

§ 441.725 Person-centered service plan.

* * * * *

(c) Reviewing the person-centered service plan. The State must ensure that the person-centered service plan is reviewed, and revised, as appropriate, based upon the reassessment of functional need as required in § 441.720, at least every 12 months, when the individual's circumstances or needs change significantly, and at the request of the individual. States must adhere to the requirements of § 441.301(c)(3).

* * * * *

■ 24. Amend § 441.745 by—

■ a. Redesignating paragraph (a)(1)(iii) as paragraph (a)(1)(iv);

■ b. Adding new paragraphs (a)(iii) and (a)(v) through (vii);

■ c. Revising paragraph (b)(1)(i); and

■ d. Adding paragraph (b)(1)(v).

The revision and additions read as follows:

§ 441.745 State plan HCBS administration: State responsibilities and quality improvement.

* * * * *

(a) * * *

(1) * * *

(iii) *Grievances.* A State must provide individuals with the opportunity to file a grievance as defined in section § 441.301(c)(7).

* * * * *

(v) A State must implement an incident management system in accordance with § 441.302(a)(6).

(vi) A State must assure payment rates are adequate to ensure a sufficient direct care workforce to meet the needs of beneficiaries and provide access to services in the amount, duration, and scope specified in the person-centered service plan, in accordance with § 441.302(k).

(vii) A State must assure the submission of data and information as required in § 441.311.

* * * * *

(b) * * *

(1) * * *

(i) Incorporate a continuous quality improvement process that includes monitoring, remediation, and quality improvement, including recognizing and reporting critical incidents, as defined in § 441.302(a)(6)(i)(A).

* * * * *

(v) Implementation of the Home and Community-Based Services Quality Measure Set in accordance with § 441.312.

* * * * *

■ 25. Section § 441.750 is added to subpart M to read as follows—

§ 441.750 Website transparency.

For States subject to the requirements of subpart M, the State must operate a website consistent with § 441.313.

* * * * *

PART 447—PAYMENT FOR SERVICES

■ 26. The authority citation for part 447 is revised to read as follows:

Authority: 42 U.S.C. 1302, and 1396r–8, and Pub. L. 111–148.

■ 27. Amend § 447.203 by revising paragraph (b) and adding paragraph (c) to read as follows:

§ 447.203 Documentation of access to care and service payment rates.

* * * * *

(b)(1) *Payment rate transparency.* The State agency is required to publish all Medicaid fee-for-service payment rates on a website developed and maintained by the single State agency that is accessible to the general public. Published Medicaid fee-for-service payment rates include fee schedule payment rates made to providers delivering Medicaid services to Medicaid beneficiaries through a fee-for-service delivery system. The website where the State agency publishes its Medicaid fee-for-service payment rates must be easily reached from a hyperlink on the State Medicaid agency's website. Medicaid fee-for-service payment rates must be organized in such a way that a member of the public can readily determine the amount that Medicaid would pay for the service and, in the case of a bundled or similar payment methodology, identify each constituent service included within the rate and how much of the bundled payment is allocated to each constituent service under the State's methodology. If the rates vary, the State must separately identify the Medicaid fee-for-service payment rates by population (pediatric and adult), provider type, and geographical location, as applicable. The initial publication of the Medicaid fee-for-service payment rates shall occur no later than January 1, 2026 and include approved Medicaid fee-for-service payment rates in effect as of January 1, 2026. The agency is required to include the date the payment rates were last updated on the State Medicaid agency's website and to ensure these data are kept current where any necessary update must be made no later than 1 month following the date of CMS approval of the State plan amendment, section 1915(c) HCBS waiver amendment, or similar amendment revising the provider payment rate or methodology. In the event of a payment rate change that occurs in accordance with a previously approved rate methodology, the State will update its payment rate transparency publication no later than 1 month after the effective date of the most recent update to the payment rate.

(2) *Comparative payment rate analysis and payment rate disclosure.* The State agency is required to develop and publish a comparative payment rate analysis of Medicaid payment rates for each of the following categories of services in paragraphs (b)(2)(i) through (iii) of this section and a payment rate disclosure of Medicaid payment rates for each of the following categories of services in paragraph (b)(2)(iv) of this section, as specified in paragraph (b)(3) of this section. If the rates vary, the State must separately identify the payment rates by population (pediatric and adult), provider type, and geographical location, as applicable.

(i) Primary care services.

(ii) Obstetrical and gynecological services.

(iii) Outpatient behavioral health services.

(iv) Personal care, home health aide, and homemaker services, as specified in § 440.180(b)(2) through (4), provided by individual providers and providers employed by an agency.

(3) *Comparative payment rate analysis and payment rate disclosure requirements.* The State agency must develop and publish, consistent with the publication requirements described in paragraph (b)(1) of this section for payment rate transparency data, a comparative payment rate analysis and a payment rate disclosure.

(i) For the categories of services described in paragraph (b)(2)(i) through (iii) of this section, the comparative payment rate analysis must compare the State agency's Medicaid fee-for-service payment rates to the most recently published Medicare payment rates effective for the same time period for the evaluation and management (E/M) codes applicable to the category of service. The State must conduct the comparative payment rate analysis at the Current Procedural Terminology (CPT) or Healthcare Common Procedure Coding System (HCPCS) code level, as applicable, using the most current set of codes published by CMS, and the analysis must meet the following requirements:

(A) The State must organize the analysis by category of service as described in paragraphs (b)(2)(i) through (iii) of this section.

(B) The analysis must clearly identify the Medicaid base payment rates for each E/M CPT/HCPCS code identified by CMS under the applicable category of service, including, if the rates vary, separate identification of the payment rates by population (pediatric and adult), provider type, and geographical location, as applicable.

(C) The analysis must clearly identify the Medicare non-facility payment rates effective for the same time period for the same set of E/M CPT/HCPCS codes, and for the same geographical location as the Medicaid base payment rates, that correspond to the Medicaid base payment rates identified under paragraph (b)(3)(i)(B) of this section, including, separate identification of the payment rates by provider type.

(D) The analysis must specify the Medicaid base payment rate identified under paragraph (b)(3)(i)(B) of this section as a percentage of the Medicare non-facility payment rate identified under paragraph (b)(3)(i)(C) of this section for each of the services for which the Medicaid base payment rate is published pursuant to paragraph (b)(3)(i)(B) of this section.

(E) The analysis must specify the number of Medicaid-paid claims and the number of Medicaid enrolled beneficiaries who received a service within a calendar year for each of the services for which the Medicaid base payment rate is published pursuant to paragraph (b)(3)(i)(B) of this section.

(ii) For each category of services specified in paragraph (b)(2)(iv) of this section, the State agency is required to publish a payment rate disclosure that expresses the State's payment rates as the average hourly payment rates, separately identified for payments made to individual providers and to providers employed by an agency, if the rates vary. The payment rate disclosure must meet the following requirements:

(A) The State must organize the payment rate disclosure by category of service as specified in paragraph (b)(2)(iv) of this section.

(B) The disclosure must identify the average hourly payment rates by applicable category of service, including, if the rates vary, separate identification of the average hourly payment rates for payments made to individual providers and to providers employed by an agency, by population (pediatric and adult), provider type, and geographical location, as applicable.

(C) The disclosure must identify the number of Medicaid-paid claims and the number of Medicaid enrolled beneficiaries who received a service within a calendar year for each of the services for which the average hourly payment rates are published pursuant to paragraph (b)(3)(ii)(B) of this section.

(4) *Comparative payment rate analysis and payment rate disclosure timeframe.* The State agency must publish the initial comparative payment rate analysis and payment rate disclosure of its Medicaid payment rates in effect as of January 1, 2025 as required under paragraphs (b)(2) and (b)(3) of this section, by no later than January 1, 2026. Thereafter, the State agency must update the comparative payment rate analysis and payment rate disclosure no less than every 2 years, by no later than January 1 of the second year following the most recent update. The comparative payment rate analysis and payment rate disclosure must be published consistent with the publication requirements described in paragraph (b)(1) of this section for payment rate transparency data.

(5) *Compliance with payment rate transparency, comparative payment rate analysis, and payment rate disclosure requirements.* If a State fails to comply with the payment rate transparency, comparative payment rate analysis, and payment rate disclosure requirements in paragraphs (b)(1) through (b)(4) of this section, including requirements for the time and manner of publication, future grant awards may be reduced under the procedures set forth at 42 CFR part 430, subparts C and D by the amount of FFP CMS estimates is attributable to the State's administrative expenditures relative to the total expenditures for the categories of services specified in paragraph (b)(2) of this section for which the State has failed to comply with applicable requirements, until such time as the State complies with the requirements. Unless otherwise prohibited by law, deferred FFP for those expenditures will be released after the State has fully complied with all applicable requirements.

(6) *Interested parties advisory group for rates paid for certain services.* (i) The State agency must establish an advisory group for interested parties to advise and consult on provider rates with respect to service categories under the Medicaid State plan, 1915(c) waiver, and demonstration programs, as applicable, where payments are made to the direct care workers specified in § 441.302(k)(1)(ii) for the self-directed or agency-directed services found at § 440.180(b)(2) through (4).

(ii) The interested parties advisory group must include, at a minimum, direct care workers, beneficiaries, beneficiaries' authorized representatives, and other interested parties impacted by the services rates in question, as determined by the State.

(iii) The interested parties advisory group will advise and consult with the Medicaid agency on current and proposed payment rates, HCBS payment adequacy data as required at § 441.311(e), and access to care metrics described in § 441.311(d)(2), associated with services found at § 440.180(b)(2) through (4), to ensure the relevant Medicaid payment rates are sufficient to ensure access to personal care, home health aide, and homemaker services for Medicaid beneficiaries at least as great as available to the general population in the geographic area and to ensure an adequate number of qualified direct care workers to provide self-directed personal assistance services.

(iv) The interested parties advisory group shall meet at least every 2 years and make recommendations to the Medicaid agency on the sufficiency of State plan, 1915(c) waiver, and demonstration direct care worker payment rates, as applicable. The State agency will ensure the group has access to current and proposed payment rates, HCBS provider payment adequacy minimum performance and reporting standards as described in § 441.311(e), and applicable access to care metrics as described in § 441.311(d)(2) for HCBS in order to produce these recommendations. The process by which the State selects interested party advisory group members and convenes its meetings must be made publicly available.

(v) The Medicaid agency must publish the recommendations produced under paragraph (b)(6)(iv) of the interested parties advisory group consistent with the publication requirements described in paragraph (b)(1) of this section for payment rate transparency data, within 1 month of when the group provides the recommendation to the agency.

(c)(1) *Initial State analysis for rate reduction or restructuring.* For any State plan amendment that proposes to reduce provider payment rates or restructure provider payments in circumstances when the changes could result in diminished access where the criteria in paragraphs (c)(1)(i) through (iii) of this section are met, the State agency must provide written assurance and relevant supporting documentation that the following conditions are met as well as a description of the State's procedures for monitoring continued compliance with section 1902(a)(30)(A) of the Act, as part of the State plan amendment submission in a format

prescribed by CMS as a condition of approval:

(i) Medicaid payment rates in the aggregate (including base and supplemental payments) following the proposed reduction or restructuring for each benefit category affected by the proposed reduction or restructuring would be at or above 80 percent of the most recently published Medicare payment rates for the same or a comparable set of Medicare-covered services.

(ii) The proposed reduction or restructuring, including the cumulative effect of all reductions or restructurings taken throughout the current State fiscal year, would be likely to result in no more than a 4 percent reduction in aggregate fee-for-service Medicaid expenditures for each benefit category affected by proposed reduction or restructuring within a State fiscal year.

(iii) The public processes described in paragraph (c)(4) of this section and § 447.204 of this part yielded no significant access to care concerns from beneficiaries, providers, or other interested parties regarding the service(s) for which the payment rate reduction or payment restructuring is proposed, or if such processes did yield concerns, the State can reasonably respond to or mitigate the concerns, as appropriate, as documented in the analysis provided by the State pursuant to § 447.204(b)(3).

(2) *Additional State rate analysis.* For any State plan amendment that proposes to reduce provider payment rates or restructure provider payments in circumstances when the changes could result in diminished access where the requirements in paragraphs (c)(1)(i) through (iii) of this section are not met, the State must also provide the following to CMS as part of the State plan amendment submission as a condition of approval, in addition to the information required under paragraph (c)(1) of this section, in a format prescribed by CMS:

(i) A summary of the proposed payment change, including the State's reason for the proposal and a description of any policy purpose for the proposed change, including the cumulative effect of all reductions or restructurings taken throughout the current State fiscal year in aggregate fee-for-service Medicaid expenditures for each benefit category affected by proposed reduction or restructuring within a State fiscal year.

(ii) Medicaid payment rates in the aggregate (including base and supplemental payments) before and after the proposed reduction or restructuring for each benefit category affected by proposed reduction or restructuring, and a comparison of each (aggregate Medicaid payment before and after the reduction or restructuring) to the most recently published Medicare payment rates for the same or a comparable set of Medicare-covered services and, as reasonably feasible, to the most recently available payment rates of other health care payers in the State or the geographic area for the same or a comparable set of covered services.

(iii) Information about the number of actively participating providers of services in each benefit category affected by the proposed reduction or restructuring. For this purpose, an actively participating provider is a provider that is participating in the Medicaid program and actively seeing and providing services to Medicaid beneficiaries or accepting Medicaid beneficiaries as new patients. The State must provide the number of actively participating providers of services in each affected benefit category for each of the 3 years immediately preceding the State plan amendment submission date, by State-specified geographic area (for example, by county or parish), provider type, and site of service. The State must document observed trends in the number of actively participating providers in each geographic area over this period. The State may provide estimates of the anticipated effect on the number of actively participating providers of services in each benefit category affected by the proposed reduction or restructuring, by geographic area.

(iv) Information about the number of Medicaid beneficiaries receiving services through the FFS delivery system in each benefit category affected by the proposed reduction or restructuring. The State must provide the number of beneficiaries receiving services in each affected benefit category for each of the 3 years immediately preceding the State plan amendment submission date, by State-specified geographic area (for example, by county or parish). The State must document observed trends in the number of Medicaid beneficiaries receiving services in each affected benefit category in each geographic area over this period. The State must provide quantitative and qualitative information about the beneficiary populations receiving services in the affected benefit categories over this period, including the number and proportion of beneficiaries who are adults and children and who are living with disabilities, and a description of the State's consideration of the how the proposed payment changes may affect access to care and service delivery for beneficiaries in various populations. The State must provide estimates of the anticipated effect on the number of Medicaid beneficiaries receiving services through the FFS delivery system in each benefit category affected by the proposed reduction or restructuring, by geographic area.

(v) Information about the number of Medicaid services furnished through the FFS delivery system in each benefit category affected by the proposed reduction or restructuring. The State must provide the number Medicaid services furnished in each affected benefit category for each of the 3 years immediately preceding the State plan amendment submission date, by State-specified geographic area (for example, by county or parish), provider type, and site of service. The State must document observed trends in the number of Medicaid services furnished in each affected benefit category in each geographic area over this period. The State must provide quantitative and qualitative information about the Medicaid services furnished in the affected benefit categories over this period, including the number and proportion of Medicaid services furnished to adults and children and who are living with disabilities, and a description of the State's consideration of the how the proposed payment changes may affect access to care and service delivery. The State must provide estimates of the anticipated effect on the number of Medicaid services furnished through the FFS delivery system in each benefit category affected by the proposed reduction or restructuring, by geographic area.

(vi) A summary of, and the State's response to, any access to care concerns or complaints received from beneficiaries, providers, and other interested parties regarding the service(s) for which the payment rate reduction or restructuring is proposed as required under § 447.204(a)(2).

(3) *Compliance with requirements for State analysis for rate reduction or restructuring.* A State that submits a State plan amendment that proposes to reduce provider payment rates or restructure provider payments in circumstances when the changes could result in diminished access that fails to provide the information and analysis to support approval as specified in paragraphs (c)(1) and (2) of this section, as applicable, may be subject to State plan amendment disapproval under § 430.15(c) of this chapter. Additionally, States that submit relevant information, but where there are unresolved access to care concerns related to the proposed

State plan amendment, including any raised by CMS in its review of the proposal and any raised through the public process as specified in paragraph (c)(4) of this section or under § 447.204(a)(2), may be subject to State plan amendment disapproval. If State monitoring of beneficiary access after the payment rate reduction or restructuring takes effect shows a decrease in Medicaid access to care, such as a decrease in the provider-to-beneficiary ratio for any affected service, or the State or CMS experiences an increase in beneficiary or provider complaints or concerns about access to care that suggests possible noncompliance with the access requirements in section 1902(a)(30)(A) of the Act, CMS may take a compliance action using the procedures described in § 430.35 of this chapter.

(4) *Mechanisms for ongoing beneficiary and provider input.* (i) States must have ongoing mechanisms for beneficiary and provider input on access to care (through hotlines, surveys, ombudsman, review of grievance and appeals data, or another equivalent mechanisms), consistent with the access requirements and public process described in § 447.204.

(ii) States should promptly respond to public input through these mechanisms citing specific access problems, with an appropriate investigation, analysis, and response.

(iii) States must maintain a record of data on public input and how the State responded to this input. This record will be made available to CMS upon request.

(5) *Addressing access questions and remediation of inadequate access to care.* When access deficiencies are identified, the State must, within 90 days after discovery, submit a corrective action plan with specific steps and timelines to address those issues. While the corrective action plan may include longer-term objectives, remediation of the access deficiency should take place within 12 months.

(i) The State's corrective actions may address the access deficiencies through a variety of approaches, including, but not limited to: Increasing payment rates, improving outreach to providers, reducing barriers to provider enrollment, providing additional transportation to services, providing for telemedicine delivery and telehealth, or improving care coordination.

(ii) The resulting improvements in access must be measured and sustainable.

(6) *Compliance actions for access deficiencies.* To remedy an access deficiency, CMS may take a compliance action using the procedures described at § 430.35 of this chapter.

■ 28. Amend § 447.204 by—

■ a. Revising paragraphs (a)(1) and (b); and

■ b. Removing paragraph (d).

The revisions read as follows:

§ 447.204 Medicaid provider participation and public process to inform access to care.

(a) * * *

(1) The data collected, and the State analysis performed, under § 447.203(c).

* * * * *

(b) The State must submit to CMS with any such proposed State plan amendment affecting payment rates documentation of the information and analysis required under § 447.203(c) of this chapter.

* * * * *

Dated: April 24, 2023.

Xavier Becerra,

Secretary, Department of Health and Human Services.

[FR Doc. 2023–08959 Filed 4–27–23; 4:15 pm]

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Part III

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 430, 438, and 457
Medicaid Program; Medicaid and Children's Health Insurance Program (CHIP) Managed Care Access, Finance, and Quality; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 430, 438, and 457

[CMS–2439–P]

RIN 0938–AU99

Medicaid Program; Medicaid and Children's Health Insurance Program (CHIP) Managed Care Access, Finance, and Quality

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Proposed rule.

SUMMARY: This proposed rule would advance CMS' efforts to improve access to care, quality and health outcomes, and better address health equity issues for Medicaid and Children's Health Insurance Program (CHIP) managed care enrollees. The proposed rule would specifically address standards for timely access to care and States' monitoring and enforcement efforts, reduce burden for some State directed payments and certain quality reporting requirements, add new standards that would apply when States use in lieu of services and settings (ILOSs) to promote effective utilization and specify the scope and nature of ILOS, specify medical loss ratio (MLR) requirements, and establish a quality rating system for Medicaid and CHIP managed care plans.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, by July 3, 2023.

ADDRESSES: In commenting, please refer to file code CMS–2439–P.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the ''Submit a comment'' instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–2439–P, P.O. Box 8016, Baltimore, MD 21244–8016.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–2439–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT:

John Giles, (410) 786–5545, Medicaid Managed Care.

Laura Snyder, (410) 786–3198, Medicaid Managed Care State Directed Payments.

Tara Caulder, (410) 786–8252, Medicaid Managed Care State Directed Payments Value-Based Initiatives and Evaluation.

Alex Loizias, (410) 786–2435, Medicaid Managed Care State Directed Payments Contract Requirements.

Andrew Wilson, (410) 786–8515, Medicaid Managed Care State Directed Payments Medicare Fee Schedules and Appeals Process.

Carlye Burd, (720) 853–2780, Medicaid Managed Care Quality.

Amanda Paige Burns, (410) 786–8030, Medicaid Quality Rating System.

Joshua Bougie, (410) 786–8117, CHIP.

SUPPLEMENTARY INFORMATION: *Inspection of Public Comments:* All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: *http://www.regulations.gov.* Follow the search instructions on that website to view public comments. CMS will not post on *Regulations.gov* public comments that make threats to individuals or institutions or suggest that the individual will take actions to harm the individual. CMS continues to encourage individuals not to submit duplicative comments. We will post acceptable comments from multiple unique commenters even if the content is identical or nearly identical to other comments.

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Applicability and Complicace Timeframes

CMS proposes that the proposed new requirements would be applicable, and therefore, States required to comply by the effective date of the final rule or as otherwise specified in regulatory text.

I. Medicaid and CHIP Managed Care

A. Background

As of September 2022, the Medicaid program provided essential health care coverage to more than 83 million [1] individuals, and, in 2020, had annual outlays of more than $671 billion. In 2021, the Medicaid program accounted for 17 percent of national health expenditures.[2] The program covers a broad array of health benefits and services critical to underserved populations, including low-income adults, children, parents, pregnant individuals, the elderly, and people with disabilities. For example, Medicaid pays for approximately 42 percent of all births in the U.S.[3] and is the largest payer of long-term services and supports (LTSS),[4] services to treat substance use disorder, and services to prevent and treat the Human Immunodeficiency Virus.[5]

Ensuring beneficiaries can access covered services is a crucial element of the Medicaid program. Depending on the State and its Medicaid program structure, beneficiaries access their health care services using a variety of care delivery systems; for example, fee-for-service (FFS) and managed care, including through demonstrations and waiver programs. In 2020, 72 percent [6]

[1] September 2022 Medicaid and CHIP Enrollment Snapshot. Accessed at *https://www.medicaid.gov/medicaid/national-medicaid-chip-program-information/downloads/september-2022-medicaid-chip-enrollment-trend-snapshot.pdf.*

[2] CMS National Health Expenditure Accounts. National Health Expenditures 2021 Highlights. Accessed at *https://www.cms.gov/files/document/highlights.pdf.*

[3] National Center for Health Statistics. Key Birth Statistics (2020 Data. Final 2022 Data forthcoming). Accessed at *https://www.cdc.gov/nchs/nvss/births.htm.*

[4] Colello, Kirsten J. *Who Pays for Long-Term Services and Supports?* Congressional Research Service. Updated June 15, 2022. Accessed at *https://crsreports.congress.gov/product/pdf/IF/IF10343.*

[5] Dawson, L. and Kates, J. Insurance Coverage and Viral Suppression Among People with HIV, 2018. September 2020. Kaiser Family Foundation. Accessed at *https://www.kff.org/hivaids/issue-brief/insurance-coverage-and-viral-suppression-among-people-with-hiv-2018/.*

[6] MACPAC 2022 Analysis of T–MSIS data February 2022. Exhibit 30. Percentage of Medicaid Enrollees in Managed Care by State and Eligibility

of Medicaid beneficiaries were enrolled in comprehensive managed care plans; the remaining individuals received all of their care or some services that have been carved out of managed care through FFS.

With a program as large and complex as Medicaid, to promote consistent access to health care for all beneficiaries across all types of care delivery systems in accordance with statutory requirements, access regulations need to be multi-factorial. Strategies to enhance access to health care services should reflect how people move through and interact with the health care system. We view the continuum of health care access across three dimensions of a person-centered framework: (1) enrollment in coverage; (2) maintenance of coverage; and (3) access to services and supports. Within each of these dimensions, accompanying regulatory, monitoring, and/or compliance actions may be needed to ensure access to health care is achieved and maintained.

In early 2022, we released a request for information (RFI)[7] to collect feedback on a broad range of questions that examined topics such as: challenges with eligibility and enrollment; ways we can use data available to measure, monitor, and support improvement efforts related to access to services; strategies we can implement to support equitable and timely access to providers and services; and opportunities to use existing and new access standards to help ensure that Medicaid and Children's Health Insurance Program (CHIP) payments are sufficient to enlist enough providers. Some of the most common feedback we received through the RFI related to promoting cultural competency in access to and the quality of services for beneficiaries across all dimensions of health care and using payment rates as a driver to increase provider participation in Medicaid and CHIP programs. Commenters were also interested in opportunities to align approaches for payment regulation and compliance across Medicaid and CHIP delivery systems and services.

As noted above, the first dimension of access focuses on ensuring that eligible people are able to enroll in the Medicaid program. Access to Medicaid enrollment requires that a potential beneficiary know if they are or may be eligible for Medicaid, be aware of Medicaid coverage options, and be able to easily apply for and enroll in coverage. The second dimension of access in this continuum relates to maintaining coverage once the beneficiary is enrolled in the Medicaid program initially. Maintaining coverage requires that eligible beneficiaries are able to stay enrolled in the program without interruption, or that they know how to and can smoothly transition to other health coverage, such as CHIP, Exchange coverage, or Medicare, when they are no longer eligible for Medicaid coverage. In September 2022, we published a proposed rule, *Streamlining the Medicaid, Children's Health Insurance Program, and Basic Health Program Application, Eligibility, Determination,* Enrollment, *and Renewal Processes* (87 FR 54760; hereinafter the ''Streamlining Eligibility & Enrollment proposed rule'') to simplify the processes for eligible individuals to enroll and retain eligibility in Medicaid, CHIP, and the Basic Health Program (BHP).

The third dimension, which is the focus of this proposed rule, is access to services and supports. This rule is focused on addressing additional critical elements of access: (1) potential access (for example, provider availability and network adequacy); (2) beneficiary utilization (the use of health care and health services); and (3) beneficiaries' perceptions and experiences with the care they did or did not receive. These terms and definitions build upon our previous efforts to examine how best to monitor access.[8]

In addition to the three proposed rules (the Streamlining Eligibility & Enrollment proposed rule, this proposed rule on managed care, and Medicaid Program; Ensuring Access to Medicaid Services proposed rule), we are also engaged in non-regulatory activities (for example, best practices toolkits and technical assistance to States) to improve access to health care services across Medicaid delivery systems. As noted earlier, the Streamlining Eligibility & Enrollment proposed rule addresses the first two dimensions of access to health care: (1) enrollment in coverage and (2) maintenance of coverage. Through that proposed rule, we sought to streamline Medicaid, CHIP and BHP eligibility and enrollment processes, reduce administrative burden on States and applicants toward a more seamless eligibility and enrollment process, and increase the enrollment and retention of eligible individuals. Through the Ensuring Access to Medicaid Services proposed rule, and this proposed rule involving managed care, we outline additional proposed steps to address the third dimension of the health care access continuum: access to services, while also in this rule addressing quality and financing of services in the managed care context. We seek to address a range of access-related challenges that impact how beneficiaries are served by Medicaid across all of its delivery systems.

The use of managed care in Medicaid has grown from 81 percent in 2016 to 84 percent in 2020,[9] with 72 percent of Medicaid beneficiaries enrolled in comprehensive managed care organizations in 2020. We note that States may implement a Medicaid managed care delivery system using four Federal authorities—sections 1915(a), 1915(b), 1932(a), and 1115(a) of the Social Security Act (the Act); each is described briefly below.

Under section 1915(a) of the Act, States can implement a voluntary managed care program by executing a contract with organizations that the State has procured using a competitive procurement process. To require beneficiaries to enroll in a managed care program to receive services, a State must obtain approval from CMS under two primary authorities:

- Through a State plan amendment (SPA) that meets standards set forth in section 1932(a) of the Act, States can implement a mandatory managed care delivery system. This authority does not allow States to require beneficiaries who are dually eligible for Medicare and Medicaid (dually eligible beneficiaries), American Indians/Alaska Natives (except as permitted in section 1932(a)(2)(C) of the Act), or children with special health care needs to enroll in a managed care program. State plans, once approved, remain in effect until modified by the State.
- We may grant a waiver under section 1915(b) of the Act, permitting a State to require all Medicaid beneficiaries to enroll in a managed care delivery system, including dually eligible beneficiaries, American Indians/Alaska Natives, or children with special health care needs. After approval, a State may operate a section 1915(b) waiver for a 2-year period (certain waivers can be operated for up to 5

Group *https://www.macpac.gov/wp-content/uploads/2022/12/EXHIBIT-30.-Percentage-of-Medicaid-Enrollees-in-Managed-Care-by-State-and-Eligibility-Group-FY-2020.pdf.*

[7] CMS Request for Information: Access to Coverage and Care in Medicaid & CHIP. February 2022. For a full list of question from the RFI, see *https://www.medicaid.gov/medicaid/access-care/downloads/access-rfi-2022-questions.pdf.*

[8] Kenney, Genevieve M., Kathy Gifford, Jane Wishner, Vanessa Forsberg, Amanda I. Napoles, and Danielle Pavliv. ''Proposed Medicaid Access Measurement and Monitoring Plan.'' Washington, DC: The Urban Institute. August 2016. Accessed at *https://www.medicaid.gov/sites/default/files/2019-12/monitoring-plan.pdf.*

[9] *https://www.medicaid.gov/medicaid/managed-care/enrollment-report/index.html.*

years if they include dually eligible beneficiaries) before requesting a renewal for an additional 2- (or 5-) year period.

We may also authorize managed care programs as part of demonstration projects under section 1115(a) of the Act that include waivers permitting a State to require all Medicaid beneficiaries to enroll in a managed care delivery system, including dually eligible beneficiaries, American Indians/Alaska Natives, and children with special health care needs. Under this authority, States may seek additional flexibility to demonstrate and evaluate innovative policy approaches for delivering Medicaid benefits, as well as the option to provide services not typically covered by Medicaid. Such demonstrations are approvable only if it is determined that the demonstration would promote the objectives of the Medicaid statute and the demonstration is subject to evaluation.

The above authorities all permit States to operate their Medicaid managed care programs without complying with the following standards of Medicaid law outlined in section of 1902 of the Act:

- *Statewideness* (section 1902(a)(1) of the Act): States may implement a managed care delivery system in specific areas of the State (generally counties/parishes) rather than the whole State;
- *Comparability of Services* (section 1902(a)(10)(B) of the Act): States may provide different benefits to people enrolled in a managed care delivery system; and
- *Freedom of Choice* (section 1902(a)(23)(A) of the Act): States may generally require people to receive their Medicaid services only from a managed care plan's network of providers or primary care provider.

States that elect to operate a separate CHIP within a managed care delivery system do not need specific statutory authority to offer benefits through a managed care program. However, sections 2103(f)(3) and 2107(e)(1)(N) and (R) of the Act apply certain provisions of sections 1903 and 1932 of the Act related to Medicaid managed care to separate CHIPs. States that elect a Medicaid expansion CHIPs that operate within a managed care delivery system are subject to all requirements under section 1932 of the Act.

In the May 6, 2016 **Federal Register** (81 FR 27498), we published the ''Medicaid and Children's Health Insurance Program (CHIP) Programs; Medicaid Managed Care, CHIP Delivered in Managed Care, and Revisions Related to Third Party Liability'' final rule (hereinafter referred to as ''the 2016 final rule'') that modernized the Medicaid and CHIP managed care regulations to reflect changes in the use of managed care delivery systems. The 2016 final rule aligned many of the rules governing Medicaid and CHIP managed care with those of other major sources of coverage; implemented applicable statutory provisions; strengthened actuarial soundness payment provisions to promote the accountability of managed care program rates; strengthened efforts to reform delivery systems that serve Medicaid and CHIP beneficiaries; and enhanced policies related to program integrity. The 2016 final rule applied many of the Medicaid managed care rules to separate CHIP, particularly in the areas of access, finance, and quality through cross-references to 42 CFR part 438.

In the January 18, 2017 **Federal Register** (82 FR 5415), we published the ''Medicaid Program; The Use of New or Increased Pass-Through Payments in Medicaid Managed Care Delivery Systems'' final rule (hereinafter referred to as ''the 2017 final rule''). In the 2016 final rule, we defined pass-through payments at § 438.6(a) as any amount required by the State (and considered in calculating the actuarially sound capitation rate) to be added to the contracted payment rates paid by the MCO, PIHP, or PAHP to hospitals, physicians, or nursing facilities that is not for the following purposes: a specific service or benefit provided to a specific enrollee covered under the contract; a provider payment methodology permitted under § 438.6(c)(1)(i) through (iii) for services and enrollees covered under the contract; a subcapitated payment arrangement for a specific set of services and enrollees covered under the contract; graduate medical education (GME) payments; or Federally-qualified health center (FQHC) or rural health clinic (RHC) wrap around payments. On June 29th, 2016, we also published the CMCS Informational Bulletin (CIB) concerning ''The Use of New or Increased Pass-Through Payments in Medicaid Managed Care Delivery Systems.'' The 2017 final rule codified the information in the CIB as well as gave States the option to eliminate physician and nursing facility payments immediately or phase down these payments over the 5-year transition period if they prefer and specified the maximum amount of pass-through payments permitted annually during the transition periods under Medicaid managed care contract(s) and rate certification(s). That final rule prevented increases in pass-through payments and the addition of new pass-through payments beyond those in place when the pass-through payment transition periods were established in the 2016 final rule.

In the November 13, 2020 **Federal Register** (85 FR 72754), we published the ''Medicaid Program; Medicaid and Children's Health Insurance Program (CHIP) Managed Care'' final rule (hereinafter referred to as the ''2020 final rule'') which streamlined the Medicaid and CHIP managed care regulatory framework to relieve regulatory burdens; support State flexibility and local leadership; and promote transparency, flexibility, and innovation in the delivery of care. The rule was intended to ensure that the regulatory framework was efficient and feasible for States to implement in a cost-effective manner and ensure that States can implement and operate Medicaid and CHIP managed care programs without undue administrative burdens.

Since publication of the 2020 final rule, the COVID–19 public health emergency (PHE) challenged States' ability to ensure beneficiaries' access to high-quality care, ensure adequate provider payment during extreme workforce challenges, and provide adequate program monitoring and oversight. On January 28, 2021, Executive Order (E.O.) 14009, *Strengthening Medicaid and the Affordable Care Act,* was signed and established the policy objective to protect and strengthen Medicaid and the Affordable Care Act (ACA) and to make high-quality health care accessible and affordable for every American, and directed executive departments and agencies to review existing regulations, orders, guidance documents, and policies to determine whether such agency actions are inconsistent with this policy. On April 25, 2022, Executive Order 14070 directed agencies with responsibilities related to Americans' access to health coverage to review agency actions to identify ways to continue to expand the availability of affordable health coverage, to improve the quality of coverage, to strengthen benefits, and to help more Americans enroll in quality health coverage. This proposed rule aims to fulfill Executive Orders 14009 and 14070 by helping States to use lessons learned from the PHE and build stronger managed care programs to better meet the needs of the Medicaid and CHIP populations by improving access to and quality of care provided.

In addition, this rule proposes new standards to help States improve their monitoring of access to care by requiring establishment of new standards for appointment wait times, use of secret shopper surveys, use of enrollee experience surveys, and requiring States to submit a managed care plan analysis of payments made by plans to providers, for specific services, to more closely monitor plans' network adequacy. It also proposes provisions that would reduce burden for States that choose to direct MCOs, PIHPs, or PAHPs in certain ways to use their capitation payments to pay specified providers specified amounts, address impermissible redistribution arrangements related to State directed payments, and add clarity to the requirements related to medical loss ratio calculations. To improve transparency and provide valuable information to enrollees, providers, and CMS, this rule proposes to enhance existing State website requirements for content and ease of use. Lastly, this proposed rule would make quality reporting more transparent and meaningful for driving quality improvement, reduce burden on certain quality reporting requirements, and establish State requirements for implementing a Medicaid and CHIP quality rating system aimed at ensuring monitoring of performance by Medicaid and CHIP managed care plans and empowering beneficiary choice in managed care.

Finally, we believe it is important to acknowledge the role of health equity within this proposed rule. Medicaid and CHIP are the primary source of health care coverage for over one in three people of color in this country. Consistent with Executive Order 13985 [10] which calls for advancing equity for underserved populations, we are working to advance health equity across CMS programs consistent with the goals and objectives we have outlined in the CMS Framework for Health Equity 2022–2032 [11] and the HHS Equity Action Plan.[12] That effort includes increasing our understanding of the needs of those we serve to ensure that all individuals have access to equitable care and coverage.

A key part of our approach will be to work with States to improve measurement of health disparities through the stratification of State reporting on certain measures to identify potential differences in access, quality, and outcomes based on demographic factors like race, ethnicity, age, rural/urban status, disability, language, sex, sexual orientation, and gender identity, as well as social determinants of health.

The ''Medicaid Program and CHIP; Mandatory Medicaid and Children's Health Insurance Program (CHIP) Core Set Reporting'' proposed rule appeared in the August 22, 2022 **Federal Register** (87 FR 51303) (hereinafter referred to as the''Mandatory Medicaid and CHIP Core Set Reporting proposed rule''). In that proposed rule, we proposed that the Secretary would specify, through annual subregulatory guidance, which measures in the Medicaid and CHIP Child Core Set, the behavioral health measures of the Medicaid Adult Core Set, and the Health Home Core Sets, States would be required to stratify, and by which factors, such as race, ethnicity, sex, age, rural/urban status, disability, language or other factors specified by the Secretary. CMS also proposed a phased-in timeline for stratification of measures in these Core Sets. In the Medicaid Program; Ensuring Access to Medicaid Services proposed rule, published elsewhere in the **Federal Register**, we also proposed a similar phased-in timeline and process for mandatory reporting and stratification of the Home and Community-Based Services (HCBS) Quality Measure Set.

Measuring health disparities, reporting these results, and driving improvements in quality are cornerstones of the CMS approach to advancing health equity and also align with the CMS Strategic Priorities.[13] In this proposed rule, we establish our intent to align with the stratification factors required for Core Set measure reporting, which we believe would minimize State and health plan burden to report stratified measures. To further reduce burden on States, we would permit States to report, if finalized, the same measurement and stratification methodologies and classifications as those proposed in the Mandatory Medicaid and CHIP Core Set Reporting proposed rule and the Ensuring Access to Medicaid Services proposed rule. We believe these measures and methodologies would be appropriate to include in States' Managed Care Program Annual Report (MCPAR) because § 438.66(e)(2)(vii) requires information on and an assessment of the operation of each managed care program and an evaluation of managed care plan performance on quality measures. Reporting these measures in MCPAR would minimize State and provider burden while allowing more robust CMS monitoring and oversight of the quality of the health care provided at a managed care plan and program level. We would also anticipate publishing additional subregulatory guidance and adding specific fields in MCPAR that would accommodate this measure and data stratification reporting to simplify the process for States.

B. Provisions of the Proposed Regulations

Throughout this document, the term ''PAHP'' is used to mean a prepaid ambulatory health plan that does not exclusively provide non-emergency medical transportation services. Whenever this document is referencing a PAHP that exclusively provides non-emergency medical transportation services, it is specifically addressed as a ''Non-Emergency Medical Transportation (NEMT) PAHP.'' Throughout this document, the use of the term ''managed care plan'' includes managed care organizations (MCOs), prepaid inpatient health plans (PIHPs), and prepaid ambulatory health plans (PAHPs) and is used only when the provision under discussion applies to all three arrangements. An explicit reference is used in the preamble if the provision applies to primary care case management (PCCMs) or PCCM entities.

For CHIP, the preamble uses ''CHIP'' when referring collectively to separate child health programs and Medicaid expansion programs. We use ''separate CHIP'' specifically in reference to separate child health programs and also in reference to any proposed changes in subpart L of part 457, which are only applicable to separate child health programs operating in a managed care delivery system. Also note in this proposed rule, all proposed changes to Medicaid managed care regulations are equally applicable to Medicaid expansion managed care programs as described at § 457.1200(c).1. Access (42 CFR 438.2, 438.10, 438.66, 438.68, 438.206, 438.207, 438.214, 438.602, 457.1207, 457.1218, 457.1230, 457.1250, 457.1285)

a. Enrollee Experience Surveys (§§ 438.66(b) and (c), 457.1230(b))

In the 2016 final rule, we renamed and expanded § 438.66 *State Monitoring Requirements* to ensure that States had robust systems to monitor their

[10] Executive Order 13985, *https://www.whitehouse.gov/briefing-room/presidential actions/2021/01/20/executive-order-advancingracial-equity-and-support-or-underservedcommunities-through-the-federal-government/.*

[11] CMS Framework for Health Equity 2022–2032: *https://www.cms.gov/files/document/cmsframework-health-equity.pdf.*

[12] HHS Equity Action Plan, *https://www.hhs.gov/sites/default/files/hhs-equity-action-plan.pdf.*

[13] CMS Strategic Plan 2022, *https://www.cms.gov/cms-strategic-plan.*

managed care programs, utilize the monitoring results to make program improvements, and report to CMS annually the results of their monitoring activities. Existing regulations at § 438.66(c)(5) require States to use the data collected from their monitoring activities to improve the performance of their managed care programs, including results from any enrollee or provider satisfaction surveys conducted by the State or managed care plan. Some States currently use surveys to gather direct input from their managed care enrollees, which we believe is a valuable source of information on enrollees' actual and perceived access to services. As a general matter, disparities in access to care related to demographic factors such as race, ethnicity, language, or disability status are, in part, a function of the availability of the accessible providers who are willing to provide care and are competent in meeting the needs of populations in medically underserved communities. Surveys can focus on matters that are important to enrollees and for which they are the best and, sometimes, only source of information. Patient experience surveys can also focus on how patients experienced or perceived key aspects of their care, not just on how satisfied they were with their care. For example, experience surveys can focus on asking patients whether or how often they accessed health care, barriers they encountered in accessing health care, and their experience including communication with their doctors, understanding their medication instructions, and the coordination of their health care needs. Some States already use enrollee experience surveys and report that the data is an asset in their efforts to assess whether the managed care program is meeting its enrollees' needs.

One of the most commonly used enrollee experience survey in the health care industry, including for Medicare Advantage organizations, is the Consumer Assessment of Healthcare Providers and Systems (CAHPS®).[14] CAHPS experience surveys are available for health plans, dental plans, and home and community-based services (HCBS) programs, as well as for patient experience with providers such as home health, condition specific care such as behavioral health, or facility-based care such as in a nursing home. A survey specially designed to measure the impact of long-term services and supports (LTSS) on the quality of life and outcomes of enrollees is the National Core Indicators-Aging and Disabilities (NCI–AD®) Adult Consumer Survey™.[15] Whichever survey is chosen by a State, it should complement data gathered from other network adequacy and access monitoring activities to provide the State with a more complete assessment of their managed care programs' success at meeting their enrollees' needs. To ensure that States' managed care program monitoring systems, required at § 438.66(a), appropriately capture the enrollee experience, we propose to revise § 438.66(b)(4) to explicitly include ''enrollee experience.'' Section 438.66(c)(5) currently requires States to use the results from any enrollee or provider satisfaction surveys they choose to conduct to improve the performance of its managed care program. To ensure that States have the data from an enrollee experience survey to include in their monitoring activities and improve the performance of their managed care programs, we propose to revise § 438.66(c)(5) to require that States conduct an annual enrollee experience survey. To reflect this, we propose to revise § 438.66(c)(5) to add ''an annual'' before ''enrollee'' and add ''experience survey conducted by the State'' after ''enrollee.'' We also propose to replace ''or'' with ''and'' to be explicit that use of provider survey results alone would not be sufficient to comply with § 438.66(c)(5). While we encourage States and managed care plans to utilize provider surveys, we are not proposing to mandate them at this time. We believe other proposals in this rule, such as enrollee surveys and secret shopper surveys, may yield information that would inform our decision on the use of provider surveys in the future. We invite comment on whether we should mandate the use of a specific enrollee experience survey, define characteristics of acceptable survey instruments, and the operational considerations of enrollee experience surveys States use currently.

To reflect these proposals in the annual assessment of the operation of the managed care program report called the Managed Care Program Annual Report (MCPAR) required at § 438.66(e), we propose conforming edits in § 438.66(e)(2)(vii). We propose to include the results of an enrollee experience survey to the list of items that States must evaluate in their report and add ''provider'' before ''surveys'' to distinguish them from enrollee experience surveys. Additionally, consistent with the transparency proposals described in section I.B.1.f. of this section, we propose to revise § 438.66(e)(3)(i) to require that States post the report required in § 438.66(e)(1) on their website within 30 calendar days of submitting it to CMS. Currently § 438.66(e)(3)(i) only requires that the report be posted on the State's website but does not specify a timeframe; we believe that adding further specificity about the timing of when the report should be posted would be helpful to interested parties and bring consistency to this existing requirement. This proposal is authorized by section 1902(a)(6) of the Act which requires that States provide reports, in such form and containing such information, as the Secretary may from time to time require.

For an enrollee experience survey to yield robust, usable results, it should be easy to understand, simple to complete, and readily accessible for all enrollees that receive it; therefore, we believe they should meet the interpretation, translation, and tagline criteria in § 438.10(d)(2). Therefore, we propose to add enrollee experience surveys as a document subject to the requirements in § 438.10(d)(2). This would ensure that enrollees that receive a State's enrollee experience survey would be fully notified that oral interpretation in any language and written translation in the State's prevalent languages would be readily available, and how to request auxiliary aids and services, if needed.

These proposals are authorized by section 1932(b)(5) of the Act which requires managed care organizations to demonstrate adequate capacity and services by providing assurances to the State and CMS that it has the capacity to serve the expected enrollment in its service area, including assurances that it offers an appropriate range of services and access to preventive and primary care services for the population expected to be enrolled in such service area, and maintains a sufficient number, mix, and geographic distribution of providers of services. The authority for our proposals is extended to prepaid inpatient health plans (PIHPs) and prepaid ambulatory health plans (PAHPs) through regulations based on our authority under section 1902(a)(4) of the Act. Because enrollee experience survey results would provide direct and candid input from enrollees, States and managed care plans could use the results to determine if their networks offer an appropriate range of services and access as well as if it provides a sufficient number, mix, and geographic distribution of providers to meet their enrollees' needs. Enrollee experience survey data would enable managed care plans to assess whether their networks

[14] The acronym ''CAHPS'' is a registered trademark of the Agency for Healthcare Research and Quality.

[15] NCI–AD Adult Consumer Survey™ is a copyrighted tool.

are providing sufficient capacity as experienced by their enrollees and that assessment would inform the assurances that the plan is required to provide to the State and CMS. These proposals are also authorized by section 1932(c)(1)(A)(i) and (iii) of the Act which require States that contract with MCOs to develop and implement a quality assessment and improvement strategy that includes: standards for access to care so that covered services are available within reasonable timeframes and in a manner that ensures continuity of care and adequate primary care and specialized services capacity and procedures for monitoring and evaluating the quality and appropriateness of care and services to enrollees and requirements for provision of quality assurance data to the State. Data from enrollee experience surveys would enable States to use the results to evaluate whether their plans' networks are providing access to covered services within reasonable timeframes and in a manner that ensures continuity of care. These data would also inform the development and maintenance of States' quality assessment and improvement strategies and would be critical to States' monitoring and evaluation of the quality and appropriateness of care and services provided to enrollees.

We remind States that in addition to the mandatory external quality review (EQR) activities under § 438.358(b), there is an existing optional EQR activity under § 438.358(c)(2) for the administration or validation of consumer or provider surveys of quality of care. States that contract with MCOs and use external quality review organizations (EQROs) to administer or validate the proposed enrollee experience surveys may be eligible to receive up to a 75 percent enhanced Federal match, pursuant to § 438.370, to reduce the financial burden of conducting or validating the proposed enrollee survey(s).

We request comment on the cost and feasibility of implementing enrollee experience surveys for each managed care program as well as the extent to which States already use enrollee experience surveys for their managed care programs.

We propose that States would have to comply with § 438.66(b) and (c) no later than the first managed care plan rating period that begins on or after 3 years after the effective date of the final rule as we believe this is a reasonable timeframe for compliance. We have proposed this applicability date in § 438.66(f).

We did not adopt the managed care State monitoring requirements described at § 438.66 in the 2016 final rule for separate CHIPs because we wished to limit administrative burden on separate CHIP managed care plans, which typically serve smaller populations. Since we did not adopt MCPAR, we do not plan to adopt the new Medicaid enrollee experience survey requirements proposed at § 438.66(b) and (c) for separate CHIPs. However, States currently collect enrollee experience data for CHIP through annual CAHPS surveys as required at section 2108(e)(4) of the Act. Currently, there are no requirements for States to use these data to evaluate their separate CHIP managed care plans network adequacy or to make these survey results available to beneficiaries to assist in selecting a managed care plan. We believe that enrollee experience data can provide an invaluable window into the performance of managed care plans and assist States in their annual review and certification of network adequacy for separate CHIP MCOs, PIHPs, and PAHPs. For this reason, we propose to amend § 457.1230(b) to require States to evaluate annual CAHPS survey results as part of the State's annual analysis of network adequacy as described in § 438.207(d). Since States already collect CAHPS survey data for CHIP and would likely not need the same timeframe to implement as needed for implementing the proposed Medicaid enrollee experience surveys requirement, we propose for the provision at § 457.1230(b) to be applicable 60 days after the effective date of the final rule. However, we are open to a later applicability date such as 1, 2, or 3 years after the effective date of the final rule. We invite comment on the appropriate applicability date for this provision.

We also believe that access to enrollee experience data is critical in affording separate CHIP beneficiaries the opportunity to make informed decisions when selecting their managed care plan(s). To this end, we propose at § 457.1207 to require States to post comparative summary results of CAHPS surveys by managed care plan annually on State websites as described at § 438.10(c)(3). The posted summary results must be updated annually and allow for easy comparison between the managed care plans available to separate CHIP beneficiaries. We seek public comment on other approaches to including CHIP CAHPS survey data for the dual purposes of improving access to managed care services and enabling beneficiaries to have useful information when selecting a managed care plan.

b. Appointment Wait Time Standards (§§ 438.68(e), 457.1218)

In the 2020 final rule, we revised § 438.68(b)(1) and (2) by replacing the requirement for States to set time and distance standards with a more flexible requirement that States set a quantitative network adequacy standard for specified provider types. We explained that quantitative network adequacy standards that States may elect to use included minimum provider-to-enrollee ratios; maximum travel time or distance to providers; a minimum percentage of contracted providers that are accepting new patients; maximum wait times for an appointment; hours of operation requirements (for example, extended evening or weekend hours); and combinations of these quantitative measures. We encouraged States to use the quantitative standards in combination- not separately- to ensure that there are not gaps in access to, and availability of, services for enrollees. (85 FR 72802)

Key to the effectiveness of the Medicaid and CHIP program is ensuring that it provides timely access to high-quality services in a manner that is equitable and consistent. During the COVID–19 public health emergency (PHE), managed care plans have faced many challenges ensuring access to covered services and those challenges shed light on opportunities for improvement in monitoring timely access. These challenges include workforce shortages, changes in providers' workflows and operating practices, providers relocating leaving shortages in certain areas, and shifts in enrollee utilization such as delaying or forgoing preventive care. Some of these challenges may become permanent and thus, States and managed care plans need to adjust their monitoring, evaluation, and planning strategies to ensure equitable access to all covered services.

On February 17, 2022, we issued a request for information [16] (RFI) soliciting public input on improving access in Medicaid and CHIP, including ways to promote equitable and timely access to providers and services. Barriers to accessing care represented a significant portion of comments received, with common themes related to providers not accepting Medicaid and

[16] CMS Request for Information: Access to Coverage and Care in Medicaid & CHIP. February 2022. For a full list of question from the RFI, see *https://www.medicaid.gov/medicaid/access-care/downloads/access-rfi-2022-questions.pdf.*

recommendations calling for us to set specific quantitative access standards. Many commenters urged us to consider developing a Federal standard for timely access to providers and services, but giving State Medicaid and CHIP agencies the flexibility to impose more stringent requirements. A recently published study [17] examined the extent to which Medicaid managed care plan networks may overstate the availability of physicians in Medicaid, and evaluated the implications of discrepancies in the ''listed'' and ''true'' networks for beneficiary access. The authors concluded that findings suggest that current network adequacy standards might not reflect actual access and that new methods are needed that account for physicians' willingness to serve Medicaid patients. Another review of 34 audit studies demonstrated that Medicaid is associated with a 1.6-fold lower likelihood in successfully scheduling a primary care appointment and a 3.3-fold lower likelihood in successfully scheduling a specialty appointment when compared with private insurance.[18]

Based on the RFI comments received, research, engagement with interested parties, and our experience in monitoring State managed care programs, we are persuaded about the need for increased oversight of network adequacy and overall access to care, and propose a new quantitative network adequacy standard. Specifically, we propose to redesignate existing § 438.68(e) regarding publication of network adequacy standards to § 438.68(g) and create a new § 438.68(e) titled ''Appointment wait time standards.''

In § 438.68(e)(1)(i) through (iv), we propose that States develop and enforce wait time standards for routine appointments for four types of services: outpatient mental health and substance use disorder (SUD)-adult and pediatric, primary care- adult and pediatric, obstetrics and gynecology (OB/GYN), and an additional type of service determined by the State (in addition to the three listed) in an evidence-based manner for Medicaid. We include ''If covered in the MCO's, PIHP's, or PAHP's contract'' before the first three service types (paragraphs (e)(1)(i) through (iii)) to be clear that standards only need to be developed and enforced if the service is covered by the managed care plan's contract, but the forth service (paragraph (e)(1)(iv)) must be one that is covered by the plan's contract. For example, we understand that primary care and OB/GYN is likely not covered by a behavioral health PIHP; therefore, a State would not be required to set appointment wait time standards for primary care and OB/GYN for the behavioral health PIHP and would only have to set appointment wait time standards for mental health and SUD as well as one State-selected provider type. To ensure that our proposal to have States set appointment wait time standards for mental health and SUD as well as one State-selected provider type for behavioral PIHPs and PAHPs is feasible, we request comment on whether behavioral health PIHPs and PAHPs include provider types other than mental health and SUD in their networks. Although we believe behavioral health PIHPs and PAHPs may include other provider types, we want to validate our understanding. We propose to adopt the proposed wait time standards for separate CHIP through an existing cross-reference at § 457.1218. We are proposing primary care, OB/GYN, and mental health and SUD because they are indicators of core population health; therefore, we believe proposing to require States to set appointment wait time standards for them would have the most impact on access to care for Medicaid and CHIP managed care enrollees.

At § 438.68(e)(1)(iv), we propose that States select a provider type in an evidence-based manner to give States the opportunity to use an appointment wait time standard to address an access challenge in their local market. We are not proposing to specify the type of evidence to be used in this rule; rather, we defer to States to consider multiple sources, such as encounter data, appeals and grievances, and provider complaints, as well as to consult with their managed care plans to select a provider type. We believe proposing that States select one of the provider types subject to an appointment wait time standard would encourage States and managed care plans to analyze network gaps effectively and then innovate new ways to address the challenges that impede timely access. States would identify the provider type(s) they choose in existing reporting in MCPAR, per § 438.66(e), and the Network Adequacy and Access Assurances Report, per § 438.207(d).

To be clear that the appointment wait time standards proposed in § 438.68(e) cannot be the quantitative network adequacy standard required in § 438.68(b)(1), we propose to add ''. . . , other than for appointment wait times . . .'' in § 438.68(b)(1). We are not proposing to define routine appointments in this rule; rather, we defer to States to define it as they deem appropriate. We encourage States to work with their managed care plans and their network providers to develop a definition of ''routine'' that would reflect usual patterns of care and current clinical standards. We acknowledge that defining ''urgent'' and ''emergent'' for appointment wait time standards could be much more complex given the standards of practice by specialty and the patient-specific considerations necessary to determine those situations. We invite comments on defining these terms should we undertake additional rulemaking in the future. We clarify that setting appointment wait time standards for routine appointments as proposed at § 438.68(e)(1) would be a minimum; States are encouraged to set additional appointment wait time standards for other types of appointments. For example, States may consider setting appointment wait time standards for emergent or urgent appointments as well.

To provide States with flexibility to develop appointment wait time standards that reflect the needs of their Medicaid and CHIP managed care populations and local provider availability while still setting a level of consistency, we propose maximum appointment wait times at § 438.68(e)(1): State developed appointment wait times must be no longer than 10 business days for routine outpatient mental health and substance use disorder appointments in § 438.68(e)(1)(i) and no longer than 15 business days for routine primary care in § 438.68(e)(1)(ii) and OB/GYN appointments in § 438.68(e)(1)(iii). We are not proposing a maximum appointment wait time standard for the State-selected provider type. These proposed maximum timeframes were informed by standards for the individual insurance Marketplace established under the Affordable Care Act that will begin in 2024 of 10 business days for behavioral health and 15 business days for primary care services; we note that we elected not to adopt the Marketplace's appointment wait time standard of 30 business days for non-urgent specialist appointments as we believe focusing on primary care, OB/GYN, and mental health and SUD is the most appropriate starting place for Medicaid managed care standards. These proposed timeframes were also

[17] *https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2021.01747.*

[18] W. Hsiang, A. Lukasiewicz, and M. Gentry, ''Medicaid Patients Have Greater Difficulty Scheduling Health Care Appointments Compared With Private Insurance Patients: A Meta-Analysis,'' SAGE Journals, April 5, 2019, available at *https://journals.sagepub.com/doi/full/10.1177/0046958019838118.*

informed by engagement with interested parties, including comments in response to the RFI. We are proposing to require appointment wait times for routine appointments only in this rule as we believe that providers utilize more complex condition and patient-specific protocols and clinical standards of care to determine scheduling for urgent and emergent care. We may address standards for other types of appointments in future rulemaking and hope that information from the use of appointment wait time standards for routine appointments may inform future proposals.

In developing this proposal, we considered appointment wait time standards between 30-calendar days and 45-calendar days. Some interested parties stated that these standards would be more appropriate for routine appointments and would more accurately reflect current appointment availability for most specialties. However, we believe 30-calendar days and 45-calendar days as the maximum wait time may be too long as a standard; we understand it may be a realistic timeframe currently for some specialist appointments but we were not convinced that they should be the standard for outpatient mental health and substance use disorder, primary care, and OB/GYN appointments. We invite comment on aligning with the Marketplace standards at 10- and 15-business days, or whether wait time standards should differ, and if so, what standards would be the most appropriate.

To make the appointment wait time standards as effective as possible, we defer to States on whether and how to vary appointment wait time standards for the same provider type; for example, by adult versus pediatric, telehealth versus in-person, geography, service type, or other ways. However, wait time standards must, at a minimum, reflect the timing proposed in § 438.68(e)(1). We encourage States to consider the unique access needs of certain enrollees when setting their appointment wait time standards to facilitate obtaining meaningful results when assessing managed care plan compliance with the standards.

As a general principle, we seek to align across Medicaid managed care, CHIP managed care, the Marketplace, and Medicare Advantage (MA) when reasonable to build consistency for individuals that may change coverage over time and to enable more effective and standardized comparison and monitoring across programs. Proposing 90 percent compliance with 10- and 15-business day maximum appointment wait time standards would be consistent with standards set for Marketplace plans for plan year 2024.[19] However, we note that for MA, CMS expects MA plans to set reasonable standards for primary care services for urgently needed services or emergencies immediately; services that are not emergency or urgently needed, but in need of medical attention within one week; and routine and preventive care within 30 days.[20]

To ensure that managed care plans' contracts reflect their obligation to comply with the appointment wait time standards, we propose to revise § 438.206(c)(1)(i) to include appointment wait time standards as a required provision in MCO, PIHP, and PAHP contracts for Medicaid, which is included in separate CHIP regulations through an existing cross-reference at § 457.1230(a). We believe this is necessary since our proposal at § 438.68(e)(1) to develop and enforce appointment wait time standards is a State responsibility; proposing this revision to § 438.206(c)(1)(i) would specify the corresponding managed care plan responsibility.

We propose to revise the existing applicability date in § 438.206(d) for Medicaid, which is applicable for separate CHIPs through an existing cross-reference at § 457.1230(a) and a proposed cross-reference at § 457.1200(d), to reflect that States would have to comply with § 438.206(c)(1)(i) no later than the first managed care plan rating period that begins on or after 4 years after the effective date of the final rule. We believe this is a reasonable timeframe for compliance.

Current requirements at § 438.68(c)(1) and (2) for Medicaid, and through a cross-reference at § 457.1218 for separate CHIP, direct States to consider twelve elements when developing their network adequacy standards. We remind States that § 438.68(c)(1)(ix) includes the availability and use of telemedicine, e-visits, and/or other evolving and innovative technological solutions as an element that States must consider when developing their network adequacy standards. Services delivered via telehealth seek to improve a patient's health through two-way, real time interactive communication between the patient, and the provider. Services delivered in this manner can, for example, be used for assessment, diagnosis, intervention, consultation, and supervision across distances. Services can be delivered via telehealth across all populations served in Medicaid including, but not limited to children, individuals with disabilities, and older adults. States have broad flexibility to cover telehealth through Medicaid and CHIP, including the methods of communication (such as telephonic or video technology commonly available on smart phones and other devices) to use.[21] States need to balance the use of telehealth with the availability of providers that can provide in-person care and enrollees' preferences for receiving care to ensure that they establish network adequacy standards under § 438.68 that accurately reflect the practical use of both types of care in their State. Therefore, States should review encounter data to gauge telehealth use by enrollees over time and the availability of telehealth appointments by providers and account for that information when developing their appointment wait time standards. We also remind States that they have broad flexibility with respect to covering services provided via telehealth and may wish to include quantitative network adequacy standards or specific appointment wait time standards for telehealth *in addition* to in-person appointment standards, as appropriate based on current practices and the extent to which network providers offer telehealth services. Although States have broad flexibility in this area, we remind States of their responsibility under section 504 of the Rehabilitation Act and section 1557 of the Affordable Care Act to ensure effective communications for patients with disabilities for any telehealth services that are offered and to provide auxiliary aids and services at no cost to the individual to ensure that individuals with disabilities are able to access and utilize services provided via telehealth; we also remind States of their responsibilities under Title VI of the Civil Rights Act of 1964, including the obligation to take reasonable steps to ensure meaningful language access for persons with limited English proficiency when providing telehealth services.[22]

Current Medicaid regulations at § 438.68(e), and through a cross-reference at § 457.1218 for separate

[19] *https://www.cms.gov/sites/default/files/2022-04/Final-2023-Letter-to-Issuers_0.pdf.*

[20] MCM Chapter 4 (*www.cms.gov*).

[21] *https://www.medicaid.gov/medicaid/benefits/downloads/medicaid-chip-telehealth-toolkit.pdf.*

[22] US Department of Justice, Civil Rights Division and Department of Health and Human Services, Office for Civil Rights, ''Guidance on Nondiscrimination in Telehealth: Federal Protections to Ensure Accessibility to People with Disabilities and Limited English Proficient Persons,'' July 29, 2022, available online at *https://www.hhs.gov/civil-rights/for-individuals/disability/guidance-on-nondiscrimination-in-telehealth/index.html.*

CHIP, require States to publish the network adequacy standards required by § 438.68(b)(1) and (2) on their websites and to make the standards available upon request at no cost to enrollees with disabilities in alternate formats or through the provision of auxiliary aids and services. To ensure transparency and inclusion of the new proposed appointment wait time standards in this provision, we propose several revisions: to redesignate § 438.68(e) to § 438.68(g); to replace ''and'' with a comma after ''(b)(1);'' add ''(b)'' before ''(2)'' for clarity; and add a reference to (e) after ''(b)(2).'' We believe these changes make the sentence clearer and easier to read. Lastly, § 438.68(e) currently includes ''. . . the website required by § 438.10.'' For additional clarity in redesignated § 438.68(g), we propose to replace ''438.10'' with ''§ 438.10(c)(3)'' to help readers more easily locate the requirements for State websites. These proposed changes apply equally to separate CHIP managed care through existing cross-references at §§ 457.1218 and 457.1207.

At § 438.68(e)(2), which is included in separate CHIP regulations through an existing cross-reference at § 457.1218, we propose that managed care plans would be deemed compliant with the standards established in paragraph (e)(1) when secret shopper results, described in section I.B.1.c. of this rule, reflect a rate of appointment availability that meets State established standards at least 90 percent of the time. By proposing a minimum compliance rate for appointment wait time standards, we would provide States with leverage to hold their managed care plans accountable for ensuring that their network providers offer timely appointments. Further, ensuring timely appointment access 90 percent of the time would be an important step toward helping States ensure that the needs of their Medicaid and CHIP populations are being met timely. As with any provision of part 438 and subpart L of part 457, we may require States to take corrective action to address noncompliance.

To ensure that appointment wait time standards would be an effective measure of network adequacy, we believe we need some flexibility to add provider types to address new access or capacity issues at the national level. Therefore, at § 438.68(e)(3), which is included in separate CHIP regulations through an existing cross-reference at § 457.1218, we propose that CMS may select additional types of appointments to be added to § 438.68(e)(1) after consulting with States and other interested parties and providing public notice and opportunity to comment. From our experience with the COVID–19 PHE as well as multiple natural disasters in recent years, we believe it prudent to explicitly state that we may utilize this flexibility as we deem appropriate in the future.

We recognize that situations may arise when an MCO, PIHP, or PAHP may need an exception to the State established provider network standards, including appointment wait times. Section 438.68(d) currently provides that, to the extent a State permits an exception to any of the provider-specific network standards, the standard by which an exception would be evaluated and approved must be specified in the MCO, PIHP, or PAHP contract and must be based, at a minimum, on the number of providers in that specialty practicing in the MCO's, PIHP's, or PAHP's service area. We propose to make minor grammatical revisions to § 438.68(d)(1) by deleting ''be'' before the colon and inserting ''be'' as the first word of § 438.68(d)(1)(i) and (ii), which is included in separate CHIP regulations through an existing cross-reference at § 457.1218. We also propose to add a new standard at § 438.68(d)(1)(iii) for Medicaid, and through an existing cross-reference at § 457.1218 for separate CHIP, for reviews of exception requests, which would require States to consider the payment rates offered by the MCO, PIHP, or PAHP to providers included in the provider group subject to the exception. Managed care plans sometimes have difficulty building networks that meet network adequacy standards due to low payment rates. We believe that States should consider whether this component is a contributing factor to a plan's inability to meet the standards required by § 438.68(b)(1) and (2) and (e), when determining whether a managed care plan should be granted an exception. We remind States of their obligation at § 438.68(d)(2) to monitor enrollee access on an ongoing basis to the provider types in managed care networks that operate under an exception and report their findings as part of the annual Medicaid MCPAR required at § 438.66(e).

Our proposal for States to develop and enforce appointment wait time standards proposed at § 438.68(e) and the accompanying secret shopper surveys of plan's compliance with them (described in section I.B.1.c. of this proposed rule) proposed at § 438.68(f) are authorized by section 1932(b)(5) of the Act, and is extended to PIHPs and PAHPs through regulations based on our authority under section 1902(a)(4) of the Act, and authorized for CHIP through section 2103(f)(3) of the Act. We believe that secret shopper surveys could provide unbiased, credible, and representative data on how often network providers are offering routine appointments within the State's appointment wait time standards and these data would aid managed care plans as they assess their networks, pursuant to § 438.207(b), and provide an assurance to States that their networks have the capacity to serve the expected enrollment in their service area and that it offers appropriate access to preventive and primary care services for their enrollees. States should find the results of the secret shopper surveys a rich source of information to assess compliance with the components of their quality strategy that address access to care and determine whether covered services are available within reasonable timeframes, as required in section 1932(c)(1)(A)(i) of the Act and required for CHIP through section 2103(f)(3) of the Act.

Section 1932(d)(5) of the Act requires that, no later than July 1, 2018, contracts with MCOs and PCCMs, as applicable, must include a provision that providers of services or persons terminated (as described in section 1902(kk)(8) of the Act) from participation under this title, title XVIII, or title XXI must be terminated from participating as a provider in any network. Although States have had to comply with this provision for several years, we believe we should reference this important provision in 42 CFR part 438, as well as use our authority under section 1902(a)(4) of the Act to apply it to PIHPs and PAHPs. To do this, we propose a new § 438.214(d)(2) to reflect that States must ensure through their MCO, PIHP, and PAHP contracts that providers of services or persons terminated (as described in section 1902(kk)(8) of the Act) from participation under this title, title XVIII, or title XXI must be terminated from participating as a provider in any Medicaid managed care plan network.

We propose that States would have to comply with § 438.68(b)(1), (e), and (g) no later than the first MCO, PIHP, or PAHP rating period that begins on or after 3 years after the effective date of the final rule as we believe this is a reasonable timeframe for compliance. We propose that States would have to comply with § 438.68(f) no later than the first MCO, PIHP, or PAHP rating period that begins on or after 4 years after the effective date of the final rule. We propose that States would have to comply with § 438 (d)(1)(iii) no later than the first MCO, PIHP, or PAHP rating period that begins on or after 2

years after the effective date of the final rule. We have proposed these applicability dates in § 438.68(h) for Medicaid, and for separate CHIPs through an existing cross-reference at § 457.1218 and a proposed cross-reference at § 457.1200(d).

c. Secret Shopper Surveys (§§ 438.68(f), 457.1207, 457.1218)

We recognize that in some States and for some services, Medicaid beneficiaries face significant gaps in access to care. Evidence suggests that in some localities and for some services, it takes Medicaid beneficiaries longer to access medical appointments compared to individuals with other types of health coverage.[23] This may be exacerbated by difficulties in accessing accurate information about managed care plans' provider networks; although Medicaid and CHIP managed care plans are required to make regular updates to their online provider directories in accordance with §§ 438.10(h)(3) and 457.1207 respectively, analyses of these directories suggest that a significant share of provider listings include inaccurate information on, for example, how to contact the provider, the provider's network participation, and whether the provider is accepting new patients.[24] Relatedly, analyses have shown that the vast majority of services delivered to Medicaid beneficiaries are provided by a small subset of health providers listed in managed care plan provider directories, with a substantial share of listed providers delivering little or no care for Medicaid beneficiaries.[25] Some measures of network adequacy may not be as meaningful as intended if providers are ''network providers'' because they have a contract with a managed care plan, but in practice are not actually accepting new Medicaid enrollees or impose a cap on the number of Medicaid enrollees they will see.

To add a greater level of validity and accuracy to States' efforts to measure network adequacy and access, we propose to require States to use secret shopper surveys as part of their monitoring activities. Secret shopper surveys are a form of research that can provide high-quality data and actionable feedback to States and managed care plans and can be performed either as ''secret'' meaning the caller does not identify who they are performing the survey for or ''revealed'' meaning the caller identifies the entity for which they are performing the survey. While both types of surveys can produce useful results, we believe the best results are obtained when the survey is done as a secret shopper and the caller pretends to be an enrollee (or their representative) trying to schedule an appointment. Results from these surveys should be unbiased, credible, and reflect what it is truly like to be an enrollee trying to schedule an appointment, which is a perspective not usually provided by, for example, time and distance measures or provider-to-enrollee ratios. Many States and managed care plans currently use some type of survey to monitor access; however, we believe there should be some consistency to their use for Medicaid managed care programs to enable comparability.

To ensure consistency, we propose a new § 438.68(f), and propose to require that States use independent entities to conduct annual secret shopper surveys of managed care plan compliance with appointment wait time standards proposed at § 438.68(e) and the accuracy of certain data in all managed care plans' electronic provider directories required at § 438.10(h)(1). These proposed changes apply equally to separate CHIPs through existing cross-references at §§ 457.1218 and 457.1207. We believe that the entity that conducts these surveys must be independent of the State Medicaid or CHIP agency and its managed care plans subject to the survey to ensure unbiased results. Therefore, at § 438.68(f)(3)(i), we propose to consider an entity to be independent of the State if it is not part of the State Medicaid agency and, at § 438.68(f)(3)(ii), to consider an entity independent of a managed care plan subject to a secret shopper survey if the entity is not an MCO, PIHP, or PAHP; is not owned or controlled by any of the MCOs, PIHPs, or PAHPs subject to the surveys; and does not own or control any of the MCOs, PIHPs, or PAHPs subject to the surveys. Given the valuable data the proposed secret shopper surveys could provide States, we believe requiring the use of an independent entity to conduct the surveys would be critical to ensure unbiased results.

We also propose to require States to use secret shopper surveys to determine the accuracy of certain provider directory information in MCOs', PIHPs', and PAHPs' most current electronic provider directories at § 438.68(f)(1)(i). Since we believe that paper directory usage is dwindling due to the ever-increasing use of electronic devices and because electronic directory files are usually used to produce paper directories, we are not requiring secret shopper validation of paper directories. Rather, we propose in § 438.68(f)(1)(i)(A) through (C) to require surveys of electronic provider directory data for primary care providers, OB/GYN providers, and outpatient mental health and substance use disorder providers, if they are included in the managed care plan's provider directories. We are proposing these provider types because they are the provider types with the highest utilization in many Medicaid managed care programs.

To ensure that a secret shopper survey can be used to validate directory data for every managed care plan, we propose in § 438.68(f)(1)(i)(D) to require secret shopper surveys for provider directory data for the provider type selected by the State for its appointment wait time standards in § 438.68(e)(1)(iv). We recognize that the State-chosen provider type may vary across managed care plan types and thus, States may have to select multiple provider types to accommodate all of their managed care programs. For example, a State may select a provider type from their MCOs' directories that is not a provider type included in their mental health PIHP's directories; just as the State may select a provider type from their behavioral health PIHPs' directories that is not a provider type included in their dental PAHPs' directories. We note that the State-chosen provider type cannot vary among plans of the same type within the same managed care program. Although this degree of variation between States would limit comparability, we believe that the value of validating provider directory data outweighs this limitation and that having results for provider types that would be important to State specific access issues would be a rich source of data for States to evaluate managed care plan performance and require the impacted plan to implement timely remediation, if needed.

At § 438.68(f)(1)(ii)(A) through (D), we propose to require that States use

[23] W. Hsiang, A. Lukasiewicz, and M. Gentry, ''Medicaid Patients Have Greater Difficulty Scheduling Health Care Appointments Compared With Private Insurance Patients: A Meta-Analysis,'' SAGE Journals, April 5, 2019, available at *https://journals.sagepub.com/doi/full/10.1177/0046958019838118.*

[24] A. Burman and S. Haeder, ''Directory Accuracy and Timely Access in Maryland's Medicaid Managed Care Program,'' Journal of Health Care for the Poor and Underserved, available at *https://pubmed.ncbi.nlm.nih.gov/35574863/;* A. Bauman and S. Haeder, ''Potemkin Protections: Assessing Provider Directory Accuracy and Timely Access for Four Specialties in California,'' Journal of Health Politics, Policy and Law, 2022, available at *https://pubmed.ncbi.nlm.nih.gov/34847230/.*

[25] A. Ludomirsky, et. al., ''In Medicaid Managed Care Networks, Care is Highly Concentrated Among a Small Percentage of Physicians,'' Health Affairs, May 2022, available at *https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2021.01747.*

independent entities to conduct annual secret shopper surveys to verify the accuracy of four pieces of data in each MCO, PIHP, or PAHP electronic provider directory required at § 438.10(h)(1): the active network status with the MCO, PIHP, or PAHP; the street address as required at § 438.10(h)(1)(ii); the telephone number as required at § 438.10(h)(1)(iii); and whether the provider is accepting new enrollees as required at § 438.10(h)(1)(vi). We believe these are the most critical pieces of information that enrollees rely on when seeking network provider information. Inaccuracies in this information can have a tremendously detrimental effect on enrollees' ability to access care since finding providers that are not in the managed care plan's network, have inaccurate addresses and phone numbers, or finding providers that are not accepting new patients listed in a plan's directory can delay their ability to contact a network provider and ultimately, receive care.

To maximize the value of using secret shopper surveys to validate provider directory data, identified errors must be corrected as quickly as possible. Therefore, at § 438.68(f)(1)(iii) and (iv) respectively, we propose that States must receive information on all provider directory data errors identified in secret shopper surveys no later than 3 business days from identification by the entity conducting the secret shopper survey and that States must then send that data to the applicable managed care plan within 3 business days of receipt. We also propose in § 438.68(f)(1)(iii) that the information sent to the State must be ''sufficient to facilitate correction'' to ensure that enough detail is provided to enable the managed care plans to quickly investigate the accuracy of the data and make necessary corrections. We note that States could delegate the function of forwarding the information to the managed care plans to the entity conducting the secret shopper surveys so that the State and managed care plans receive the information at the same time. This would hasten plans' receipt of the information as well as alleviate State burden. To ensure that managed care plans use the data to update their electronic directories, we propose at § 438.10(h)(3)(iii) to require MCOs, PIHPs, and PAHPs to use the information from secret shopper surveys required at § 438.68(f)(1) to obtain corrected information and update provider directories no later than the timeframes specified in § 438.10(h)(3)(i) and (ii), and included in separate CHIP regulations through an existing cross-reference at § 457.1207. While updating provider directory data after it has been counted as an error in secret shopper survey results would not change a managed care plan's compliance rate, it would improve provider directory accuracy more quickly and thus, improve access to care for enrollees.

To implement section 5123 of the Consolidated Appropriations Act of 2023,[26] we propose to revise § 438.10(h)(1) by adding ''searchable'' before ''electronic form'' to require that managed care plan electronic provider directories be searchable. We also propose to add paragraph (ix) to § 438.10(h)(1) to require that managed care plan provider directories include information on whether each provider offers covered services via telehealth. These proposals would align the text in § 438.10(h) with section 1932(a)(5) of the Act, as amended by section 5123 of the Consolidated Appropriations Act of 2023. Section 5123 of the Consolidated Appropriations Act of 2023 specifies that the amendments to section 1932(a)(5) of the Act will take effect on July 1, 2025; therefore, we propose that States would have to comply with the revisions to § 438.10(h)(1) and new (h)(1)(ix) by July 1, 2025.

Our proposals for a secret shopper survey of provider directory data proposed at § 438.68(f)(1) are authorized by section 1932(a)(5)(B)(i) of the Act for Medicaid and through section 2103(f)(3) of the Act for CHIP, which require each Medicaid MCO to make available the identity, locations, qualifications, and availability of health care providers that participate in their network. The authority for our proposals is extended to PIHPs and PAHPs through regulations based on our authority under section 1902(a)(4) of the Act. We propose that secret shopper surveys include verification of certain providers' active network status, street address, telephone number, and whether the provider is accepting new enrollees; these directory elements reflect the identity, location, and availability, as required for Medicaid in section 1932(a)(5)(B)(i) of the Act and required for CHIP through section 2103(f)(3) of the Act. Although the statute does not explicitly include ''accurate'' to describe ''the identity, locations, qualifications, and availability of health care providers,'' we believe it is the intent of the text and therefore, utilizing secret shopper surveys to identify errors in provider directories would help managed care plans ensure the accuracy of the information in their directories. Further, our proposal at § 438.10(h)(3)(iii) for managed care plans to use the data from secret shopper surveys to make timely corrections to their directories would also be consistent with statutory intent to reflect accurate identity, locations, qualifications, and availability information. Secret shopper survey results would provide vital information to help managed care plans fulfill their obligations to make the identity, locations, qualifications, and availability of health care providers that participate in the network available to enrollees and potential enrollees.

We believe using secret shopper surveys could also be a valuable tool to help States meet their enforcement obligations of appointment wait time standards, required in § 438.68(e). Secret shopper surveys are perhaps the most commonly used tool to assess health care appointment availability and can produce unbiased, actionable results. At § 438.68(f)(2), we propose to require States to determine each MCO's, PIHP's, and PAHP's rate of network compliance with the appointment wait time standards proposed in § 438.68(e)(1). We also propose in § 438.68(f)(2)(i) that, after consulting with States and other interested parties and providing public notice and opportunity to comment, we may select additional provider types to be added to secret shopper surveys of appointment wait time standards. We believe that after reviewing States' assurances of compliance and accompanying analyses of secret shopper survey results as proposed at § 438.207(d), and through an existing cross-reference at § 457.1230(b) for separate CHIP, we may propose additional provider types be subject to secret shopper surveys in future rulemaking.

In section I.B.1.b. of this proposed rule, we explained that States need to balance the use of telehealth with the availability of providers that can provide in-person care and enrollees' preferences for receiving care to ensure that they establish network adequacy standards under § 438.68(e) that accurately reflect the practical use of telehealth and in-person appointments in their State. To ensure that States reflect this, in § 438.68(f)(2)(ii), we propose that appointments offered via telehealth only be counted towards compliance with appointment wait time standards if the provider also offers in-person appointments and that telehealth visits offered during the secret shopper survey be separately identified in the survey results. We believe it would be appropriate to prohibit managed care plans from meeting appointment wait time standards with telehealth

[26] *BILLS-117hr2617enr.pdf* (*congress.gov*).

appointments alone and by separately identifying telehealth visits in the results because this would help States determine if the type of appointments being offered by providers is consistent with expectations and enrollees' needs. We note that this proposal is consistent with the requirement for QHPs beginning in 2024.[27] Managed care encounter data in Transformed Medicaid Statistical Information system (T–MSIS) reflects that most care is still provided in-person and that use of telehealth has quickly returned to near pre-pandemic levels. We believe by explicitly proposing to limit the counting of telehealth visits to meet appointment wait time standards, as well as the segregation of telehealth and in-person appointment data, secret shopper survey results would produce a more accurate reflection of what enrollees actually experience when attempting to access care. We considered aligning appointment wait times and telehealth visits with the process used by MA for demonstrating overall network adequacy, which permits MA organizations to receive a 10-percentage point credit towards the percentage of beneficiaries residing within published time and distance standards for the applicable provider specialty type and county when the plan includes one or more telehealth providers that provide additional telehealth benefits. However, we believe our proposal would provide States and CMS with more definitive data to assess the use of telehealth and enrollee preferences and would be the more appropriate method to use at this time. We request comment on this proposal.

Our proposal for secret shopper surveys of plans' compliance with appointment wait time standards proposed at § 438.68(f)(2) is authorized by section 1932(b)(5) of the Act for Medicaid and through section 2103(f)(3) of the Act for CHIP, because secret shopper surveys could provide unbiased, credible, and representative data on how often network providers are offering routine appointments within the State's appointment wait time standards. This data should aid managed care plans as they assess their networks, pursuant to § 438.207(b), and provide an assurance to States that their networks have the capacity to serve the expected enrollment in their service area. States should find the results of the secret shopper surveys a rich source of information to assess compliance with the components of their quality strategy that address access to care and determine whether covered services are available within reasonable timeframes, as required in section 1932(c)(1)(A)(i) of the Act for Medicaid and section 2103(f)(3) of the Act for CHIP.

It is critical that secret shopper survey results be obtained in an unbiased manner using professional techniques that ensure objectivity. To reflect this, we propose at § 438.68(f)(3) that any entity that conducts secret shopper surveys must be independent of the State Medicaid agency and its managed care plans subject to a secret shopper survey. In § 438.68(f)(3)(i) and (ii), we propose the criteria for an entity to be considered independent: Section 438.68(f)(3)(i) proposes that an entity cannot be a part of any State governmental agency to be independent of a State Medicaid agency and § 438.68(f)(3)(ii) proposes that to be independent of the managed care plans subject to the survey, an entity would not be an MCO, PIHP, or PAHP, would not be owned or controlled by any of the MCOs, PIHPs, or PAHPs subject to the surveys, and would not own or control any of the MCOs, PIHPs, or PAHPs subject to the surveys. We propose to define ''independent'' by using criteria that is similar, but not as restrictive, as the criteria used for independence of enrollment brokers and specified at § 438.810(b)(1). We believe this consistency in criteria would make it easier for States to evaluate the suitability of potential survey entities. We remind States that the optional EQR activity at § 438.358(c)(5) could be used to conduct the secret shopper surveys proposed at § 438.68(f) and for secret shopper surveys conducted for MCOs, States may be able to receive enhanced Federal financial participation (FFP), pursuant to § 438.370.

Secret shopper surveys can be conducted in many ways, using varying levels of complexity and gathering a wide range of information. We want to give States flexibility to design their secret shopper surveys to produce results that not only validate managed care plans' compliance with provider directory data accuracy as proposed at § 438.68(f)(1) and appointment wait time standards at § 438.68(f)(2), but also provide States the opportunity to collect other information that would assist them in their program monitoring activities and help them achieve programmatic goals. To provide this flexibility, we are proposing a limited number of methodological standards for the required secret shopper surveys. In § 438.68(f)(4), we propose that secret shopper surveys would have to be completed for a statistically valid sample of providers and: (1) use a random sample; and (2) include all areas of the State covered by the MCO's, PIHP's, or PAHP's contract. We believe these would be the most basic standards that all secret shopper surveys would have to meet to produce useful results that enable comparability between plans and among States. We propose in § 438.68(f)(4)(iii) that secret shopper surveys to determine plan compliance with appointment wait time standards would have to be completed for a statistically valid sample of providers to be clear that a secret shopper surveys must be administered to the number providers identified as statistically valid for each plan. To ensure consistency, equity, and context to the final compliance rate for each plan, we believe it would be important that inaccurate provider directory data not reduce the number of surveys administered. Therefore, as a practical matter, if the initial data provided by a State to the entity performing the survey does not permit surveys to be completed for a statistically valid sample, the State would need to provide additional data to enable completion of the survey for an entire statistically valid sample. We do not believe this provision would need to apply to secret shopper surveys of provider directory data proposed in paragraph (f)(1) since the identification of incorrect directory data is the intent of those surveys and should be reflected in a plan's compliance rate.

Because we believe secret shopper survey results can produce valuable data for States, managed care plans, enrollees and other interested parties, we propose at § 438.68(f)(5), that the results of these surveys would be reported to CMS and posted on the State's website. Specifically, at § 438.68(f)(5)(i), we propose that the results of the secret shopper surveys of provider directory data validation at § 438.68(f)(1) and appointment wait time standards at § 438.68(f)(2) would be reported to CMS annually using the content, form, and submission times proposed in § 438.207(d). At § 438.68(f)(5)(ii), we propose that States post the results on the State's website required at § 438.10(c)(3) within 30 calendar days of the State submitting them to CMS. We believe using the existing report required at § 438.207(d) would lessen burden on States, particularly since we published the Network Adequacy and Access Assurances Report template [28] in July 2022 and are also developing an electronic reporting portal to facilitate States' submissions. We anticipate

[27] *https://www.cms.gov/sites/default/files/2022-04/Final-2023-Letter-to-Issuers_0.pdf.*

[28] *https://www.medicaid.gov/medicaid/managed-care/downloads/network-assurances-template.xlsx.*

revising the data fields in the Network Adequacy and Access Assurances Report [29] to include specific fields for secret shopper results, including the provider type chosen by the State as required in § 438.68(e)(1)(iv) and (f)(1)(i)(D). This proposal is authorized by section 1902(a)(6) of the Act which requires that States provide reports, in such form and containing such information, as the Secretary may from time to time require.

We recognize that implementing secret shopper surveys would be a significant undertaking, especially for States not already using them; but we believe that the data produced by successful implementation of them would be a valuable addition to States' and CMS' oversight efforts. As always, technical assistance would be available to help States effectively implement and utilize secret shopper surveys. We invite comment on the type of technical assistance that would be most useful for States as well as States' best practices and lessons learned from using secret shopper surveys.

We also propose that States would have to comply with § 438.68(f) no later than the first MCO, PIHP, or PAHP rating period that begins on or after 4 years after the effective date of the final rule.

d. Assurances of Adequate Capacity and Services—Provider Payment Analysis (§§ 438.207(b), 457.1230(b))

We believe there needs to be greater transparency in Medicaid and CHIP provider payment rates in order for States and CMS to monitor and mitigate payment-related access barriers. There is considerable evidence that Medicaid payment rates, on average, are lower than Medicare and commercial rates for the same services and that provider payment influences access, with low rates of payment limiting the network of providers willing to accept Medicaid patients, capacity of those providers who do participate in Medicaid, and investments in emerging technology among providers that serve large numbers of Medicaid beneficiaries. However, there is no standardized, comprehensive, cross-State comparative data source available to assess Medicaid and CHIP payment rates across clinical specialties, health plans, and States. Given that a critical component of building a managed care plan network is payment, low payment rates can harm access to care for Medicaid and CHIP enrollees in a number of ways. Evidence suggests that low Medicaid physician fees limit physicians' participation in the program, particularly for behavioral health and primary care providers.[30] [31] Relatedly, researchers have found that increases in the Medicaid payment rates are directly associated with increases in provider acceptance of new Medicaid patients. In short, two key drivers of access—provider network size and capacity—are inextricably linked with Medicaid provider payment levels and acceptance of new Medicaid patients.[32] [33] While many factors affect provider participation, given the important role rates play in assuring access, greater transparency is needed to understand when and to what extent provider payment may influence access in State Medicaid and CHIP programs to specific provider types or for Medicaid and CHIP beneficiaries enrolled in specific plans.

We also believe that greater transparency and oversight is warranted as managed care payments have grown significantly as a share of total Medicaid payments; in FY 2021, the Federal government spent nearly $250 billion on payments to managed care plans.[34] With this growth, we seek to develop, use, and facilitate State use of data to generate insights into important, provider rate related indicators of access. Unlike fee-for-service (FFS) Medicaid and CHIP programs, managed care plans generally have the ability to negotiate unique reimbursment rates for individual providers. Generally, unless imposed by States through a State directed payment or mandated by statute (such as Federally qualified health centers payment requirements established under section 1902(bb) of the Act), there are no Federal regulatory or statutory minimum or maximum limits on the payment rates a managed care plan can negotiate with a network provider. As such, there can be tremendous variation among plans' payment rates, and we often do not have sufficient visibility into those rates to perform analyses that would promote a better understanding of how these rates are impacting access. Section 438.242(c)(3) for Medicaid, and through cross-reference at § 457.1233(d) for separate CHIP, requires managed care plans to submit to the State all enrollee encounter data, including allowed amounts and paid amounts, that the State is required to report to CMS. States are then required to submit those data to T–MSIS as required in § 438.818 for Medicaid, and through cross-reference at § 457.1233(d) for separate CHIP. However, variation in the quantity and quality of T–MSIS data, particularly for data on paid amounts, remains. We believe that provider payment rates in managed care are inextricably linked with provider network sufficiency and capacity and seek to propose a process through which managed care plans must report, and States must review and analyze, managed care payment rates to providers as a component of States' responsibility to ensure network adequacy and enrollee access consistent with State and Federal standards. Linking payment levels to quality of care is consistent with a strategy that we endorsed in our August 22, 2022 CIB [35] urging States to link Medicaid payments to quality measures to improve the safety and quality of care.

To ensure comparability in managed care plans' payment analyses, we propose to require a payment analysis that managed care plans would submit to States per § 438.207(b)(3) and States would review and include in the assurance and analysis to CMS per § 438.207(d). Specifically, we propose to replace the periods at the end of § 438.207(b)(1) and (2) with semi-colons and add ''and'' after § 438.207(b)(2) to make clear that (b)(1) through (3) would all be required for Medicaid managed care, and for separate CHIP through an existing cross-reference at § 457.1230(b).

At § 438.207(b)(3) for Medicaid, and for separate CHIP through an existing cross-reference at § 457.1230(b), we propose to require that MCOs, PIHPs, and PAHPs submit annual documentation to the State that demonstrates a payment analysis showing their level of payment for certain services, if covered by the managed care plan's contract. We

[29] *https://www.medicaid.gov/medicaid/managed-care/guidance/medicaid-and-chip-managed-care-reporting/index.html#NETWORK:~:text=Report.%20%C2%A0The%20current-,excel%20template,-(XLSX%2C%20218.99%20KB.*

[30] Holgash K, Heberlein M. Physician acceptance of new Medicaid patients. Washington (DC): Medicaid and CHIP Payment and Access Commission; 2019 Jan 24. Available from *https://www.macpac.gov/wp-content/uploads/2019/01/Physician-Acceptance-of-New-Medicaid-Patients.pdf.*

[31] Zuckerman S, Skopec L, and Aarons J. Medicaid Physician Fees Remained Substantially Below Fees Paid by Medicare in 2019. *Health Aff (Millwood).* 2021;40(2). doi:10.1377/hlthaff.2020.00611.

[32] National Bureau of Economic Research, ''Increased Medicaid Reimbursement Rates Expand Access to Care,'' October 2019, available at *https://www.nber.org/bh-20193/increased-medicaid-reimbursement-rates-expand-access-care.*

[33] Zuckerman S, Skopec L, and Aarons J. Medicaid Physician Fees Remained Substantially Below Fees Paid by Medicare in 2019. *Health Aff (Millwood).* 2021;40(2). doi:10.1377/hlthaff.2020.00611.

[34] Congressional Budget Office, ''Baseline Projections—Medicaid,'' May 2022, available at *https://www.cbo.gov/system/files/2022-05/51301-2022-05-medicaid.pdf.*

[35] *https://www.medicaid.gov/federal-policy-guidance/downloads/cib08222022.pdf.*

propose that the analysis would use paid claims data from the immediate prior rating period to ensure that all payments are captured, including those that are negotiated differently than a plan's usual fee schedule. We also believe it is important to use claims data to ensure that utilization would be considered to prevent extremely high or low payments from inappropriately skewing the results. We acknowledge that paid claims data would likely not be complete within 180 days of the end of a rating period, which is when this analyis is proposed to be reported by the State in § 438.207(d)(3)(ii). However, we believe that the data would be sufficiently robust to produce a reasonable percentage that reflects an appropriate weighting to each payment based on actual utilization and could be provided to the State far enough in advance of the State submitting its reporting to CMS to be incorporated. We believe this analysis of payments would provide States and CMS with vital information to assess the adequacy of payments to providers in managed care programs, particularly when network deficiencies or quality of care issues are identified or grievances are filed by enrollees regarding access or quality.

In § 438.207(b)(3)(i) for Medicaid, and for separate CHIP through an existing cross-reference at § 457.1230(b), we propose to require that each MCO, PIHP, and PAHP would use paid claims data from the immediate prior rating period to determine the total amount paid for evaluation and management current procedural terminology (CPT) codes for primary care, OB/GYN, mental health, and SUD services. Due to the unique payment requirements in section 1902(bb) of the Act for Federally qualified health centers and rural health clinics, we propose in § 438.207(b)(3)(iv) to exclude these provider types from the analysis. We further propose that this analysis provide the percentage that results from dividing the total amount the managed care plan paid by the published Medicare payment rate for the same codes on the same claims. Meaning, the payment analysis would reflect the comparison of how much the managed care plan paid for the evaluation and managment CPT codes to the published Medicare payment rates including claim-specific factors such as provider type, geographic location where the service was rendered, and the site of service. In § 438.207(b)(3)(i)(A) for Medicaid, and for separate CHIP through an existing cross-reference at § 457.1230(b), we also propose that the plans would include in the analysis separate total amounts paid and separate comparison percentages to Medicare for primary care, OB/GYN, mental health, and substance use disorder services for ease of analysis and clarity. Lastly in § 438.207(b)(3)(i)(B) for Medicaid, and for separate CHIP through an existing cross-reference at § 457.1230(b), we propose that the percentages would have to be reported separately if they differ between adult and pediatric services. We believe the proposals in § 438.207(b)(3)(i)(A) and (B) would ensure sufficient detail in the data to enable more granular analysis across plans and States as well as to prevent some data from obscuring issues with other data. For example, if payments for adult primary care are significantly lower than pediatric primary care, providing separate totals and comparison percentages would prevent the pediatric data from artificially inflating the adult totals and percentages. We believe this level of detail would be necessary to prevent misinterpretation of the data.

We propose in § 438.207(b)(3)(ii) for Medicaid, and for separate CHIP through an existing cross-reference at § 457.1230(b), to require that the payment analysis provide the total amount paid for homemaker services, home health aide services, and personal care services and the percentage that results from dividing the total amount paid by the amount the State's Medicaid or CHIP FFS program would have paid for the same claims. We propose two differences between this analysis and the analysis in § 438.207(b)(3)(i): first, this analysis would use all codes for the services as there are no evaluation and management CPT codes for these LTSS; and second, we propose the comparison be to Medicaid or CHIP FFS payment rates, as applicable, due to the lack of comparable Medicare rates for these services. We propose these three services as we believe these have high impact to help keep enrollees safely in the community and avoid institutionalization. Again, we believe this analysis of payment rates would be important to provide States and CMS with information to assess the adequacy of payments to providers in managed care programs, particularly when enrollees have grievances with services approved in their care plans not being delivered or not delivered in the authorized quantity. We request comment on whether in-home habilitation provided to enrollees with IDD should be added to this analysis.

We believe that managed care plans could perform the analyses in § 438.207(b)(3)(i) and (ii) by: (1) Identifying paid claims in the prior rating period for each required service type; (2) identifying the appropriate codes and aggregating the payment amounts for the required service types; and (3) calculating the total amount that would be paid for the same codes on the claims at 100 percent of the appropriate published Medicare rate, or Medicaid/CHIP FFS rate for the analysis in § 438.207(b)(3)(ii), applicable on the date of service. For the aggregate percentage, divide the total amount paid (from 2. above) by the amount for the same claims at 100 percent of the appropriate published Medicare rate or Medicaid/CHIP FFS, as appropriate (from 3. above). We believe this analysis would require a manageable number of calculations using data readily available to managed care plans.

To ensure that the payment analysis proposed in paragraph (b)(3) is appropriate and meaningful, we propose at § 438.207(b)(3)(iii) for Medicaid, and for separate CHIP through an existing cross-reference at § 457.1230(b), to exclude payments for claims for the services in (b)(3)(i) for which the managed care plan is not the primary payer. A comparison to payment for cost sharing only or payment for a claim for which another payer paid a portion would provide little, if any, useful information.

The payment analysis proposed at § 438.207(b)(3) is authorized by sections 1932(c)(1)(A)(ii) and 2103(f)(3) of the Act, which requires States' quality strategies to include an examination of other aspects of care and service directly related to the improvement of quality of care. The authority for our proposals is extended to PIHPs and PAHPs through regulations based on our authority under section 1902(a)(4) of the Act. Because the proposed payment analysis would generate data on each managed care plan's payment levels for certain provider types as a percent of Medicare or Medicaid FFS rates, States could use the analysis in their examination of other aspects of care and service directly related to the improvement of quality of care, particularly access. Further, sections 1932(c)(1)(A)(iii) and 2103(f)(3) of the Act authorizes the proposals in this section as enabling States to compare payment data among managed care plans in their program could provide useful data to fulfill their obligations for monitoring and evaluating quality and appropriateness of care.

We also propose to revise § 438.207(f) to reflect that States would have to comply with § 438.207(b)(3) no later than the first rating period that begins on or after 2 years after the effective date

of the final rule as we believe this is a reasonable timeframe for compliance.

e. Assurances of Adequate Capacity and Services Reporting (§§ 438.207(d), 457.1230(b))

Currently at § 438.207(d), States are required to review the documentation submitted by their managed care plans, as required at § 438.207(b), and then submit to CMS an assurance of their managed care plans' compliance with §§ 438.68 and 438.206. To make States' assurances and analyses more comprehensive, we propose to revise § 438.207(d) to explicitly require States to include the results from the secret shopper surveys proposed in § 438.68(f) (see section I.B.1.c. of this proposed rule) and included in separate CHIP regulations through an existing cross-reference at § 457.1230(b). We also propose to require States to include the payment analysis proposed in § 438.207(b)(3) (see section I.B.1.d. of this proposed rule) to their assurance and analyses reporting. Additionally, on July 6, 2022, we published a CIB [36] that provided a reporting template Network Adequacy and Access Assurances Report [37] for the reporting required at § 438.207(d). To be clear that States would have to use the published template, we propose to explicitly require that States submit their assurance of compliance and analyses required in § 438.207(d) in the ''format prescribed by CMS.'' The published template would fulfill this requirement as would future versions including any potential electronic formats. We believe the revision proposed in § 438.207(d) would be necessary to ensure consistent reporting to CMS and enable effective analysis and oversight. Lastly, because we propose new requirements related to the inclusion of the payment analysis and the timing of the submission of this reporting to CMS, we propose to redesignate the last sentence in § 438.207(d) as § 438.207(d)(1) and create a new § 438.207(d)(2) and (3).

In § 438.207(d)(2) for Medicaid and included in separate CHIP regulations through an existing cross-reference at § 457.1230(b), we propose that the States' analysis required in § 438.207(d)(1) must include the payment analysis required of plans in § 438.207(b)(3) and provide the elements specified in paragraphs (d)(2)(i) and (ii). Specifically, § 438.207(d)(2)(i) proposes to require States to include the data submitted by each plan and § 438.207(d)(2)(ii) proposes to require States to use the data from its plans' reported payment analysis percentages and weight them using the member months associated with the applicable rating period to produce a Statewide payment percentage for each service type. We believe these data elements would provide valuable new data to support States' assurances of network adequacy and access and we would revise the Network Adequacy and Access Assurances Report template published in July 2022 to add fields for States to easily report these data. We remind States that § 438.66(a) and (b) require States to have a monitoring system for all of their managed care programs and include all aspects, including the performance of their managed care plans in the areas of availability and accessibility of services, medical management, provider network management, and appeals and grievances. Accordingly, States should have ample data from their existing monitoring activities and which would be supplemented by the proposal requirements in this rule, to improve the performance of their managed care programs for all covered services, as required in § 438.66(c). Because concerns around access to primary care, mental health, and SUD services have been raised nationally, we expect States to review and analyze their plans' data holistically to provide a robust, comprehensive analysis of the adequacy of each plan's network and level of realistic access and take timely action to address deficiencies.

Section 438.207(d) was codified in 2002 (67 FR 41010) as part of the implementing regulations for section 1932(b)(5) of the Act ''Demonstration of Adequate Capacity and Services.'' In the 2016 final rule, we made minor revisions to the language but did not address the timing of States' submission of their assurance and analysis. Given the July 2022 release of the Network Adequacy and Access Assurances Report template for the assurance and analysis, we believe it would be appropriate to clarify this important aspect of the reporting requirement. To simplify the submission process and enable States and CMS to allot resources most efficiently, we propose to establish submission times in § 438.207(d)(3)(i) through (iii) that correspond to the times for managed care plans to submit documentation to the State in § 438.207(c)(1) through (3). Specifically for Medicaid, we propose that States submit their assurance and analysis at § 438.207(d)(3): (1) at the time it submits a completed readiness review, as specified at § 438.66(d)(1)(iii); (2) on an annual basis and no later than 180 calendar days after the end of each contract year; and (3) any time there has been a significant change as specified in § 438.207(c)(3) and with the submission of the associated contract. We also propose in § 438.207(d)(3) that States must post the report required in § 438.207(d) on their website within 30 calendar days of submission to CMS. We believe the information in this report would be important information for interested parties to have access to on a timely basis and 30 calendar days seems adequate for States to post the report after submitting.

Since we did not adopt the MCPAR requirements for separate CHIP managed care in the 2016 final rule, we are also not adopting the proposed submission timeframe at § 438.207(d)(3)(i). However, we propose for separate CHIPs to align with Medicaid for the proposed network adequacy analysis submission timeframes at § 438.207(d)(3)(ii) and (iii) through the existing cross-reference at § 457.1230(b).

In § 438.207(e), we propose a conforming revision to add a reference to the secret shopper evaluations proposed at § 438.68(f) as part of the documentation that States must make available to CMS, upon request, and included in separate CHIP regulations through an existing cross-reference at § 457.1230(b). We believe this would be necessary as the current text of § 438.207(e) only addresses the documentation provided by the managed care plans.

Sections 1932(b)(5) and 2103(f)(3) of the Act require Medicaid and CHIP MCOs to demonstrate adequate capacity and services by providing assurances to the State and CMS, as specified by the Secretary, that it has the capacity to serve the expected enrollment in its service area, including assurances that it offers an appropriate range of services and access to preventive and primary care services for the population expected to be enrolled in such service area, and maintains a sufficient number, mix, and geographic distribution of providers of services. The authority for our proposals is extended to PIHPs and PAHPs through regulations based on our authority under section 1902(a)(4) of the Act. Our proposals to require States to include the secret shopper surveys proposed in § 438.68(f) as well as the reimbursment analysis proposed in § 438.207(b)(3) to their assurance and analyses reporting proposed at § 438.207(d) are authorized by section 1932(b)(5) of the Act for Medicaid and

[36] *https://www.medicaid.gov/federal-policy-guidance/downloads/cib07062022.pdf.*

[37] *https://www.medicaid.gov/medicaid/managed-care/downloads/network-assurances-template.xlsx.*

authorized for CHIP through section 2103(f)(3) of the Act because the States' reports reflect the documentation and assurances provided by their managed care plans of adequate capacity, an appropriate range of services, and access to a sufficient number, mix, and geographic distribution of network providers. Sections 1932(b)(5) and 2103(f)(3) of the Act also require that the required assurances be submitted to CMS in a time and manner determined by the Secretary; that information is proposed in § 438.207(d)(3)(i) through (iii) and corresponds to the requirements for submission of documenation from managed care plans in § 438.207(c)(3).

We also propose to revise § 438.207(g) to reflect that States would have to comply with paragraph (d)(2) no later than the first managed care plan rating period that begins on or after 2 years after the effective date of the final rule and paragraph (d)(3) no later than the first managed care plan rating period that begins on or after 1 year after the effective date of the final rule. We propose that States would not be held out of compliance with the requirements of paragraphs (e) of this section prior to the first MCO, PIHP, or PAHP rating period that begins on or after 4 years after the effective date of the final rule, so long as they comply with the corresponding standard(s) codified in paragraph (e) contained in the 42 CFR, parts 430 to 481, most recently published before the final rule. We propose that States would have to comply with paragraph (f) no later than the first managed care plan rating period that begins on or after 4 years after the effective date of the final rule. We believe these are reasonable timeframes for compliance given the level of new burden imposed by each.

f. Remedy Plans To Improve Access (§ 438.207(f))

For FFS programs, we rely on § 447.203(b)(8) to require States to submit corrective action plans when access to care issues are identified. Because of the numerous proposals in this rule that would strengthen States' monitoring and enforcement of access requirements and the importance of timely remediation of access issues, we believe we should have a similar process set forth in part 438 for managed care programs. In § 438.68(e), we propose a process that would require States to carefully develop and enforce their managed care plans' use of appointment wait time standards to ensure access to care for Medicaid managed care enrollees. As proposed in a new § 438.207(f), when the State, MCO, PIHP, PAHP, or CMS identifies any access issues, including any access issues with the standards specified in §§ 438.68 and 438.206, the State would be required to submit a plan to remedy the access issues consistent with this proposal. If we determine that an access issue revealed under monitoring and enforcement rises to the level of a violation of access requirements under section 1932(c)(1)(A)(i) of the Act, as incorporated in section 1903(m)(2)(A)(xii) of the Act, we have the authority to disallow Federal financial participation (FFP) for the payments made under the State's managed care contract for failure to ensure adequate access to care. We intend to closely monitor any State remedy plans that would be needed under this proposal to ensure that both us and States would adequately and appropriately address emerging access issues in Medicaid managed care programs. Using § 447.203(b)(8) as a foundation, we propose to redesignate existing § 438.207(f) as § 438.207(g) and propose a new requirement for States to submit remedy plans in new § 438.207(f), titled Remedy plans *to* improve access. In § 438.207(f)(1), we propose that when the State, MCO, PIHP, PAHP, or CMS identifies an issue with a managed care plan's performance with regard to any State standard for access to care under this part, including the standards at §§ 438.68 and 438.206, States would follow the steps set forth in paragraphs (i) through (iv). First, in paragraph (1)(i), States would have to submit to CMS for approval a remedy plan no later than 90 calendar days following the date that the State becomes aware of an MCO's, PIHP's, or PAHP's access issue. We believe 90 calendar days would be sufficient time for States to effectively assess the degree and impact of the issue and develop an effective set of steps including timelines for implementation and completion, as well as responsible parties. In § 438.207(f)(1)(ii), we propose that the State would have to develop a remedy plan to address the identified issue that if addressed could improve access within 12 months and that identifies specific steps, timelines for implementation and completion, and responsible parties. We believe 12 months would be a reasonable amount of time for States and their managed care plans to implement actions to address the access issue and improve access to services by enrollees of the MCO, PIHP, or PAHP. We do not propose to specify that the remedy plan would be implemented by the managed care plans or the State; rather, we propose that the remedy plan would identify the responsible party required to make the access improvements at issue, which would often include actions by both States and their managed care plans. Additionally, we believe this proposal acknowledges that certain steps that may be needed to address provider shortages can only be implemented by States. For example, changing scope of practice laws to enable more providers to fill gaps in access or joining interstate compacts to enable providers to practice geographically due to the opportunity to hold one multistate license valid for practice in all compact States, streamlined licensure requirements, reduced expenses associated with obtaining multiple single-State licenses, and the creation of systems that enable electronic license application processes. Lastly, in § 438.207(f)(1)(ii), we propose some approaches that States could consider to address the access issue, such as increasing payment rates to providers, improving outreach and problem resolution to providers, reducing barriers to provider credentialing and contracting, providing for improved or expanded use of telehealth, and improving the timeliness and accuracy of processes such as claim payment and prior authorization.

We propose in § 438.207(f)(1)(iii) to require States to ensure that improvements in access are measurable and sustainable. We believe it would be critical that the remedy plan produce measurable results in order to monitor progress and, ultimately, bring about the desired improvements in access under the managed care plan. We also propose that the improvements in access achieved by the actions be sustainable so that enrollees would be able to continue receiving the improved access to care and managed care plans would continue to ensure its provision. In paragraph (f)(1)(iv) of this section, we propose that States submit quarterly progress updates to CMS on implementation of the remedy plan so that we would be able to determine if the State was making reasonable progress toward completion and that the actions in the plan are effective. Not properly monitoring progress of the remedy plan could significantly lessen the effectiveness of it and allow missed opportunities to make timely revisions and corrections.

Lastly, in paragraph (f)(2) of this section we propose that if the remedy plan required in paragraph (f)(1) of this section does not address the managed care plan's access issue within 12 months, we may require the State to continue to take steps to address the

issue for another 12 months and may require revision to the remedy plan. We believe proposing that we be able to extend the duration of actions to improve access and/or require the State to make revision to the remedy plan would be critical to ensuring that the State's and managed care plans' efforts are effective at addressing the identified access issue.

These proposals are authorized by section 1902(a)(4)(A) of the Act, which provides for methods of administration found necessary by the Secretary for the proper and efficient operation of the plan as we believe States taking timely action to address identified access issues is fundamental and necessary to the operation of an effective and efficient Medicaid program. The proposal for States to submit quarterly progress reports is authorized by section 1902(a)(6) of the Act which requires that States provide reports, in such form and containing such information, as the Secretary may from time to time require. Lastly, we believe these proposals are also authorized by section 1932(c)(1)(A)(i) and (iii) of the Act which require States that contract with MCOs to develop and implement a quality assessment and improvement strategy that includes (and extended to PIHPs and PAHPs through regulations based on our authority under section 1902(a)(4) of the Act): standards for access to care so that covered services are available within reasonable timeframes and in a manner that ensures continuity of care and adequate primary care and specialized services capacity and procedures for monitoring and evaluating the quality and appropriateness of care and services to enrollees and requirements for provision of quality assurance data to the State. Implementing timely actions to address managed care plan access issues would be an integral operational component of a State's quality assessment and improvement strategy.

g. Transparency (§§ 438.10(c), 438.602(g), 457.1207, 457.1285)

In the 2016 final rule, we finalized § 438.10(c)(3) for Medicaid, which is included in separate CHIP regulations through cross-reference at § 457.1207, which required States to operate a website that provides specific information, either directly or by linking to individual MCO, PIHP, PAHP, or PCCM entity websites. A State's website may be the single most important resource for information about its Medicaid program and there are multiple requirements for information to be posted on a State's website throughout 42 CFR part 438. Current regulations at § 438.10(c)(6)(ii) require certain information to be ''prominent and readily accessible'' and § 438.10(a) defines ''readily accessible'' as ''electronic information and services which comply with modern accessibility standards such as section 508 guidelines, section 504 of the Rehabilitation Act, and W3C's Web Content Accessibility Guidelines (WCAG) 2.0 AA and successor versions.'' Despite these requirements, we have received input from numerous and varied interested parties since the 2016 final rule about how challenging it can be to locate regulatorily required information on some States' websites.

There is variation in how ''user-friendly'' States' websites are, with some States making navigation on their website fairly easy and providing information and links that are readily available and presenting required information on one page. However, we have not found this to be the case for most States. Some States have the required information scattered on multiple pages that requires users to click on many links to locate the information they seek. While such websites may meet the current minimum standards in part 438, they do not meet our intent of providing one place for interested parties to look for all required information. Therefore, we believe revisions are necessary to ensure that all States' websites required by § 438.10(c)(3) provide a consistent and easy user experience. We acknowledge that building websites is a complex and costly endeavor that requires consideration of many factors, but we believe that States and managed care plans share an obligation to build websites that quickly and easily meet the needs of interested parties without undue obstacles. We note that State and managed care plan websites must be compliant with civil rights laws, including the Americans with Disabilities Act (ADA), section 504 of the Rehabilibation Act, Title VI of the Civil Rights Act of 1964, and section 1557 of the Affordable Care Act. In this proposed rule, we believe that there are several minimal qualities that all websites should include, such as being able to:

- Function quickly and as expected by the user;
- Produce accurate results;
- Use minimal, logical navigation steps;
- Use words and labels that users are familiar with for searches;
- Allow access, when possible, without conditions such as establishment of a user account or password;
- Provide reasonably comparable performance on computers and mobile devices;
- Provide easy access to assistance via chat; and
- Provide multilingual content for individuals with LEP.

We also believe that States and managed care plans should utilize web analytics to track website utilization and inform design changes. States should create a dashboard to regularly quantify website traffic, reach, engagement, sticking points, and audience characteristics. Given the critical role that websites fill in providing necessary and desired program information, we believe proposing additional requirements on States' websites are appropriate.

We acknowledge that States and managed care plans may have information accessible through their websites that is not public facing; for example, enrollee specific protected health information. Proper security mechanisms should continue to be utilized to prevent unauthorized access to non-public facing information, such as the establishment of a user account and password or entry of other credentials. Data security must always be a priority for States and managed care plans and the proposals in § 438.10(c)(3) in no way diminish that obligation for States.

To increase the effectiveness of States' websites and add some consistency to website users' experence, we propose in § 438.10(c)(3) to revise ''websites'' to ''web pages'' in the reference to managed care plans. We propose this change to clarify that if States provide required content on their website by linking to individual MCO, PIHP, PAHP, or PCCM entity websites, the link on the State's site would have to be to the specific page that includes the requested information. We believe this would prevent States from showing links to a landing page for the managed care plan that then leaves the user to start searching for the specific information needed. Next, we propose to add ''States must:'' to paragraph (c)(3) before the items specified in new (c)(3)(i) through (iv). In § 438.10(c)(3)(i), we propose to require that all information, or links to the information, required in this part to be posted on the State's website, be available from one page. We believe that when website users have to do repeated searches or click through multiple pages to find information, they are more likely to give up trying to locate it. As such, we have carefully chosen the information that is required in 42 CFR part 438 to be posted on States' websites to ensure effective

communication of information and believe it represents an important step toward eliminating common obstacles for States' website users.

At § 438.10(c)(3)(ii), we propose to require that States' websites use clear and easy to understand labels on documents and links so that users can easily identify the information contained in them. We believe that using terminology and the reading grade level consistent with that used in other enrollee materials, such as handbooks and notices, would make the website more familiar and easy to read for enrollees and potential enrollees. Similar to having all information on one page, using clear labeling would reduce the likelihood of users having to make unncessary clicks as they search for specific information.

In § 438.10(c)(3)(iii), we propose to require that States check their websites at least quarterly to verify that they are functioning as expected and that the information is the most currently available. Malfunctioning websites or broken links can often render a website completely ineffective, so monitoring a website's performance and content is paramount. While we are proposing that a State's website be checked for functionality and information timeliness no less than quarterly, we believe this is a minimum standard and that States should implement continual monitoring processes to ensure the accuracy of their website's performance and content.

Lastly, in § 438.10(c)(3)(iv), to enable maximum effectiveness of States' websites, we propose to require that States' websites explain that assistance in accessing the information is available at no cost to them, including information on the availability of oral interpretation in all languages and written translation in each prevalent non-English language, alternate formats, auxiliary aids and services, and a toll-free TTY/TDY telephone number. This proposal is consistent with existing information requirements in § 438.10(d) and section 1557 of the Affordable Care Act. Clear provision of this information would help to ensure that all users have access to States' websites and can obtain assistance when needed.

The Medicaid managed care website transparency revisions proposed at § 438.10(c)(3)(i) through (iv) would apply to separate CHIP through the existing cross-reference at § 457.1207.

To help States monitor their website for required content, we propose to revise § 438.602(g) to contain a more complete list of information. While we believe the list proposed in § 438.602(g) would help States verify their website's compliance, we clarify that a requirement to post materials on a State's website in 42 CFR part 438 or any other Federal regulation but omitted from § 438.602(g), is still in full force and effect. Further, requirements on States to post specific information on their websites intentionally remain throughout 42 CFR part 438 and are not replaced, modified, or superceded by the items proposed in § 438.602(g)(5) through (12). Currently § 438.602(g) specifies four types of information that States must post on their websites; we propose to add nine more as (g)(5) through (g)(13): (5) enrollee handbooks, provider directories, and formularies required at § 438.10(g), (h), and (i); (6) information on rate ranges required at § 438.4(c)(2)(iv); (7) reports required at §§ 438.66(e) and 438.207(d); (8) network adequacy standards required at § 438.68(b)(1) and (2), and (e); (9) secret shopper survey results required at § 438.68(f); (10) State directed payment evaluation reports required in § 438.6(c)(2)(v)(C); (11) links to all required Application Programming Interfaces including as specified in § 431.60(d) and (f); (12) quality related information required in §§ 438.332(c)(1), 438.340(d), 438.362(c) and 438.364(c)(2)(i); and (13) documentation of compliance with requirements in subpart K—Parity in Mental Health and Substance Use Disorder Benefits. Although we are proposing to itemize these nine types of information in § 438.602(g)(5) through (13), we note that all but the following three are currently required to be posted on States' websites: the report at § 438.207(d), secret shopper survey results at § 438.68(f), and State directed payment evaluation reports at § 438.6(c)(2)(v)(C). Lastly, in § 438.10(c)(3), we propose to make the list of website content more complete by removing the current references to paragraphs (g) through (i) only and including a reference to § 438.602(g) and ''elsewhere in this part.''

We propose to revise § 438.10(j) to reflect that States would have to comply with § 438.10(c)(3) no later than the first managed care plan rating period that begins on or after 2 years after the effective date of the final rule and that States would have to comply with § 438.10(d)(2) no later than the first managed care plan rating period that begins on or after 3 years after the effective date of the final rule. Lastly, we propose that States must comply with § 438.10(h)(3)(iii) no later than the first managed care plan rating period that begins on or after 4 years after the effective date of the final rule. We believe these proposed compliance dates would provide reasonable time for compliance given the varying levels of State and managed care plan burden.

We propose to add § 438.602(j) to require States to comply with § 438.602(g)(5) through (13) no later than the first managed care plan rating period that begins on or after 2 years after the effective date of the final rule. We believe this is a reasonable timeframe for compliance.

For separate CHIP managed care, we currently require States to comply with the transparency requirements at § 438.602(g) through an existing cross-reference at § 457.1285. We propose to align with Medicaid in adopting most of the consolidated requirements for posting on a State's website proposed at § 438.602(g)(5) through (13) for separate CHIP.

We propose to adopt the provision at § 438.602(g)(5) (which specifies that States must post enrollee handbooks, provider directories, and formularies on the State's website) because requirements at § 438.10(g) through (i) are currently required for separate CHIP through an existing cross-reference at § 457.1207.

We do not plan to adopt the provision at § 438.602(g)(6) (which requires that States must post information on rate ranges on their websites) because we do not regularly review rates for separate CHIP.

We propose to adopt the provision at § 438.602(g)(7) (which specifies that States must post their assurances of network adequacy on the State's website) since the proposed network adequacy reporting at § 438.207(d) would apply to separate CHIP through an existing cross-reference at § 457.1230(b) (see section I.B.1.e. of this proposed rule). Since we did not adopt the managed care program annual reporting requirements at § 438.66(e) for separate CHIP, we propose to exclude this reporting requirement at § 457.1230(b).

We propose to adopt the provision at § 438.602(g)(8) (which requires State network adequacy standards to be posted on the State's website) for separate CHIP because we propose to adopt the new appointment wait time reporting requirements through an existing cross-reference at § 457.1230(b) (see section I.B.1.e. of this proposed rule), though we propose to exclude references to LTSS as not applicable to separate CHIP.

We propose to adopt the provision at § 438.602(g)(9) (which specifies that States must post secret shopper survey results on the State's website) for separate CHIP network access reporting to align with our proposed adoption of

secret shopper reporting at § 438.68(f) through an existing cross-reference at § 457.1218 (see section I.B.1.c. of this proposed rule).

We do not propose to adopt the provision at § 438.602(g)(10) (which directs States to post SDP evaluation reports on the State's website) because State directed payments are not applicable to separate CHIP.

We propose to adopt the provision at § 438.602(g)(11) (which specifies that States must post required information for Application Programming Interfaces on the State's website) given the existing requirements at § 457.1233(d).

We propose to adopt the provision at § 438.602(g)(12) (which requires States to post quality-related information on the State's website) for separate CHIP as required through cross-references at § 457.1240(c) and (e), as well as the applicable EQR report through a cross-reference at § 457.1250(a). However, we propose to exclude the reference to § 438.362(c) since MCO EQR exclusion is not applicable to separate CHIP.

We propose to adopt the provision at § 438.602(g)(13) (which requires States to post documentation of compliance with parity in mental health and substance use disorder benefits on the State's website) for separate CHIP through the existing cross-reference at § 457.1285. However, we propose to replace the reference to subpart K of part 438 with CHIP parity requirements at § 457.496 in alignment with contract requirements at § 457.1201(l).

We propose to amend § 457.1285 to state, the State must comply with the program integrity safeguards in accordance with the terms of subpart H of part 438 of this chapter, except that the terms of §§ 438.66(e), 438.362(c), 438.602(g)(6) and (10), 438.604(a)(2) and 438.608(d)(4) and references to LTSS of this chapter do not apply and that references to subpart K under part 438 should be read to refer to parity requirements at § 457.496.

Our proposals for requirements for States' websites at § 438.10(c)(3) and the list proposed in § 438.602(g) are authorized by sections 1932(a)(5)(A) and 2103(f)(3) of the Act for Medicaid and which require each State, enrollment broker, or managed care entity to provide all enrollment notices and informational and instructional materials in a manner and form which may be easily understood by enrollees and potential enrollees. The authority for our proposals is extended to PIHPs and PAHPs through regulations based on our authority under section 1902(a)(4) of the Act. We believe that our proposals would make States' websites easier to use by incorporating easily understood labels, having all information accessible from one page, verifying the accurate functioning of the site, and clearly explaining the availability of assistance—all of which would directly help States fulfill their obligation to provide informational materials in a manner and form which may be easily understood.

h. Terminology (§§ 438.2, 438.3(e), 438.10(h), 438.68(b), 438.214(b))

Throughout 42 CFR part 438, we use ''behavioral health'' to mean mental health and SUD. However, it is an imprecise term that does not capture the full array of conditions that are intended to be included, and some in the SUD treatment community have raised concerns with its use. It is important to use clear, unambiguous terms in regulatory text. Therefore, we propose to change ''behavioral health'' throughout 42 CFR part 438 as described here. In the definition of PCCM entity at § 438.2 and for the provider types that must be included in provider directories at § 438.10(h)(2)(iv), we propose to replace ''behavioral health'' with ''mental health and substance use disorder;'' for the provider types for which network adequacy standards must be developed in § 438.68(b)(1)(iii), we propose to remove ''behavioral health'' and the parentheses; and for the provider types addressed in credentialing policies at § 438.214(b), we propose to replace ''behavioral'' with ''mental health.'' We also propose in the definition of PCCM entity at § 438.2 to replace the slash between ''health systems'' and ''providers'' with ''and'' for grammatical accuracy.

Similarly, we also propose to change ''psychiatric'' to ''mental health'' in § 438.3(e)(2)(v) and § 438.6(e). We believe that ''psychiatric'' does not capture the full array of services that can be provided by IMDs.

These proposals are authorized by section 1902(a)(4)(A) of the Act, which provides for methods of administration found necessary by the Secretary for the proper and efficient operation of the plan, because use of clear, unambiguous terms in regulatory text is imperative for proper and efficient operation of the plan.

2. State Directed Payments (42 CFR 438.6, 438.7, 430.3)

a. Background

Section 1903(m)(2)(A) of the Act requires contracts between States and MCOs to provide payment under a risk-based contract for services and associated administrative costs that are actuarially sound. CMS has historically used our authority under section 1902(a)(4) of the Act to apply the same requirements to contracts between States and PIHPs or PAHPs. Under risk-based managed care arrangements with the State, Medicaid managed care plans have the responsibility to negotiate payment rates with providers. Subject to certain exceptions, States are generally not permitted to direct the expenditures of a Medicaid managed care plan under the contract between the State and the plan or to make payments to providers for services covered under the contract between the State and the plan (§§ 438.6 and 438.60, respectively). However, there are circumstances in which a State may believe that requiring managed care plans to make specified payments to health care providers is an important tool in furthering the State's overall Medicaid program goals and objectives; for example, funding to ensure certain minimum payments are made to safety net providers to ensure access to care, funding to enhance behavioral health care providers as mandated by State legislative directives, or funding for quality payments to ensure providers are appropriately rewarded for meeting certain program goals. Because this type of State direction reduces the plan's ability to effectively manage costs, CMS, in the 2016 final rule, established specific exceptions to the general rule prohibiting States from directing the expenditures of MCOs, PIHPs and PAHPs at § 438.6(c)(1)(i) through (iii). These exceptions came to be known as State directed payments (SDPs).

The current regulations at § 438.6(c) specify the parameters for how and when States may direct the expenditures of their Medicaid managed care plans and the associated requirements and prohibitions on such arrangements. Permissible SDPs include directives that certain providers of the managed care plan participate in value-based purchasing (VBP) models, that certain providers participate in multi-payer or Medicaid-specific delivery system reform or performance improvement initiatives, or that the managed care organization adhere to certain fee schedule requirements (for example, minimum fee schedules, maximum fee schedules, and uniform dollar or percentage increases). Among other requirements, § 438.6(c) requires SDPs to be based on the utilization and delivery of services under the managed care contract and expected to advance at least one of the objectives in the State's managed care quality strategy.

All SDPs must be included in all applicable managed care contract(s) and described in all applicable rate certification(s) as noted in § 438.7(b)(6).

Further, § 438.6(c)(2)(ii) requires that most SDPs be approved in writing prior to implementation.[38] To obtain written prior approval, States must submit a ''preprint'' form to CMS to document how the SDP complies with the Federal requirements outlined in § 438.6(c).[39] States must obtain written approval of certain SDPs in order for CMS to approve the corresponding Medicaid managed care contract(s) and rate certifications(s). States were required to comply with this prior approval requirement for SDPs no later than the rating period for Medicaid managed care contracts starting on or after July 1, 2017.

Each SDP preprint submitted to CMS is reviewed by a Federal review team to ensure that the payments comply with the regulatory requirements in § 438.6(c) and other applicable law. The Federal review team consists of subject matter experts from various components and groups within CMS, which regularly include those representing managed care policy and operations, quality, and actuarial science. Over time, these reviews have expanded to include subject matter experts on financing of the non-Federal share and demonstration authorities when needed. The CMS Federal review team works diligently to ensure a timely review and that standard operating procedures are followed for a consistent and thorough review of each preprint. Most preprints are reviewed on an annual basis; SDPs that are for VBP arrangements, delivery system reform, or performance improvement initiatives and that meet additional criteria in the Federal regulations are eligible for multi-year approval.

CMS has issued guidance to States regarding SDPs on multiple occasions. In November 2017, CMS published the initial preprint form [40] along with guidance for States on the use of SDPs.[41] In May 2020, CMS published guidance on managed care flexibilities to respond to the COVID–19 public health emergency (PHE), including how States could use SDPs in support of their COVID–19 response efforts.[42] In January 2021, CMS published additional guidance for States to clarify existing policy, and also issued a revised preprint form that States must use for rating periods beginning on or after July 1, 2021.[43] The revised preprint form is more comprehensive compared to the initial preprint, and it is designed to systematically collect the information that CMS identified as necessary as part of our review of SDPs to ensure compliance with the Federal regulatory requirements.[44] This includes identification of the estimated total dollar amount for the SDP, an analysis of provider reimbursement rates for the class(es) of providers that the SDP is targeting, and information about the sources of the non-Federal share used to finance the SDP.

Since § 438.6(c) was issued in the 2016 final rule, States have requested approval for an increasing number of SDPs. The scope, size, and complexity of the SDP arrangements submitted by States for approval has also grown steadily and quickly. In calendar year 2017, CMS received 36 preprints for our review and approval from 15 States. In contrast, in calendar year 2021, CMS received 223 preprints from 39 States. For calendar year 2022, CMS received 298 preprints from States. In total, as of December 2022, CMS has reviewed more than 1,100 SDP proposals and approved 993 proposals since the 2016 final rule was issued.[45]

SDPs also represent a notable amount of spending. The Medicaid and CHIP Payment and Access Commission (MACPAC) reported that CMS approved SDP arrangements in 37 States, with spending exceeding more than $25 billion in 2020.[46] The U.S. Government Accountability Office (GAO) also reported that at least $20 billion has been approved by CMS for preprints with payments to be made on or after July 1, 2021, across 79 approved preprints.[47] Our internal analysis of all SDPs approved from when § 438.6(c) was issued in the 2016 final rule through March 2022 estimates that the total spending for each SDP approved for the most recent rating period for States is nearly $48 billion [48] (Federal and State) with at least half being dollars that States are requiring be paid in addition to the rates negotiated between the plans and providers. The aforementioned nearly $48 billion is an annual figure.[49]

As the volume of SDP preprint submissions and total dollars flowing through SDPs continues to increase, CMS recognizes the importance of ensuring that SDPs are contributing to Medicaid quality goals and objectives as part of our review process, as well as ensuring that SDPs are developed and implemented with appropriate fiscal and program integrity guardrails. The proposed changes in this notice of proposed rulemaking are intended to ensure the following policy goals:

(1) Medicaid managed care enrollees receive access to high-quality care under SDP payment arrangements;

(2) SDPs are appropriately linked to Medicaid quality goals and objectives for the providers participating in the SDP payment arrangements; and

(3) CMS and States have the appropriate fiscal and program integrity guardrails in place to strengthen the accountability and transparency of SDP payment arrangements.

We are issuing this proposal based on our authority to interpret and implement section 1903(m)(2)(A)(iii) of the Act, which requires contracts between States and MCOs to provide

[38] State directed payments that are minimum fee schedules for network providers that provide a particular service under the contract using State plan approved rates as defined in § 438.6(a) are not subject to the written prior approval requirement at § 438.6(c)(2)(ii); however, they must comply with the requirements currently at § 438.6(c)(2)(ii)(A) through (F) (other than the requirement for prior written approval) and be appropriately documented in the managed care contract(s) and rate certification(s).

[39] *https://www.medicaid.gov/medicaid/managed-care/downloads/sdp-4386c-preprint-template.pdf.*

[40] *https://www.medicaid.gov/sites/default/files/2020-02/438-preprint.pdf.*

[41] *https://www.medicaid.gov/sites/default/files/federal-policy-guidance/downloads/cib11022017.pdf.*

[42] *https://www.medicaid.gov/sites/default/files/Federal-Policy-Guidance/Downloads/cib051420.pdf.*

[43] *https://www.medicaid.gov/Federal-Policy-Guidance/Downloads/smd21001.pdf.*

[44] *https://www.medicaid.gov/medicaid/managed-care/downloads/sdp-4386c-preprint-template.pdf.*

[45] The number of proposals includes initial preprints, renewals and amendments. An individual SDP program could represent multiple SDP proposals as described here (that is, an initial application, 1 renewal, and 3 amendments).

[46] Medicaid and CHIP Payment and Access Commission, ''Report to Congress on Medicaid and CHIP,'' June 2022, available at *https://www.macpac.gov/wp-content/uploads/2022/06/MACPAC_June2022-WEB-Full-Booklet_FINAL-508-1.pdf.* Projected payment amounts are for the most recent rating period, which may differ from calendar year or fiscal year 2020.

[47] U.S. Government Accountability Office, ''Medicaid: State Directed Payments in Managed Care,'' June 28, 2022, available at *https://www.gao.gov/assets/gao-22-105731.pdf.*

[48] This data point is an estimate and reflective of the most recent approval for all unique payment arrangements that have been approved through March 31, 2022 under CMS' standard review process. Rating periods differ by State; some States operating their managed care programs on a calendar year basis while others operate on a State fiscal year basis, which most commonly is July to June. The most recent rating period for which the SDP was approved as of March 2022 also varies based on the review process reflective of States submitting proposals later than recommended (close to or at the end of the rating period), delays in State responses to questions, and/or reviews taking longer due to complicated policy concerns (for example, financing).

[49] As part of the revised preprint form, States are asked to identify if the payment arrangement requires plans to pay an amount in addition to negotiated rates vs. limiting or replacing negotiated rates. Approximately half of the total dollars identified for the SDP actions included were identified by States for payment arrangements that required plans to pay an amount in addition to the rates negotiated between the plan and provider(s) rates.

payment under a risk-based contract for services and associated administrative costs that are actuarially sound and our authority under section 1902(a)(4) of the Act to establish methods of administration for Medicaid that are necessary for the proper and efficient operation of the State plan. As explained in the 2016 final rule, regulation of SDPs is necessary to ensure that Medicaid managed care plans have sufficient discretion to manage the risk of covering the benefits outlined in their contracts, which is integral to ensuring that capitation rates are actuarially sound as defined in § 438.4 (81 FR 27582). We have historically relied on section 1902(a)(4) of the Act to extend the same requirements adopted under section 1903(m)(2)(A)(iii) of the Act for MCOs related to actuarially sound capitation rates to PIHPs and PAHPs. Where a proposal is also based on interpreting and implementing other authority, we note that in the applicable explanation of the proposed policy.

We did not adopt the Medicaid managed care SDP requirements described at § 438.6 in the 2016 final rule for separate CHIPs because there was no statutory requirement to do so and we wished to limit the scope of new regulations and administrative burden on separate CHIP managed care plans. For similar reasons, we are not proposing to adopt the new Medicaid managed care SDP requirements proposed at §§ 438.6 and 438.7 for separate CHIPs.

We are proposing to define State directed payments as a contract arrangement that directs an MCO's, PIHP's, or PAHP's expenditures under paragraphs (c)(1)(i) through (iii) of this section. We are proposing this definition as it is currently used by States and CMS in standard interactions as well as in published guidance to describe these contract requirements. Defining this term also improves the readability of the related regulations. We have also proposed to rename the header for this section to ''*State Directed Payments under MCO, PIHP, or PAHP contracts*'' reflect this term.

In addition, we are proposing several revisions to § 438.6 to further specify and add to the existing requirements and standards for SDPs. First, we are proposing revisions, including: expanding the scope of § 438.6(c) consistent with recent guidance; exempting SDPs that establish payment rate minimums at 100 percent of the Medicare rate from written prior approval; incorporating SDPs for non-network providers in certain circumstances; setting new procedures and timeframes for the submission of SDPs and related documentation; codifying and further specifying standards and documentation requirements on total payment rates; further specifying and strengthening existing requirements related to financing as well as the connection to the utilization and delivery of services; updating and providing flexibilities for States to pursue VBP through managed care; strengthening evaluation requirements and other areas; and addressing how SDPs are incorporated into capitation rates or reflected in separate payment terms. The proposed regulatory provisions include both new substantive standards and new documentation and contract term requirements. In addition, we are proposing a new appeal process for States that are dissatisfied with CMS's determination related to a specific SDP preprint and new oversight and monitoring standards. In recognition of the scope of changes we are proposing, some of which will require significant time for States to implement, we are proposing a series of applicability dates over a roughly 5-year period for compliance. These applicability dates are discussed later in section I.B.2.p. of this proposed rule.

We solicit feedback on our proposals.

A more detailed outline of the remaining parts of this section is provided below:

b. Contract Requirements Considered to be SDPs (Grey Area Payments)
c. Medicare Exemption, SDP Standards and Prior Approval (§ 438.6(c)(1)(iii)(B), (c)(2), and (c)(5)(iii)(A)(*5*))
d. Non-Network Providers (§ 438.6(c)(1)(iii))
e. SDP Submission Timeframes (§ 438.6(c)(2)(viii) and (ix))
f. Standard for Total Payment Rates for each SDP, Establishment of Payment Rate Limitations for certain SDPs and Expenditure Limit for All SDPs (§ 438.6(c)(2)(ii)(I) and (c)(2)(iii))
g. Financing (§ 438.6(c)(2)(ii)(G) and (H))
h. Tie to Utilization and Delivery of Services for Fee Schedule Arrangements (§ 438.6(c)(2)(vii))
i. Value-Based Payments and Delivery System Reform Initiatives (§ 438.6(c)(2)(vi))
j. Quality and Evaluation (§ 438.6(c)(2)(ii)(D) and (F), (c)(2)(iv) and (v), and (c)(7))
k. Contract Term Requirements (§ 438.6(c)(5))
l. Including SDPs in Rate Certifications and Separate Payment Terms (§§ 438.6(c)(2)(ii)(J), (c)(6), and 438.7(f))
m. SDPs included through Adjustments to Base Capitation Rates (§ 438.7(c)(4) through (6))
n. Appeals (§ 430.3(d))
o. Reporting Requirements to Support Oversight (§ 438.6(c)(4))
p. Applicability Dates (§ 438.6(c)(4), 438.6(c)(8), and 438.7(g)(2) and (3))

b. Contract Requirements Considered To Be SDPs (Grey Area Payments)

Under § 438.6(c), States are not permitted to direct the expenditures of a Medicaid managed care plan under the contract between the State and the plan unless it is an SDP that complies with § 438.6(c), is permissible in a specific provision under Title XIX, is permissible through an implementing regulation of a Title XIX provision related to payments to providers, or is a permissible pass-through payment that meets requirements in § 438.6(d). States are also not permitted to make payments directly to providers for services covered under the contract between the State and a managed care plan as specified in § 438.60.

In our November 2017 CMCS Informational Bulletin (CIB) entitled ''Delivery System and Provider Payment Initiatives under Medicaid Managed Care Contracts,'' we noted instances where States may include general contract requirements for provider payments that would not be subject to approval under § 438.6(c) as long as the State was not mandating a specific payment methodology or amounts under the contract.[50] We also noted that these types of contract requirements would not be pass-through payments subject to the requirements under § 438.6(d), as we believed they maintained a link between payment and the delivery of services. One scenario in the CIB described contract language generally requiring managed care plans to make 20 percent of their provider payments as VBP or alternative payment arrangements when the State does not mandate a specific payment methodology and the managed care plan retains the discretion to negotiate with network providers the specific terms for the amount, timing, and mechanism of such VBP or alternative payment arrangements. We continue to believe that this scenario does not meet the criteria for an SDP nor a pass-through payment but as our thinking has evolved, we believe that the aforementioned VBP scenario represents the State imposing a quality metric on the managed care plans rather than the providers. We believe that this specific

[50] *https://www.medicaid.gov/federal-policy-guidance/downloads/cib11022017.pdf.*

type of contractual condition and measure of plan accountability is permissible, so long as it meets the requirements for an incentive arrangement under § 438.6(b)(2) or, a withhold arrangement under § 438.6(b)(3).

The other scenario described the State contractually implementing a general requirement for Medicaid managed care plans to increase provider payment for covered services provided to Medicaid enrollees covered under the contract, where the State did not mandate a specific payment methodology or amount(s) and managed care plans retain the discretion for the amount, timing, and mechanism for making such provider payments. At the time, we believed that these areas of flexibility for the plan would be sufficient to exclude the State's contract requirement from the scope of § 438.6(c). However, as we have continued to review managed care contracts and rate certifications since November 2017, we have grown increasingly concerned that excluding the latter type of vague contractual requirement for increased provider payment from the requirements of § 438.6(c) created an unintended loophole in regulatory oversight, presenting a significant program integrity risk. For example, some States include general contract requirements for significant increases to provider payments that require the State to add money to the capitation rates paid to the managed care plans as part of rate development for a specific service (for example, hospital services) but without any further accountability to ensure that the additional funding included in the capitation payments is paid to providers for a specific service or benefit provided to a specific enrollee covered under the contract. While this is similar to the definition of pass-through payment in § 438.6(a), these contractual requirements do not meet all of the other requirements in § 438.6(d) to be permissible pass-through payments. We commonly refer to these types of contractual arrangements as ''grey area payments'' as they do not completely comply with § 438.6(c) nor § 438.6(d).

Upon reflection and based on our experience since the 2017 CIB, we concluded that general contractual requirements to increase provider payment rates circumvent the intent of the 2016 final rule and the subsequent 2017 Pass-Through Payment Final Rule to improve the fiscal integrity of the program and ensure the actuarial soundness of all capitation rates.[51] As we stated in the preamble of the 2016 final rule ''[w]e believe that the statutory requirement that capitation payments to managed care plans be actuarially sound requires that payments under the managed care contract align with the provision of services to beneficiaries covered under the contract. . . . In our review of managed care capitation rates, we have found pass-through payments being directed to specific providers that are generally not directly linked to delivered services or the outcomes of those services. These pass-through payments are not consistent with actuarially sound rates and do not tie provider payments with the provision of services.'' Further, ''[a]s a whole, [42 CFR] § 438.6(c) maintains the MCO's, PIHP's, or PAHP's ability to fully utilize the payment under that contract for the delivery and quality of services by limiting States' ability to require payments that are not directly associated with services delivered to enrollees covered under the contract.''

In January 2021, we published SMDL #21–001,[52] through which we sought to close the unintentional loophole created in the November 2017 CIB and realign our implementation of the regulation with the original intent of the 2016 final rule and the 2017 final rule. The 2021 SMDL provides that if a State includes a general contract requirement for provider payment that provides for or adds an amount to the provider payment rates, even without directing the specific amount, timing or methodology for the payments, and the provider payments are not clearly and directly linked specifically to the utilization and delivery of a specific service or benefit provided to a specific enrollee, then CMS will require the contractual requirement to be modified to comply with § 438.6(c) or (d) beginning with rating periods that started on or after July 1, 2021. We maintain this interpretation. At this time, we also believe it is important to further specify our stance that any State direction of a managed care plan's payments to providers, regardless of specificity or even if tied specifically to utilization and delivery of services, is prohibited unless § 438.6(c) or (d) permits the arrangement. State wishing to impose quality requirements or thresholds on managed care plans, such as the requirement that a certain percentage of provider payments be provided through a VBP arrangement, must do so within the parameters of § 438.6(b). We do not believe any changes are needed to the regulation text in § 438.6(c) or (d) to reflect this reinterpretation and clarification because this preamble provides an opportunity to again bring this important information to States' attention; CMS will continue this narrower interpretation of § 438.6(c) and (d). We solicit comments on whether additional clarification about these grey area payments is necessary or, if revision to the regulation text would be helpful.

c. Medicare Exemption, SDP Standards and Prior Approval (§ 438.6(c)(1)(iii)(B), § 438.6(c)(2), and § 438.6(c)(5)(iii)(A)(*5*))

In § 438.6(c), States are permitted to direct managed care plans' expenditures under the contract as specified in § 438.6(c)(1)(i) through (iii), subject to written prior approval based on complying with the requirements in § 438.6(c)(2). In the preamble to the 2020 final rule, we noted our observation that a significant number of proposals submitted by States for review under § 438.6(c)(2) required managed care plans to adopt minimum fee schedules specified under an approved methodology in the Medicaid State plan. In response, we adopted several revisions to § 438.6(c) in the 2020 final rule.[53] We defined ''State plan approved rates'' in § 438.6(a) as ''amounts calculated for specific services identifiable as having been provided to an individual beneficiary described under CMS approved rate methodologies in the Medicaid State plan,'' and excluded supplemental payments that are paid in addition to State plan approved rates. We also revised § 438.6(c)(1)(iii)(A) to explicitly address SDPs that are a minimum fee schedule for network providers that provide a particular service under the contract using State plan approved rates and revised § 438.6(c)(2)(ii) to exempt these specific SDP arrangements from the written prior approval requirement. However, SDPs described in paragraph § 438.6(c)(1)(iii)(A) must comply with the requirements currently at § 438.6(c)(2)(ii)(A) through (F) (other than the requirement for written prior approval) and be appropriately documented in the managed care contract(s) and rate certification(s).

[51] *https://www.federalregister.gov/documents/2017/01/18/2017-00916/medicaid-program-the-use-of-new-or-increased-pass-through-payments-in-medicaid-managed-care-delivery.*

[52] *https://www.medicaid.gov/Federal-Policy-Guidance/Downloads/smd21001.pdf.*

[53] *https://www.federalregister.gov/documents/2020/11/13/2020-24758/medicaid-program-medicaid-and-childrens-health-insurance-program-chip-managed-care.*

This piece of the 2020 final rule was, in part, intended to eliminate unnecessary and duplicative review processes in an effort to promote efficient and effective administration of the Medicaid program. This rule improved States' efforts to timely implement certain SDP arrangements that meet their local goals and objectives without drawing upon State staff time unnecessarily. We continue to believe exempting payment arrangements based on an approved State plan rate methodology from written prior approval does not increase program integrity risk or create a lack of Federal oversight. We continue to review the corresponding managed care contracts and rate certifications which include these SDPs. The State plan review and approval process ensures that Medicaid State plan approved rates are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available under the plan, at least to the extent that such care and services are available to the general population in the geographic area, as required under section 1902(a)(30) of the Act.

As we have continued to review and approve SDPs since the 2020 final rule, we believe this same rationale applies to SDPs that adopt a minimum fee schedule using Medicare approved rates for providers that provide a particular service under the contract. Medicare rates are developed under Title XVIII of the Act and there are annual rulemakings associated with Medicare payment for benefits available under Parts A and B in the Medicare Fee-for-Service (FFS) program. Additionally, section 1852(a)(2) of the Act provides that Medicare Advantage plans pay out-of-network providers at least the amount payable under FFS Medicare for benefits available under Parts A and B, taking into account cost sharing and permitted balance billing.[54] These considerations mean that prior written approval by CMS is not necessary to ensure that the standards for SDPs in current § 438.6(c)(2) are met.

Consistent with how we have considered State plan rates to be reasonable, appropriate, and attainable under §§ 438.4 and 438.5, Medicare approved rates too meet this same threshold. Therefore, we are proposing to exempt SDPs that adopt a minimum fee schedule based on total published Medicare payment rates from written prior approval as it would be unnecessary and duplicative. We propose to amend § 438.6(c) to provide specifically for SDPs that require use of a minimum fee schedule using FFS Medicare payment rates.

First, we propose to add a new definition to § 438.6(a) for ''total published Medicare payment rate'' as amounts calculated as payment for specific services that have been developed under Title XVIII Part A and Part B. We propose to re-designate the existing § 438.6(c)(1)(iii)(B) through (D) as § 438.6(c)(1)(iii)(C) through (E), respectively, and add a new § 438.6(c)(1)(iii)(B) explicitly recognizing SDP arrangements that are a minimum fee schedule using a total published Medicare payment rate in effect no more than 3 years prior to the start of the rating period as a permissible type of SDP. We are also proposing to revise proposed re-designated paragraph (c)(1)(iii)(C) to take into account the proposed new category of SDPs that use one or more total published Medicare payment rates. As part of the proposals for paragraphs (c)(1)(iii)(A) through (E), we also propose to streamline the existing regulation text to eliminate the phase ''as defined in paragraph (a)'' as unnecessary; we expect that interested parties and others who read these regulations will read them completely and recognize when defined terms are used.

We also propose to restructure § 438.6(c)(2) and amend its paragraph heading to *Standards for State directed payments* as discussed fully in later sections. As part of this restructuring, we propose to re-designate part of the provision in § 438.6(c)(2)(ii) to § 438.6(c)(2)(i) to describe which SDPs require written prior approval. This revision includes proposing a conforming revision in § 438.6(c)(2)(i) to reflect the re-designation of § 438.6(c)(1)(iii)(B) through (D) as (c)(1)(iii)(C) through (E). This revision will ensure that that SDPs described in paragraph (c)(1)(iii)(B) along with the SDPs described in paragraph (c)(1)(iii)(A), are not included in the written prior approval requirement. States that adopt a minimum fee schedule using 100 percent of total published Medicare payment rates will still need to document these SDPs in the corresponding managed care contracts and rate certifications and those types of SDPs must still comply with requirements for all SDPs other than prior written approval by CMS, just as minimum fee schedules tied to State plan approved rates described in paragraph (c)(1)(iii)(A) must comply. SDPs described under paragraphs (c)(1)(iii)(A) and (B) would still need to comply with the standards listed in the proposed restructured § 438.6(c)(2)(ii). (See sections II.2.f. through l. for proposed new requirements and revisions to existing requirements for all SDPs to be codified in paragraph (c)(2)(ii).)

Our proposal to exempt certain SDPs from written prior approval from CMS is specific to SDPs that require the Medicaid managed care plan to use a minimum fee schedule that is equal 100 percent of the total published Medicare payment rate. SDP arrangements that use a different percentage (whether higher or lower than 100 percent) of a total published Medicare payment rate as the minimum payment amount or are simply based off of an incomplete total published Medicare payment rate would be included in the SDPs described in paragraph (c)(1)(iii)(C). Our review of SDPs includes ensuring that they will result in provider payments that are reasonable, appropriate, and attainable, and will not negatively impact access to care. Accordingly, we believe that SDPs that propose provider payment rates that are incomplete or either above or below 100 percent of total published Medicare payment rates may not always meet these criteria and thus, should remain subject to written prior approval by CMS.

We are also not proposing to remove the written prior approval requirement for SDPs for provider rates tied to a Medicare fee schedule in effect more than 3 years prior to the start of the rating period. This is reflected in our proposed revision to redesignated paragraph (c)(1)(iii)(C) to describe fee schedules for providers that provide a particular service under the contract using rates other than the State plan approved rates or one or more total published Medicare payment rates described in proposed new paragraph (c)(1)(iii)(B). We propose the limit of 3 years to be consistent with how § 438.5(c)(2) requires use of data that is at least that recent for rate development. Our review of SDPs includes ensuring that they will result in provider payments that are reasonable, appropriate, and attainable, and will not negatively impact access to care. Accordingly, we believe that SDPs that propose provider payment rates tied to a total published Medicare payment rate in effect more than 3 years prior to the start of the rating period may not always meet these criteria and thus, should remain subject to written prior approval by CMS.

We solicit public comments on our proposal to specifically address SDPs

[54] See also 42 CFR 422.100(b) and 422.214 and guidance in the ''MA Payment Guide for Out of Network Payments'', April 15, 2015, available at *https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/downloads/oonpayments.pdf.*

that are for minimum fee schedules using 100 percent of the amounts in a total published Medicare payment rate for providers that provide a particular service provided that the total published Medicare payment rate was in effect no more than 3 years prior to the start of the rating period and on our proposal to exempt these specific types of SDP arrangements from the prior written approval requirement in § 438.6(c)(2)(ii).

We are also proposing to add new § 438.6(c)(5) (with the paragraph heading *Requirements for Medicaid Managed Care Contract Terms for State directed payments),* for oversight and audit purposes. Proposed new paragraph (c)(5)(iii)(A)(5) would require the managed care plan contract to include certain information about the Medicare fee schedule used in the SDP, regardless of whether the SDP was granted an exemption from written prior approval under § 438.6(c)(1)(iii)(B). That is, for SDPs which use total published Medicare payment rates, the contract would need to specify which Medicare fee schedule(s) the State directs the managed care plan to use and any relevant and material adjustments due to geography, such as rural designations, and provider type, such as Critical Access Hospital or Sole Community Hospital designation.

The managed care contract would also need to identify the time period for which the Medicare fee schedule is in effect as well as the rating period for which it is used for the SDP. Consistent with § 438.6(c)(1)(iii)(B), the Medicare fee schedule must be in effect no more than 3 years prior to the start of the rating period for the services provided in the arrangement. This 3-year requirement is similar to § 438.5 rate setting, under which data that the actuary relies upon must be from the 3 most recent years that have been completed, prior to the rating period for which rates are being developed. For example, should a State seek to implement a § 438.6(c)(1)(iii)(B) fee schedule in calendar year 2025, the Medicare fee schedule must have been in effect for purposes of Medicare payment at least at the beginning of calendar year 2021.

Requiring sufficient language in the contract regarding the Medicare fee schedule would provide clarity to CMS, managed care plans, and providers regarding the explicit Medicare payment methodology being used under the contract. For broader discussion of § 438.6(c)(5), see section I.B.2.k. of this proposed rule.

We request comment on other material or significant information about a Medicare fee schedule that would need to be included to ensure the managed care contract sufficiently describes this type of SDP.

For discussion on the proposed applicability dates for the proposals outlined in this section, see section I.B.2.p. of this proposed rule.

We solicit public comments on our proposals.

d. Non-Network Providers (§ 438.6(c)(1)(iii))

We are proposing to remove the term ''network'' from the descriptions of SDP arrangements in current (and revised as proposed) § 438.6(c)(1)(iii). Existing regulations specify that for a State to require an MCO, PIHP or PAHP to implement a fee schedule under § 438.6(c)(1)(iii), the fee schedule must be limited to ''network providers.'' This limitation is not included in § 438.6(c)(1)(i) or (ii) for SDP arrangements that are VBP and multi-payer or Medicaid-specific delivery system reform or performance improvement initiatives. In our experience working with States, limiting the descriptions of SDP arrangements subject to § 438.6(c)(iii) to those that involve only network providers has proven to be too narrow and has created an unintended barrier to States' and CMS' policy goals to ensure access to quality care for beneficiaries.

In the 2016 final rule, we finalized current § 438.6(c)(1)(iii) to include ''network'' before ''providers'' in this provision.[55] As previously noted, the regulation at § 438.6(c)(1) generally prohibits States from directing the MCO's, PIHP's or PAHP's expenditures under the contract unless it meets one of the exceptions (as provided in a specific provision in Title XIX, in another regulation implementing a Title XIX provision related to payment to providers, a SDP that complies with § 438.6(c), or a pass-through payment that complies with § 438.6(d)). Therefore, the inclusion of the word ''network'' in the SDP arrangement descriptions in the 2016 final rule has prevented States from including contract requirements to direct their Medicaid managed care plans on how to pay non-network providers.

In our work with States over the years, some States have noted concerns with the requirement that permissible SDPs only apply (or include) payments by Medicaid managed care plans to network providers. States have noted that limiting SDPs to network providers is impractical in large and diverse States. Several States had, prior to rulemaking, pre-existing contractual requirements with managed care plans that required a specific level of payment (such as the State's Medicaid FFS rates) for non-network providers. This aligns with our experience working with States as well, and we note section 1932(b)(2)(D) of the Act requires that non-network providers furnishing emergency services must accept as payment in full an amount equal to the Medicaid State plan rate for those services. Some States have historically required plans to pay non-network providers at least the Medicaid State plan approved rate or another rate established in the managed care contract. Many States with enrollees on their borders rely on providers in neighboring States to deliver specialty services, such as access to children's hospitals.

While we support States' and plans' efforts to develop strong provider networks and to focus their efforts on providers who have agreed to participate in plan networks, executing network agreements with every provider may not always be feasible for plans. For example, in large hospital systems, it may be impractical for every plan to obtain individual network agreements with each rounding physician delivering care to Medicaid managed care enrollees. In such instances, States may have an interest in ensuring that their Medicaid managed care plans pay non-network providers at a minimum level to avoid access to care concerns. We have also encountered situations in which States opt to transition certain benefits, which were previously carved out from managed care, from fee-for-service into managed care. In these instances, States would like to require their managed care plans to pay out-of-network providers a minimum fee schedule in order to maintain access to care while allowing plans and providers adequate time to negotiate provider agreements and provider payment rates for the newly incorporated services. Consequently, we are proposing these changes to provide States a tool to direct payment to non-network providers as well as network providers.

Therefore, we are proposing to remove the term ''network'' from the descriptions of permissible SDP arrangements in § 438.6(c)(1)(iii). Under this proposal, the permissible SDPs are described as payment arrangements or amounts ''for providers that provide a particular service under the contract'' and this will permit States to direct payments under their managed care contracts for both network and non-network providers, subject to the requirements in paragraph (c). We note

[55] *https://www.federalregister.gov/d/2016-09581/p-1269.*

that, as proposed, all of the standards and requirements under § 438.6(c) would still be applicable to SDPs that direct payment arrangements for non-network providers.

Finally, as pass-through payments (PTPs) are separate and distinct from SDPs, we are maintaining the phrase ''network provider'' in § 438.6(d)(1) and (6). Existing PTPs are subject to a time-limited transition period and in accordance with § 438.6(d)(3) and (5), respectively, hospital PTPs must be fully eliminated by no later than the rating period beginning July 1, 2027 and NF and physician services PTPs were required to have been eliminated by no later than the rating period July 1, 2022 with the exceptions of pass-through payments for States transitioning services and populations in accordance with § 438.6(d)(6). Therefore, we do not believe that it is appropriate or necessary to eliminate the word ''network'' from § 438.6(d).

We solicit public comments on our proposal. In particular, we seek comment on whether this change would result in negative unintended consequences.

For discussion on the proposed applicability dates for the proposals outlined in this section, see section I.B.2.p. of this proposed rule.

e. SDP Submission Timeframes (§ 438.6(c)(2)(viii) and (ix))

Since we established the ability for States to direct the expenditures of their managed care plans in the 2016 final rule, we have encouraged States to submit their requests for written prior approval 90 days in advance of the start of the rating period whenever possible. We also recommend that States seek technical assistance from CMS in advance of formally submitting the preprint for review to CMS for more complicated proposals to facilitate the review process.

Submitting 90 days in advance of the rating period provides CMS and the State time to work through the written prior approval process before the State includes the SDP in their managed care plan contracts and the associated rate certifications. If States include SDPs in managed care contracts and capitation rates before we issue written prior approval, any changes to the SDP made as a result of the review process would likely then necessitate contract and rate amendments,[56] creating additional work for States, actuaries, CMS, and managed care plans. Submitting SDP preprints at least 90 days in advance of the rating period can help reduce the need for subsequent contract and rate amendments to address any inconsistencies between the contracts and rate certifications and approved SDPs. State directed payments that are not submitted 90 days in advance of the affected rating period also cause delays in the approval of managed care contracts and rates because those approvals are dependent on the written prior approval of the SDP. Since we cannot approve only a portion of a State's Medicaid managed care contract, late SDP approvals delay approval of the entire contract and the associated capitation rates.

Some States have not been successful in submitting their SDP preprints in advance of the rating period for a variety of reasons. Sometimes it is due to changes in program design, such as a new benefit linked to the SDP being added to the Medicaid managed care contract during the rating period. Other unforeseen changes, such as public health emergencies (PHE) or natural disasters, can also create circumstances in which States need to respond to urgent concerns around access to care by implementing an SDP during the rating period. While we recognize that from time to time there may be a circumstance that necessitates a late preprint submission, we have found that some States routinely submit SDP preprints at the very end of the rating period with implementation dates retroactive to the start of the rating period. We have provided repeated technical assistance to these States, and we published additional guidance in 2021 [57] to reiterate our expectation that States submit SDP preprints before the start of a rating period. This guidance also made clear that CMS would not accept SDP preprints for rating periods that are closed; however, we have not been able to correct the situation with some States.

To make our processes more responsive to States' needs while ensuring that reviews linked to SDP approvals are not unnecessarily delayed, we propose a new § 438.6(c)(2)(viii)(A) through (C) to set the deadline for submission of SDP preprints that require written prior approval from CMS under paragraph (c)(2)(i) (redesignated from § 438.6(c)(2)(ii)). In § 438.6(c)(2)(viii)(A), we propose to require that all SDPs that require written prior approval from CMS must be submitted to CMS no later than 90 days in advance of the end of the rating period to which the SDP applies. This requirement applies if the payment arrangement for which the State is seeking written prior approval begins at least 90 days in advance of the end of the rating period. We strongly encourage all States to submit SDPs in advance of the start of the rating period to ensure CMS has adequate time to process the State's submissions and is able to support the State in incorporating these payments into their Medicaid managed care contracts and rate development. We are proposing to use a deadline of no later than 90 days prior to the end of the applicable rating period because we believe this minimum timeframe balances the need for State flexibility to address unforeseen changes that occur after the managed care plan contracts and rates have been developed with the need to ensure timely processing of managed care contracts and capitation rates. When a State fails to submit all required documentation for any SDP arrangement that requires written prior approval 90 days prior to the end of the rating period to which the SDP applies, the SDP would not be eligible for written prior approval; therefore, the State would not be able to include the SDP in its Medicaid managed care contracts and rate certifications for that rating period.

In § 438.6(c)(2)(viii)(B), we propose to address the use of shorter-term SDPs in response to infrequent events, such as PHEs and natural disasters, by permitting States to submit all required documentation before the end of the rating period for SDP proposals that would start less than 90 days before the end of the rating period. We believe this flexibility would be appropriate to allow States to effectively use SDPs during the final quarter of the rating period to address urgent situations that affect access to and quality of care for Medicaid managed care enrollees.

There are SDPs, such as VBP and delivery system reform, that can be approved under § 438.6(c)(3) for up to three rating periods. For these, we propose in § 438.6(c)(2)(viii)(C) that the same timeframes described in § 438.6(c)(2)(viii)(A) and (B) apply to the first rating period of the SDP.

To illustrate these timeframes, we are using an SDP eligible for annual approval that a State is seeking to include in their CY 2025 rating period. For example, under the current regulations, CMS would strongly recommend that a State seeking approval of an SDP for the calendar year (CY) 2025 rating period would ideally submit the preprint by October 3, 2024. However, under this proposal to revised § 438.6(c)(2)(viii), if the start of the SDP

[56] The term ''rate amendment'' is used to reference an amendment to the initial rate certification.

[57] *https://www.medicaid.gov/Federal-Policy-Guidance/Downloads/smd21001.pdf.*

was on or before October 2, 2025, the State must submit the preprint no later than October 2, 2025 in order for CMS to accept it for review; if the State submitted the preprint for review after that date, CMS could not grant written prior approval of the preprint for the CY 2025 rating period. The State could instead seek written prior approval for the CY 2026 rating period instead if the preprint could not be submitted for the CY 2025 rating period by the October 2, 2025 deadline.

We considered an alternative requiring all SDPs to be submitted prior to the start of the rating period for which the State was requesting written prior approval. This would be a notable shift from current practice, which requires all preprints be submitted prior to the end of the rating period. Requiring that States submit all preprints prior to the start of the rating period would reduce administrative burden and better align with the prospective nature of risk-based managed care. However, instituting such a deadline could potentially be too rigid for States that needed to address an unanticipated or acute concern during the rating period.

Lastly, we considered an alternative of requiring that States submit all SDPs in advance of the start of the payment arrangement itself. For example, a State may seek to start a payment arrangement halfway through the rating period (for example, an SDP for payments starting July 1, 2025 for States operating on a CY rating period). Under this alternative approach, the State would have to submit the preprint for prior approval before July 1, 2025 in order for it to be considered for written prior approval. This would provide additional flexibility for States establishing new SDPs, but would limit the additional flexibility for that SDP to that initial rating period. If the State wanted to renew the SDP the subsequent rating period (for example, CY 2026), it would have to resubmit the preprint before the start of that rating period.

As discussed in section I.B.2.p. of this proposed rule on Applicability and Compliance dates, we are proposing that States must comply with these new submission timeframes beginning with the first rating period beginning on or after 2 years after the effective date of the final rule. In the interim, we would continue our current policy of not accepting submissions for SDPs after the rating period has ended. We solicit public comment on our proposals and these alternatives, as well as additional options that would also meet our goals for adopting time limits on when an SDP can be submitted to CMS for written prior approval.

For amendments to approved SDPs, we propose at § 438.6(c)(2)(ix) to require all amendments to SDPs approved under § 438.6(c)(2)(i) (redesignated from § 438.6(c)(2)(ii)) to be submitted for written prior approval as well. We also propose at § 438.6(c)(2)(ix)(A) to require that all required documentation for written prior approval of such amendments be submitted prior to the end of the rating period to which the SDP applies in order for CMS to consider the amendment. To illustrate this, we again provide the following example for an SDP approved for one rating period (CY 2025). If that SDP was approved by CMS prior to the start of the rating period (December 31, 2024 or earlier) and it began January 1, 2025, then the State would have to submit any amendment to the preprint for that rating period before December 31, 2025. After December 31, 2025, CMS would not accept any amendments to that SDP for that CY 2025 rating period. The same would be true for an SDP that was approved for one rating period after the start of the rating period (for example, approval on October 1, 2025 for a CY 2025 rating period). the State would have until December 31, 2025 to submit any amendment to the preprint for CMS review; after December 31, 2025, CMS would not accept any amendments to that SDP for that rating period.

We further propose § 438.6(c)(2)(ix)(B) to set timelines for the submission of amendments to SDPs approved for multiple rating periods as provided in paragraph (c)(3). Under this proposal, § 438.6(c)(2)(ix)(A) and (B) would allow an amendment window for the proposal within the first 120 days of each of the subsequent rating periods for which the SDP is approved after the initial rating period. The amendment process for the first year of the multiple rating periods would work the same way as it would for any SDP approved for one rating period and be addressed by proposed paragraph (xi)(A). However, in recognition that the SDP is approved for multiple rating periods, we are proposing in § 438.6(c)(2)(ix)(B) that the State would be able to amend the approved preprint for the second (CY 2026 in our example) and third (CY 2027 in our example) rating periods within the first 120 days of the CY 2026 rating period (for example, by May 1, 2026). The requested amendment could not make any retroactive changes to the SDP for the CY 2025 rating period because the CY 2025 rating period would be closed in this example. The State would not be permitted to amend the payment arrangement after May 1, 2026 for the CY 2026 rating period. The State would be able to do the same for the CY 2027 rating period as well—amend the SDP within the first 120 days of the CY 2027 rating period, but only for the CY 2027 rating period and not for the concluded CY 2025 or CY 2026 rating periods.

As proposed, these deadlines are mandatory for written prior approval of an SDP or any amendment of an SDP. When a State fails to submit all required documentation for any amendments within these specified timeframes, the SDP would not be eligible for written prior approval. Therefore, the State would not be able to include the amended SDP in its Medicaid managed care contracts and rate certifications for that rating period. The State could continue to include the originally approved SDP as documented in the preprint in its contracts for the rating period for which the SDP was originally approved. We note that written prior approval of an SDP does not obligate a State to implement the SDP. If a State chose not to implement an SDP for which CMS has granted prior approval, elimination of an SDP would not require any prior approval, under our current regulations or this proposal. We solicit comment on this aspect of our proposal.

We are proposing regulatory changes in §§ 438.6(c)(5)(vi) and 438.7(c)(6) to require the submission of related contract requirements and rate certification documentation no later than 120 days after the start of the SDP or the date we granted written prior approval of the SDP, whichever is later. States should submit their rate certifications prior to the start of the rating period, and § 438.7(c)(2) requires that any rate amendments [58] comply with Federal timely filing requirements. However, we believe given the nature of SDPs, there should be additional timing restrictions on when revised rate certifications that include SDPs can be provided for program integrity purposes. We also remind States that these proposals do not supersede other requirements regarding submission of contract and rate certification documentation when applicable, including but not limited to those that require prior approval or approval prior to the start of the rating period such as requirements outlined in §§ 438.3(a), 438.4(c)(2), and 438.6(b)(1). These proposals are discussed in later sections: section I.B.2.k on Contract Requirements for SDPs; section I.B.2.l on Separate Payment Terms; and section

[58] The term ''rate amendment'' is used to reference an amendment to the initial rate certification.

I.B.2.m on SDPs included as adjustments to base rates.

We are making these proposed regulatory changes to institute submission timeframes to ensure efficient and proper administration of the Medicaid program. We had also considered an alternative of requiring that States submit all amendments to SDPs for written prior approval within either 120 days of the start of the payment arrangement or 120 days of CMS issuing written prior approval, whichever was later. To illustrate this, we again provide the following example for an SDP approved for one rating period (CY 2025). If that SDP was approved by CMS prior to the start of the rating period (December 31, 2024 or earlier) and it began January 1, 2025, then the State would have 120 days after the start of the payment arrangement (May 1, 2025) to submit any amendment to the preprint for that rating period. After May 1, 2025, CMS would not accept any amendments to that SDP for that CY 2025 rating period. If, however, that SDP were approved after the start of the rating period (for example, October 1, 2025 for a CY 2025 rating period); the State would have 120 days from that written prior approval (January 29, 2026) to submit any amendment to the preprint for CMS review; after January 29, 2026, CMS would not accept any amendments to that SDP for that rating period. Requiring that States submit any amendments to the SDP preprint within 120 days of either the start of the payment arrangement or the initial approval could reduce some administrative burden by limiting the time period for amendments to preprints. However, the time frame would be specific to each preprint, which could present some challenges in ensuring compliance. Additionally, it would not preclude States from submitting amendments after the end of the rating period; in fact, it may encourage States to submit SDP preprints toward the end of the rating period to preserve the ability to amend the preprint after the end of the rating period. CMS does not believe such practices are in alignment with the prospective nature of risk-based managed care. We solicit public comment on our proposals and these alternatives, as well as additional options that would also meet our goals for adopting time limits on when amendments to SDPs can be submitted to CMS for written prior approval.

For discussion on the proposed applicability dates for the proposals outlined in this section, see section I.B.2.p. of this proposed rule.

We solicit public comments on these proposals.

f. Standard for Total Payment Rates for Each SDP, Establishment of Payment Rate Limitations for Certain SDPs, and Expenditure Limit for All SDPs (§ 438.6(c)(2)(ii)(I), 438.6(c)(2)(iii))

Standard for Total Payment Rates for Each SDP. Section 1903(m)(2)(A)(iii) of the Act requires contracts between States and managed care plans that provide for payments under a risk-based contract for services and associated administrative costs to be actuarially sound. Under section 1902(a)(4) of the Act, CMS also has authority to establish methods of administration for Medicaid that are necessary for the proper and efficient operation of the State plan. Further, actuarially sound capitation rates are projected to provide for all reasonable, appropriate, and attainable costs that are required under the terms of the contract and for the operation of the managed care plan for the time period and the population covered under the terms of the contract. In risk-based managed care, managed care plans have the responsibility to manage the financial risk of the contract, and one of the primary tools plans use is negotiating payment rates with providers. Absent Federal statutory requirements or specific State contractual restrictions, the specific payment rates and conditions for payment between risk-bearing managed care plans and their network providers are subject to negotiations between the plans and providers, as well as overall private market conditions. As long as plans are meeting the requirements for ensuring access to care and network adequacy, States typically provide managed care plans latitude to develop a network of providers to ensure appropriate access to covered services under the contract for their enrollees and fulfill all of their contractual obligations while managing the financial risk.

As noted earlier, both the volume of SDP preprints being submitted by States for approval and the total dollars flowing through SDPs have grown steadily and quickly since § 438.6(c) was promulgated in the 2016 final rule. MACPAC reported that CMS approved SDP arrangements in 37 States, with spending exceeding more than $25 billion.[59] Our internal analysis of all SDPs approved from when § 438.6(c) was issued in the 2016 final rule through March 2022, provides that the total spending approved for each SDP for the most recent rating period for States is nearly $48 billion[60] with at least half of that spending being dollars that States are requiring be paid in addition to negotiated rates.[61] This $48 billion figure is an estimate of annual spending. As SDP spending continues to increase, we believe it is appropriate to apply additional regulatory requirements with respect to the totality of provider payment rates under SDPs to ensure proper fiscal and programmatic oversight in Medicaid managed care programs, and we are proposing several related regulatory changes as well as exploring other potential payment rate and expenditure limits.

As noted in the 2016 final rule, section 1903(m)(2)(A)(iii) of the Act requires that contracts between States and Medicaid managed care organizations for coverage of benefits use prepaid payments to the entity that are actuarially sound. By regulation based on section 1902(a)(4) of the Act, CMS extended the requirement for actuarially sound capitation rates to PIHPs and PAHPs. The regulations addressing actuarially sound capitation rates are at §§ 438.4 through 438.7.

Currently § 438.6(c)(2) specifies that SDPs must be developed in accordance with § 438.4, the standards specified in § 438.5 and generally accepted actuarial principles and practices. Under the definition in § 438.4, actuarially sound capitation rates are ''projected to provide for all reasonable, appropriate, and attainable costs that are required under the terms of the contract and for the operation of the MCO, PIHP, or PAHP for the time period and the population covered under the terms of the contract . . .'' Consistent with this

[59] Medicaid and CHIP Payment and Access Commission, ''Report to Congress on Medicaid and CHIP,'' June 2022, available at *https://www.macpac.gov/wp-content/uploads/2022/06/MACPAC_June2022-WEB-Full-Booklet_FINAL-508-1.pdf.*

[60] This data point is an estimate and reflective of the most recent approval for all unique payment arrangements that have been approved through March 31, 2022 under CMS' standard review process. Rating periods differ by State; some States operating their managed care programs on a calendar year basis while others operate on a State fiscal year basis, which most commonly is July to June. The most recent rating period for which the SDP was approved as of March 2022 also varies based on the review process reflective of States submitting proposals later than recommended (close to or at the end of the rating period), delays in State responses to questions, and/or reviews taking longer due to complicated policy concerns (for example, financing).

[61] As part of the revised preprint form, States are asked to identify if the payment arrangement requires plans to pay an amount in addition to negotiated rates vs. limiting or replacing negotiated rates. Approximately half of the total dollars identified for the SDP actions included were identified by States for payment arrangements that required plans to pay an amount in addition to the rates negotiated between the plan and provider(s) rates.

definition in § 438.4, we noted in the State Medicaid Director Letter #21–001 published on January 8, 2021 that CMS requires States to demonstrate that SDPs result in provider payment rates that are reasonable, appropriate, and attainable as part of the preprint review process. We are proposing here to codify this standard regarding the provider payment rates for each SDP more clearly in the regulation. As part of the proposed revisions in § 438.6(c)(2)(ii) to specify the standards that each SDP must meet, we are proposing a new standard at § 438.6(c)(2)(ii)(I) to codify our current policy that each SDP ensure that the total payment rate for each service, and each provider class included in the SDP must be reasonable, appropriate and attainable and, upon request from CMS, the State must provide documentation demonstrating the total payment rate for each service and provider class. We propose in § 438.6(a) to define ''total payment rate'' as the aggregate for each managed care program of: (1) the average payment rate paid by all MCOs, PIHPs, or PAHPs to all providers included in the specified provider class for each service identified in the SDP; (2) the effect of the SDP on the average rate paid to providers included in the specified provider class for the same service for which the State is seeking written prior approval; (3) the effect of any and all other SDPs on the average rate paid to providers included in the specified provider class for the same service for which the State is seeking written prior approval; and (4) the effect of any and all allowable pass-through payments, as defined in § 438.6(a), paid to any and all providers in the provider class specified in the SDP for which the State is seeking written prior approval on the average rate paid to providers in the specified provider class. We note that while the total payment rate described above is collected for each SDP, the information provided for each SDP must account for the effects of all payments from the managed care plan (for example, other SDPs or pass-through payments) to any providers included in the provider class specified by the State for the same rating period. We assess if the total payment level across all SDPs in a managed care program is reasonable, appropriate and attainable.

We note that, currently, § 438.6(c)(1)(iii)(A) describes an SDP that sets a minimum fee schedule using Medicaid State plan approved rates for a particular service. As proposed in section I.B.2.c, § 438.6(c)(1)(iii)(B) would describe an SDP that sets a minimum fee schedule using 100 percent of the total published Medicare payment rate that was in effect no more than 3 years prior to the start of the applicable rating period for a particular service. An SDP that sets a minimum fee schedule using Medicaid State plan approved rates for a particular service does not currently require prior written approval by CMS per § 438.6(c)(2)(ii), and we are proposing in § 438.6(c)(2)(i) to not require prior approval for an SDP that sets a minimum fee schedule using 100 percent of the total published Medicare payment rate. We also believe that both of these specific payment rates would be (and therefore meet the requirement that) reasonable, appropriate and attainable because CMS has reviewed and determined these payment rates to be appropriate under the applicable statute and implementing regulations for Medicaid and Medicare respectively. However, for other SDP arrangements, additional analysis and consideration is necessary to ensure that the payment rates directed by the State meet the standard of reasonable, appropriate and attainable.

The proposed standard at § 438.6(c)(2)(ii)(I) also includes a requirement that upon request from CMS, the State must provide documentation demonstrating the total payment rate for each service and provider class. While we are not proposing to require States to provide documentation in a specified format to demonstrate that the total payment rate is reasonable, appropriate and attainable for all services (see next section for documentation requirements for some SDPs), we intend to continue requesting information from all States for all SDPs documenting the different components of the total payment rate as described earlier in section I.B.2.f. of this proposed rule using a standardized measure (for example, Medicaid State plan approved rates or Medicare) for each service and each class included in the SDP. We formalized this process in the revised preprint form [62] published in January 2021, and described it in the accompanying SMDL. We will continue to review and monitor all payment rate information submitted by States for *all* SDPs as part of our oversight activities and to ensure managed care payments are reasonable, appropriate and attainable. Based on our ongoing monitoring of payment rates, we may issue guidance further detailing documentation requirements and a specified format to demonstrate that the total payment rate is reasonable, appropriate and attainable for all services.

We solicit comments on our proposed changes.

Establishment of Payment Rate Limitations for Certain SDPs. As noted, a number of other entities, including MACPAC [63] and GAO,[64] have released reports focused on SDPs. Both noted concerns about the growth of SDPs and lack of a regulatory payment ceiling. Our proposed standard at § 438.6(c)(2)(ii)(I) would codify our current practice of determining whether the total payment rate is reasonable, appropriate, and attainable for each SDP. However, neither in our guidance nor in our proposed regulatory requirement at § 438.6(c)(2)(ii)(I) have we defined the terms ''reasonable, appropriate and attainable'' as they are used for SDPs. To address this, we are proposing several regulatory standards to establish when the total payment rates for certain SDPs are reasonable, appropriate and attainable. We are proposing to adopt at § 438.6(c)(2)(iii) both specific standards and the documentation requirements necessary for ensuring compliance with the specific standards for the types of SDPs described in paragraphs (c)(1)(i),(ii), and (iii)(C) through (E) where the SDP is for one or more of the following types of services: inpatient hospital services, outpatient hospital services, nursing facility services, and qualified practitioner services at an academic medical center.

To explain and provide context for proposed new paragraph (c)(2)(iii), we discuss the historical use of the average commercial rate (ACR) benchmark for SDPs, the proposed payment limit for inpatient hospital services, outpatient hospital services, qualified practitioner services at academic medical centers and nursing facility services (including proposed definitions for these types of services) and some alternatives we are also considering, the proposed requirement for States to demonstrate the ACR, and the proposed requirements for States to demonstrate compliance with the ACR and total payment rate comparison requirement. We have included further sub-headers to help guide the reader through this section.

[62] *https://www.medicaid.gov/medicaid/managed-care/downloads/sdp-4386c-preprint-template.pdf.*

[63] *https://www.macpac.gov/publication/june-2022-report-to-congress-on-medicaid-and-chip/June 2022 Report to Congress on Medicaid and CHIP, Chapter 2.*

[64] *U.S. Government Accountability Office,* ''*Medicaid: State Directed Payments in Managed Care,*'' *June 28, 2022, available at https://www.gao.gov/assets/gao-22-105731.pdf.*

1. Historical Use of the Average Commercial Rate Benchmark for SDPs

In late 2017, we received an SDP preprint to raise inpatient hospital payment rates broadly that would result in a total payment rate that exceeded 100 percent of Medicare rates in that State, but the payments would remain below the ACR for that service and provider class in that State. We had concerns about whether the payment rates were still reasonable, appropriate, and attainable for purposes of CMS approval of the SDP as being consistent with the existing regulatory requirement that all SDPs must be developed in accordance with § 438.4, the standards specified in § 438.5, and generally accepted actuarial principles and practices. We realized that approving an SDP that exceeded 100 percent of Medicare rates would be precedent-setting for CMS. We explored using an internal total payment rate benchmark that could be applied uniformly across all SDPs to evaluate preprints for approval and to ensure that payment rates projected to be paid to providers under the SDP(s) remained reasonable, appropriate, and attainable.

Medicare is a significant payer in the health insurance market, and Medicare reimbursement is a standardized benchmark used in the industry. Medicare reimbursement is also a benchmark used in Medicaid FFS, including the Upper Payment Limits (UPLs) that apply to classes of institutional providers, such as hospitals, nursing facilities, and intermediate care facilities for individuals with intellectual disabilities (ICFs/IID), that are based on Medicare payment rates. The UPLs apply an overall payment ceiling based on how much Medicare would have paid in total as a mechanism for determining economy and efficiency of payment for State plan services while allowing for facility-specific payments.[65] Generally for inpatient and outpatient services, these UPL requirements apply to three classes of facilities based on ownership status: State-owned, non-State government-owned, and private. Hospitals within a class can be paid different amounts and facility-specific total payment rates can vary, sometimes widely, so long as in the aggregate, the total amount that Medicaid paid across the class is no more than what Medicare would have paid.

When considering the Medicaid FFS UPL methodologies, we had some concerns that applying the same standards for the total payment rate under SDPs to three classes based on ownership status, would not be appropriate for implementing the SDP requirements. In some States, SDPs have become a method to meet their quality and access goals in Medicaid managed care.

Currently, § 438.6(c)(2)(ii)(B) provides States with broader flexibility than what is required for FFS UPLs in defining the provider class for which States can implement SDPs. This flexibility has proven important for States to target their efforts to achieve their stated policy goals tied to their managed care quality strategy. For example, CMS has approved SDPs where States proposed and implemented SDPs that applied to provider classes defined by criteria such as participation in State health information systems. In other SDPs, the eligible provider class was established by participation in learning collaboratives which were focused on health equity or social determinants of health. In both cases, the provider class under the SDP was developed irrespective of the facility's ownership status. These provider classes can be significantly wider or narrower than the provider class definitions used for Medicaid UPL demonstrations in Medicaid FFS. Therefore, the provider classes in some approved SDPs did not align with the classes used in Medicaid FFS UPL demonstrations, which are only based on ownership or operation status (that is, State government-owned or operated, Non-State government-owned or operated, and privately-owned and operated facilities) and include all payments made to all facilities that fit in those ownership-defined classes. Not all providers providing a particular service in Medicaid managed care programs must be included in an SDP. Under § 438.6(c)(2)(ii)(B), States are required to direct expenditures equally, using the same terms of performance, for a *class* of providers furnishing services under the contract; however, they are not required to direct expenditures equally using the same terms of performance for *all providers* providing services under the contract.

Without alignment across provider classes, CMS could have faced challenges in applying a similar standard of the Medicaid FFS UPL to each provider class that the State specified in the SDP irrespective of how each provider class that the State specified in the SDP compared to the ownership-defined classes used in the Medicaid FFS UPL. Given the diversity in provider classes States have proposed and implemented under SDPs approved by CMS at the time (and subsequently), combined with the fact that not all providers of a service under the contract are necessarily subject to the SDP, CMS had concerns that applying the Medicaid FFS UPL to each provider class under the SDP could have resulted in situations in managed care where provider payments under SDPs would not align with Medicaid FFS policy. In some instances, payments to particular facilities could potentially be significantly higher than allowed in Medicaid FFS, and in others, facility-specific payments could potentially be significantly lower than allowed in Medicaid FFS.

We note that States have been approved to make Medicaid FFS supplemental payments up to the ACR for qualified practitioners affiliated with and furnishing services (for example, physicians under the physician services benefit) in academic medical centers, physician practices, and safety net hospitals.[66] CMS had previously approved SDPs that resulted in total payment rates up to the ACR for the same providers that States had approved State plan authority to make supplemental payments up to the ACR in Medicaid FFS. Additionally, while CMS does not review the provider payment rate assumptions for all services underlying Medicaid managed care rate development, we had recently approved Medicaid managed care contracts in one State where plans are paid capitation rates developed assuming the use of commercial rates

[65] The Upper Payment Limit regulations for FFS Medicaid are §§ 447.272 (inpatient hospital services), 447.321 (outpatient hospital services) and 447.325 (other inpatient and outpatient facility services).

[66] CMS has approved Medicaid State plan amendments authorizing such targeted Medicaid supplemental payment methodologies for qualified practitioner services up to the average commercial rate under 1902(a)(30)(A) of the Act. Additional information on this and other payment demonstrations is published on *Medicaid.gov* at *https://www.medicaid.gov/medicaid/financial-management/payment-limit-demonstrations/index.html*. Instructions specific to qualified practitioner services ACR are further described in the following instructions: *https://www.medicaid.gov/medicaid/downloads/upl-instructions-qualified-practitioner-services-replacement-new.pdf#:~:text=CMS%20has%20approved%20SPAs%20that%20use%20the%20following,payments%20or%20an%20alternate%20fee%20schedule%20is%20used.* As practitioner payments are not subject to Medicaid UPL requirements under 42 CFR part 447 subparts C and F, the ACR is a mechanism by which CMS can review Medicaid practitioner supplemental payments compared to average commercial market rates where private insurance companies have an interest in setting reasonable, competitive rates in a manner that may give assurance that such rates are economic and efficient, consistent with section 1902(a)(30)(A) of the Act.

paid to providers for all services covered in the contract.

For these reasons, in 2018, CMS ultimately interpreted the current § 438.6(c)(2)(i) (which we propose to re-designate as § 438.6(c)(2)(ii)(I) and (J) along with revisions to better reflect our interpretation) to allow total payment rates in an SDP up to the ACR. The statutory and regulatory requirements for the UPL in Medicaid FFS do not apply to risk-based managed care plans; therefore, permitting States to direct MCOs, PIHPs, PAHPs to make payments higher than the UPL does not violate any Medicaid managed care statutory or regulatory requirements. We adopted ACR as the standard benchmark for all SDPs. this standard benchmark for all SDPs applied ACR more broadly (that is, across more services and provider types) than allowed under Medicaid FFS, due to the Medicare payment-based UPLs applicable in FFS. Our rationale in 2018 for doing so was that using the ACR allowed States more discretion than the Medicaid FFS UPL because it allows States to ensure that Medicaid managed care enrollees have access to care that is comparable to access for the broader general public. Also, we believed using the ACR presented the least disruption for States as they were transitioning existing, and often long-standing, pass-through payments [67] into SDPs, while at the same time providing a ceiling for SDPs to protect against the potential of SDPs threatening States' ability to comply with our interpretation of current § 438.6(c)(2)(i) that total provider payment rates resulting from SDPs be reasonable, appropriate and attainable. Finally, using the ACR provided some parity with Medicaid FFS payment policy for payments for qualified practitioners affiliated with and furnishing services at academic medical centers, physician practices, and safety net hospitals where CMS has approved rates up to the ACR.[68]

Therefore, since 2018, we have used the ACR as a benchmark for total payment rates for all SDP reviews. Under this policy, States have had to document the total payment rate specific to each service type included in the SDP and specific to each provider class identified. For example, if an SDP provides a uniform increase for inpatient and outpatient hospital services with two provider classes (rural hospitals and non-rural hospitals), the State would be required to provide an analysis of the total payment rate (average base rate paid by plans, the effect of the SDP, the effect of any other approved SDP(s), and the effect of any permissible pass-through payments) using a standardized measure (for example, Medicaid State plan approved rates or Medicare) for each service and each class included in the SDP. In the example above, the State would be required to demonstrate the total payment rates for inpatient services for rural hospitals, inpatient services for non-rural hospitals, outpatient services for rural hospitals and outpatient services for non-rural hospitals separately. We formalized this process in the revised preprint form [69] published in January 2021, and described it in the accompanying SMDL. While CMS has collected this information for each SDP submitted for written prior approval, we historically requested the impact not only of the SDP under review, but any other payments made by the managed care plan (for example, other SDPs or pass-through payments) to any providers included in the provider class specified by the State for the same rating period.

When a State has not demonstrated that the total payment rate for each service(s) and provider class(es) included in each SDP arrangement is at or below either the Medicare or Medicaid FFS rate (when Medicare does not cover the service), CMS has requested documentation from the State to demonstrate that the total payment rates that exceed the Medicare or the Medicaid FFS rate do not exceed the ACR for the service and provider class. CMS has worked with States to collect documentation on the total payment rate, which has evolved over time. CMS has not knowingly approved an SDP where the total payment rate, inclusive of all payments made by the plan to any providers included in the provider class for the same rating period, was projected to exceed the ACR.

2. Proposed Payment Rate Limit for Inpatient Hospital Services, Outpatient Hospital Services, Qualified Practitioner Services at Academic Medical Centers, and Nursing Facility Services

While CMS has not knowingly approved an SDP that includes payment rates that are projected to exceed the ACR, States are increasingly submitting preprints that would push total payment rates up to the ACR. Therefore, we propose to move away from the use of an internal benchmark to a regulatory limit on the projected total payment rate, using the ACR for inpatient hospital services, outpatient hospital services, qualified practitioner services at an academic medical center, and nursing facility services. We are also considering other potential options for this limit on total payment rate for these four services.

CMS believes that using the ACR as a limit is likely appropriate as it is generally consistent with the need for managed care plans to compete with commercial plans for providers to participate in their networks to furnish comparable access to care for inpatient hospital services, outpatient hospital services, qualified practitioner services at an academic medical center and nursing facility services.

While Medicaid is a substantial payer for these services, it is not the most common payer for inpatient hospital, outpatient hospital and qualified practitioner services at an academic medical center. Looking at the National Health Expenditures data for 2020, private health insurance pays for 32 percent of hospital expenditures, followed by Medicare (25 percent) and Medicaid (17 percent). There is a similar breakdown for physician and clinical expenditures—private health insurance pays for 37 percent of physician and clinical expenditures, followed by Medicare (24 percent) and Medicaid (11 percent).[70] For these three services, commercial payers typically pay the

[67] Pass-through payments are defined in § 438.6(a) as, ''any amount required by the State to be added to the contracted payment rates, and considered in calculating the actuarially sound capitation rate between the MCO, PIHP, or PAHP and hospitals, physicians, or nursing facilities that is not for a specific service or benefit provided to a specific enrollee covered under the contract, a provider payment methodology permitted under § 438.6(c), a sub-capitated payment arrangement for a specific set of services and enrollees covered under the contract; GME payments; or FQHC or RHC wrap around payments.''

[68] CMS has approved Medicaid State plan amendments authorizing such targeted Medicaid supplemental payment methodologies for qualified practitioner services up to the average commercial rate under 1902(a)(30)(A) of the Act. Additional information on this and other payment demonstrations is published on *Medicaid.gov* at . Instructions specific to qualified practitioner services ACR are further described in the following instructions: *https://www.medicaid.gov/medicaid/downloads/upl-instructions-qualified-practitioner-services-replacement-new.pdf#:~:text=CMS%20has%20approved%20SPAs%20that%20use%20the%20following,payments%20or%20an%20alternate%20fee%20schedule%20is%20used. As practitioner payments are not subject to Medicaid UPL requirements under 42 CFR part 447 subparts C and F, the ACR is a mechanism by which CMS can review Medicaid practitioner supplemental payments compared to average commercial market rates where private insurance companies have an interest in setting reasonable, competitive rates in a manner that may give assurance that such rates are economic and efficient, consistent with section 1902(a)(30)(A) of the Act.*

[69] *https://www.medicaid.gov/medicaid/managed-care/downloads/sdp-4386c-preprint-template.pdf.*

[70] *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData.*

highest rates, followed by Medicare, followed by Medicaid.[71] [72] [73] [74]

Based on both CMS' experience with SDPs for inpatient hospital services, outpatient hospital services and qualified practitioner services at an academic medical center as well as data from the National Health Expenditure survey and other external studies examining payment rates across the Medicaid, Medicare and commercial markets, we believe that for these three services, the ACR payment rate limit would likely be reasonable, appropriate and attainable while allowing States the flexibility to further State policy objectives through implementation of SDPs.

We also believe that this proposed ACR payment rate limit aligns with the SDP actions submitted to CMS. Based on our internal data collected from our review of SDPs, the most common services for which States seek to raise total payment rates up to the ACR are qualified practitioner services at academic medical centers, inpatient hospital services, and outpatient hospital services. Looking at approvals since 2017 through March 2022, we have approved 145 preprint actions that were expected to yield SDPs equal to the ACR: 33 percent of these payments are for professional services at academic medical centers; 18 percent of these payments are for inpatient hospital services; 17 percent of these payments are for outpatient hospital services; 2 percent are for nursing facilities. Altogether, this means that at least two thirds of the SDP submissions intended to raise total payment rates up to the ACR were for these four provider classes. While States are pursuing SDPs for other types of services, very few States are pursuing SDPs that increase total payment rates up to the ACR for those other categories or types of covered services.

While there have not been as many SDP submissions to bring nursing facilities up to a total payment rate near the ACR, there have been a few that have resulted in notable payment increases to nursing facilities. In the same internal analysis referenced above, 2 percent of the preprints approved that were expected to yield SDPs equal to the ACR were for nursing facilities. There have also been concerns raised as part of published audit findings about a particular nursing facility SDP.[75] Therefore, we propose to include these four services—inpatient hospital services, outpatient hospital services, qualified practitioner services at an academic medical center, and nursing facility services—in § 438.6(c)(2)(iii) and limit the projected total payment rate for each of these four services to ACR for any SDP arrangements described in paragraphs (c)(1)(i) through (iii), excluding (c)(1)(iii)(A) and (B), that are for any of these four services. States directing MCO, PIHP or PAHP expenditures in such a manner that results in a total payment rate above the ACR for any of these four types of services would not be approvable under our proposal. Such arrangements would violate the standard proposed in § 438.6(c)(2)(ii)(I) that total payment rates be reasonable, appropriate and attainable and the standard proposed in § 438.6(c)(2)(iii) setting specific payment level limits for certain types of SDPs. We note that while the total payment rate is collected for each SDP, the information provided for each SDP must account for the effects of all payments from the managed care plan (for example, other SDPs or pass-through payments) to any providers included in the provider class specified by the State for the same rating period. The proposed total payment limit would apply across all SDPs in a managed care program; States would not be able to for example, create multiple SDPs that applied, in part or in whole, to the same provider classes and be projected to exceed the ACR. These proposals are based on our authority to interpret and implement section 1903(m)(2)(A)(iii) of the Act, which requires contracts between States and MCOs to provide payment under a risk-based contract for services and associated administrative costs that are actuarially sound and in order to apply these requirements to PIHPs and PAHPs as well as MCOs, on our authority under section 1902(a)(4) of the Act to establish methods of administration for Medicaid that are necessary for the proper and efficient operation of the State plan.

For some services where Medicaid is the most common or only payer (such as HCBS,[76] mental health services,[77] substance use disorder services,[78] and obstetrics and gynecology services,[79] [80]) interested parties have raised concerns about access to care more specifically. For example, one State recently shared data from its internal analysis of the landscape of behavioral health reimbursement in the State that showed Medicaid managed care reimbursement for behavioral health services is higher than commercial reimbursement. Further, a study [81] authorized through Oregon's Legislature outlined several disparities in behavioral health payment, including a concern that within the commercial market, behavioral health providers often receive higher payment rates when furnishing services to out-of-network patients, potentially reducing incentives for these providers to join Medicaid managed care or commercial health plan networks. Instituting a limit on SDP payment amounts that is tied to the ACR, particularly when access concerns have also been raised in the commercial markets too, may have a deleterious effect on access to care for Medicaid managed care enrollees.

We acknowledge that some States have had difficulty with providing payment rate analyses demonstrating that the total payment rate is below ACR, including for services other than

[71] Congressional Budget Office, ''The Prices That Commercial Health Insurers and Medicare Pay for Hospitals' and Physicians' Services,'' January 2022, available at *https://www.cbo.gov/system/files/2022-01/57422-medical-prices.pdf.*

[72] E. Lopez, T. Neumann, ''How Much More Than Medicare Do Private Insurers Pay? A Review of the Literature,'' Kaiser Family Foundation, April 15, 2022, available at *https://www.kff.org/medicare/issue-brief/how-much-more-than-medicare-do-private-insurers-pay-a-review-of-the-literature/.*

[73] Medicaid and CHIP Payment and Access Commission, ''Medicaid Hospital Payment: A Comparison across States and to Medicare,'' April 2017, available at *https://www.macpac.gov/wp-content/uploads/2017/04/Medicaid-Hospital-Payment-A-Comparison-across-States-and-to-Medicare.pdf.*

[74] C. Mann, A. Striar, ''How Differences in Medicaid, Medicare, and Commercial Health Insurance Payment Rates Impact Access, Health Equity, and Cost,'' The Commonwealth Fund, August 17, 2022, available at *https://www.commonwealthfund.org/blog/2022/how-differences-medicaid-medicare-and-commercial-health-insurance-payment-rates-impact.*

[75] U.S. Department of Health and Human Services Office of the Inspector General, ''Aspects of Texas' Quality Incentive Payment Program Raise Questions About Its Ability To Promote Economy and Efficiency in the Medicaid Program,'' A–06–18–07001, December 21, 2020, available at *https://oig.hhs.gov/oas/reports/region6/61807001.asp.*

[76] The National Health Expenditures data for 2020 who that Medicaid is the primary payer for other health, residential and personal care expenditures, paying for 58 percent of such expenditures where private insurance only paid for 7 percent of such services. For home health care expenditures, Medicare paid for 34 percent of such services, followed by Medicaid at 32 percent followed by private insurance (13 percent). *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData.*

[77] *https://www.medicaid.gov/medicaid/benefits/behavioral-health-services/index.html.*

[78] *https://www.kff.org/medicaid/issue-brief/medicaids-role-in-financing-behavioral-health-services-for-low-income-individuals/.*

[79] *https://www.acog.org/advocacy/policy-priorities/medicaid.*

[80] *https://www.kff.org/womens-health-policy/issue-brief/medicaid-coverage-for-women/.*

[81] J. Zhu, *et al.,* ''Behavioral Health Workforce Report to the Oregon Health Authority and State Legislature,'' February 1, 2022, available at *https://www.oregon.gov/oha/ERD/SiteAssets/Pages/Government-Relations/Behavioral%20Health%20Workforce%20Wage%20Study%20Report-Final%20020122.pdf.*

inpatient hospital services, outpatient hospital services, nursing facility services, or qualified practitioner services at academic medical centers. For example, based on our experience, some States have found it difficult to obtain data on commercial rates paid for HCBS. States have noted that this is due to the fact that commercial markets do not generally offer HCBS, making the availability of commercial rates for such services scarce or nonexistent. This same concern has been raised for other services, such as behavioral health and substance use disorder services, among others, where Medicaid is the most common payer and commercial markets do not typically provide similar levels of coverage.

Therefore, we are not proposing at this time to establish in § 438.6(c)(2)(iii) payment rate ceilings for each SDP for services other than inpatient hospital services, outpatient hospital services, nursing facility services, or qualified practitioner services at academic medical centers that States include in SDPs. While SDPs for all other services will still need to meet the proposed standard at § 438.6(c)(2)(ii)(I) that the total payment rate for each SDP (meaning the payment rate to providers) is reasonable, appropriate and attainable, at this time we believe further research is needed before codifying a specific payment rate limit for these services to ensure that such limits do not result in inappropriately reducing payment rates and negatively affecting access to care. We will continue to review and monitor all payment rate information submitted by States for all SDPs as part of our oversight activities and to ensure managed care payments are reasonable, appropriate and attainable. Depending on our future experience, we may revisit this issue as necessary.

For clarity and consistency in applying these proposed new payment limits, we propose to define several terms in § 438.6(a), including a definition for ''inpatient hospital services'' that would be the same as specified at 42 CFR 440.10, ''outpatient hospital services'' that would be the same as specified in § 440.20(a) and ''nursing facility services'' that would be the same as specified at § 440.40(a). Relying on existing regulatory definitions will prevent confusion and provide consistency across Medicaid delivery systems.

We also propose definitions in § 438.6(a) for both ''academic medical center'' and ''qualified practitioner services at an academic medical center'' to clearly articulate which SDP arrangements would be limited based on the proposed payment rate. We propose to define ''academic medical center'' as a facility that includes a health professional school with an affiliated teaching hospital. We propose to define ''qualified practitioner services at an academic medical center'' as professional services provided by physicians and non-physician practitioners affiliated with or employed by an academic medical center.

At this time, we are not proposing to establish a payment rate ceiling for qualified practitioners that are not affiliated with or employed by an academic medical center. We have not seen a comparable volume or size of SDP preprints for provider types not affiliated with hospitals or academic medical centers, and we believe establishing a payment ceiling would likely be burdensome on States and could inhibit States from pursuing SDPs for providers such as primary care physicians and mental health providers and we seek comment on this issue. Depending on our future experience, we may revisit this policy choice in the future but until then, qualified practitioner services furnished at other locations or settings will be subject to the general standard we currently use that is proposed to be codified at § 438.6(c)(2)(ii)(I) that total payment rates for each service and provider class included in the SDP must be reasonable, appropriate and attainable.

We believe that establishing a total payment rate limit of the ACR for these four services appropriately balances the need for additional fiscal guardrails while providing States flexibility in pursuing provider payment initiatives and delivery system reform efforts that further advance access to care and enhance quality of care in Medicaid managed care. In our view, utilizing the ACR in a managed care delivery system is appropriate and acknowledges the market dynamics at play to ensure that managed care plans can build provider networks that are comparable to the provider networks in commercial health insurance and ensure access to care for managed care enrollees. However, we recognize that formally codifying a payment rate limit of ACR for these four service types may raise some questions. First, codifying a payment rate limit of ACR for these four service types may incent States and interested parties to implement additional payment arrangements that raise total payment rates up to the ACR for other reasons beyond advancing access to care and enhancing quality of care in Medicaid managed care. The majority of SDPs that increase total payment rates up to the average commercial rate are primarily funded by either provider taxes, IGTs, or a combination of these two sources of the non-Federal share. These SDPs represent some of the largest SDPs in terms of total dollars that are required to be paid in addition to base managed care rates. We are concerned about incentivizing States to raise total payment rates up to the ACR based on the source of the non-Federal share, rather than based on furthering goals and objectives outlined in the State's managed care quality strategy. To mitigate this concern, which is shared not only by CMS but oversight bodies and interested parties such as MACPAC,[82] we are proposing additional regulatory changes related to financing the non-Federal share; see section I.B.2.g. of this proposed rule.

In light of these concerns, we are considering alternatives to the ACR as a total payment rate limit for inpatient hospital services, outpatient hospital services, nursing facility services, and qualified practitioner services at an academic medical center for each SDP. we are considering including in the final rule establishing the total payment rate limit at the Medicare rate; this is a standardized benchmark used in the industry, and is often a standard utilized in Medicaid FFS under upper payment limit (UPL) demonstrations in 42 CFR part 447. The Medicare rate is also not based on proprietary commercial payment data, and the payment data could be verified and audited more easily than the ACR. If we did include in the final rule a total payment rate limit at the Medicare rate, this may limit the growth in payment rates more than limiting the total payment rate to the ACR. We are also considering, and soliciting feedback on, establishing a total payment rate limit for all services, not limited to just these four services, for all SDP arrangements described in § 438.6(c)(1)(i), (ii), and (iii)(C) through (E) at the Medicare rate in the final rule. We invite public comments on these alternatives.

[82] MACPAC's report noted, ''The largest directed payment arrangements are typically targeted to hospitals and financed by them. Of the 35 directed payment arrangements projected to increase payments to providers by more than $100 million a year, 30 were targeted to hospital systems and at least 27 were financed by provider taxes or IGTs. During our interviews, interested parties noted that the amount of available IGTs or provider taxes often determined the total amount of spending for these types of arrangements. Once this available pool of funding was determined, States then worked backward to calculate the percentage increase in provider rates. Medicaid and CHIP Payment and Access Commission, ''Oversight of Managed Care Directed Payments,'' June 2022, available at *https://www.macpac.gov/wp-content/uploads/2022/06/Chapter-2-Oversight-of-Managed-Care-Directed-Payments-1.pdf*.

We do have some concerns about whether Medicare is an appropriate payment rate limit for managed care payments given the concerns and limitations we noted earlier in the ''Historical Use of the Average Commercial Rate Benchmark for SDPs'' section of this proposed rule, such as provider class limitations. Additionally, Medicare payment rates are developed for a population that differs from the Medicaid population. For example, Medicaid covers substantially more pregnant women and children than Medicare. Although Medicaid FFS UPLs are calculated as a reasonable estimate of what Medicare would pay for Medicaid services and account for population differences across the programs, it can be a challenging exercise to do so accurately. Therefore, we seek public comment to further evaluate if Medicare would be a reasonable limit for the total provider rate for the four types of services delivered through managed care that we propose, all services, and/or additional types of services. We note that beneficiaries enrolled in a managed care plan are often more aligned with individuals in commercial health insurance (such as, adults and kids), whereas the FFS population is generally more aligned with the Medicare population (older adults and individuals with complex health care needs). To acknowledge the challenges in calculating the differences between the Medicaid and Medicare programs, we are also considering, and soliciting feedback on, whether the total payment rate limit for each SDP for these four services should be set at some level between Medicare and the ACR, or a Medicare equivalent of the ACR in the final rule. We invite public comments on these alternatives.

In considering these potential alternatives, we are also considering whether robust quality goals and objectives should be a factor in setting a total payment rate limit for each SDP for these four types of services. Specifically, we are also considering including in the final rule a provision permitting a total payment rate limit for any SDP arrangements described in paragraphs (c)(1)(i) and (ii) that are for any of these four services, at the ACR, while limiting the total payment rate for any SDP arrangements described in § 438.6(c)(1)(iii)(C) through (E), at the Medicare rate. As we noted earlier, CMS believes that establishing a total payment rate limit of the ACR for these four services provides States flexibility in pursuing provider payment initiatives and delivery system reform efforts that further advance access to care and enhance quality of care in Medicaid managed care. Under this alternative policy we are considering including in the final rule, there would be an additional fiscal guardrail compared to our proposal by limiting the total payment rate for these four services to ACR for value-based initiatives only and further limiting the total payment rate for these four services to the Medicare rate for fee schedule arrangements (for example, uniform increases, minimum or maximum fee schedules). This alternative acknowledges the importance of robust quality outcomes and innovative payment models and could incentivize States to consider quality-based payment models that can better improve health outcomes for Medicaid managed care enrollees. We invite public comments on whether this potential alternative should be included in the final rule.

For each of these alternatives, we acknowledge that some States currently have SDPs that have total payment rates up to the ACR. Therefore, these alternative proposals could be more restrictive, and States could need to reduce funding from current levels, which could have a negative impact on access to care and other health equity initiatives. we also seek public comment on whether or not CMS should consider a transition period in order to mitigate any disruption to provider payment levels if we adopt one of the alternatives for a total payment rate limit on SDP expenditures in the final rule.

We seek public comment on our proposal to establish a payment rate limit for SDP arrangements at the ACR for inpatient hospital services, outpatient hospital services, qualified practitioner services at an academic medical center and nursing facility services. Additionally, we solicit public comment on the alternatives we are considering to establish a payment rate limit at the Medicare rate, a level between Medicare and the ACR, or a Medicare equivalent of the ACR for these four service types. We also solicit public comment on whether the final rule should include a provision establishing a total payment rate limit for any SDP arrangements described in paragraphs (c)(1)(i) and (ii) that are for any of these four services, at the ACR, while limiting the total payment rate for any SDP arrangements described in paragraph § 438.6(c)(1)(iii)(C) through (E), at the Medicare rate.

3. Average Commercial Rate Demonstration Requirements

In order to ensure compliance with the provision currently proposed that the total payment rate for SDPs that require written prior approval from CMS for inpatient hospital services, outpatient hospital services, qualified practitioner services at an academic medical centers and nursing facility services do not exceed the ACR for the applicable services subject to the SDP, CMS will need certain information and documentation from the State. Therefore, we propose in § 438.6(c)(2)(iii) that States provide two pieces of documentation: (1) an ACR demonstration; and (2) a total payment rate comparison to the ACR. We propose the timing for these submissions in § 438.6(c)(2)(iii)(C). The ACR demonstration would be submitted with the initial preprint submission (new, renewal, or amendment) following the applicability date of this section and then updated at least every 3 years, so long as the State continues to include the SDP in one or more managed care contracts. The total payment rate comparison to the ACR would be submitted with the preprint as part of the request for approval of each SDP and updated with each subsequent preprint submission (each amendment and renewal).

At § 438.6(c)(2)(iii)(A), we propose to specify the requirements for demonstration of the ACR if a State seeks written prior approval for an SDP that includes inpatient hospital services, outpatient hospital services, qualified practitioner services at an academic medical center or nursing facility services. This demonstration must use payment data that: (1) is specific to the State; (2) is no older than the 3 most recent and complete years prior to the start of the rating period of the initial request following the applicability date of this section; (3) is specific to the service(s) addressed by the SDP; (4) includes the total reimbursement by the third party payer and any patient liability, such as cost sharing and deductibles; (5) excludes payments to FQHCs, RHCs and any non-commercial payers such as Medicare; and (6) excludes any payment data for services or codes that the applicable Medicaid managed care plans do not cover under the contracts with the State that will include the SDP. We consider Qualified Health Plans (QHPs) operating in the ACA Marketplace to be commercial payers for purposes of this proposed provision, and therefore, payment data from QHPs should be included when available.

At proposed § 438.6(c)(2)(iii)(A)(*1*), we would require States to use payment data specific to the State for the analysis, as opposed to regional or national analyses, to provide more accurate information for assessment. Given the wide variation in payment for the same service from State to State, regional or national analyses could be misleading, particularly when determining the impact on capitation rates that are State specific. Additionally, each State's Medicaid program offers different benefits and has different availability of providers. We currently request payment rate analyses for SDPs to be done at a State level for this reason and believe it would be important and appropriate to continue to do so.

At proposed § 438.6(c)(2)(iii)(A)(*2*), we would require States to use data that is no older than the 3 most recent and complete years prior to the start of the rating period of the initial request following the applicability date of this section. This would ensure that the data is reflective of the current managed care payments and market trends. It also aligns with rate development standards outlined in § 438.5. For example, for the ACR demonstration for an SDP seeking written prior approval for inpatient hospital services, outpatient hospital services, qualified practitioner services at an academic medical center or nursing facility services for a CY 2025 rating period, the data used must be from calendar year 2021 and later. We used a calendar year for illustrative purpose only; States must use their rating period timeframe for their analysis.

We propose at § 438.6(c)(2)(iii)(A)(*3*) to require States to use data that is specific to the service type(s) included in the SDP; this would be a change from current operational practice. In provider payment rate analyses for SDPs currently, States are required to compare the total payment rate for each service and provider class to the corresponding service and provider class specific ACR. For example, States requiring their managed care plans to implement SDPs for inpatient hospital services for three classes of providers—rural hospitals, urban hospitals, and other hospitals—would have to produce payment rate analyses specific to inpatient hospital services in rural hospitals, inpatient hospital services in urban hospitals, and inpatient hospital services in other hospitals separately. Under our current operational practice, if the total payment rate for any of these three provider classes exceeds Medicare, CMS requests the State provide documentation demonstrating that the total payment rate does not exceed the ACR specific to both that service and that provider class. As noted later in this same section, we are proposing in § 438.6(c)(2)(iii)(B), to continue to require States to produce the total payment rate comparison to the ACR at a service and provider class level. However, our proposal to codify a requirement for an ACR demonstration includes changes to our approach to determining the ACR and would require States to submit the ACR demonstration, irrespective of if the total payment rate were at or below the Medicare rate or State plan rate for all preprints seeking written prior approval for the four services.

During our reviews of SDP preprints since the 2016 final rule, it has become clear that requiring an ACR analysis that is specific both to the service and provider class can have deleterious effects when States want to target Medicaid resources to those providers serving higher volumes of Medicaid beneficiaries. For example, we have often heard from States that rural hospitals commonly earn a larger share of their revenue from the Medicaid program than they do from commercial payers. There is also evidence that rural hospitals tend to be less profitable than urban hospitals and at a greater risk of closure.[83] These hospitals often serve a critical role in providing access to services for Medicaid beneficiaries living in rural areas where alternatives to care are very limited or non-existent. If States want to target funding to increase reimbursement for hospital services to rural hospitals, limiting the ceiling for such payments to the ACR for rural hospitals only would result in a lower ceiling than if the State were to broaden the category to include hospitals with a higher commercial payer mix (for example, payment data for hospital services provided at a specialty cardiac hospital, which typically can negotiate a higher rate with commercial plans). However, in doing so, the existing regulatory requirement for SDPs at § 438.6(c)(2)(ii)(B) requires that the providers in a provider class be treated the same—meaning they get the same uniform increase. This has resulted in some cases States not being able to use Medicaid funds to target hospitals that provide critical services to the Medicaid population, but instead must use some of those Medicaid funds to provide increases to hospitals that serve a lower share of Medicaid beneficiaries.

In another example to demonstrate the potential effects of requiring an ACR analysis that is specific to both the service and provider class level, a State could seek to implement an SDP that would provide different increases for different classes of hospitals (for example, rural and urban public hospitals would receive a higher percentage increase than teaching hospitals and short-term acute care hospitals). The SDP preprint could provide for separate additional increases for hospitals serving a higher percentage of the Medicaid population and certain specialty services and capabilities. However, if the average base rate that the State's Medicaid managed care plans paid was already above the ACR paid for services to one of the classes (for example, rural hospitals), the State could not apply the same increases to this class as it would the other classes, even if the average base rate paid for the one class was below the ACR when calculated across all hospitals. In this example, the State would be left with the option of either eliminating the one class (for example, rural hospitals) from the payment arrangement or withdrawing the entire SDP proposed preprint even if the State still had significant concerns about access to care as it related to the one class (for example, rural hospitals). The focus on the ACR for the service at the provider class level has the potential to disadvantage providers with less market power, such as rural hospitals or safety net hospitals, which typically receive larger portions of their payments from Medicaid than from commercial payers. These providers typically are not able to negotiate rates with commercial payers on par with providers with more market power.

To provide States the flexibility they need to design SDPs to direct resources as they deem necessary to meet their programmatic goals, we propose to require an ACR demonstration using payment data specific to the service type (that is, by the specific type of service). This would allow States to provide an ACR analysis at just the service level instead of at the service and provider class level. For example, States could establish a tiered fee schedule or series of uniform increases, directing a higher payment rate to facilities that provide a higher share of services to Medicaid enrollees than to the payment rate to facilities that serve a lower share of services to Medicaid enrollees. States would still have a limit of the ACR, but allowing this to be measured at the service level and not at

[83] MACPAC Issue Brief, ''Medicaid and Rural Health.'' Published April 2021 *https://www.macpac.gov/wp-content/uploads/2021/04/Medicaid-and-Rural-Health.pdf.*

the service and provider class level would provide States flexibility to target funds to those providers that serve more Medicaid beneficiaries. Based on our experience, facilities that serve a higher share of Medicaid enrollees, such as rural hospitals and safety net hospitals, tend to have less market power to negotiate higher rates with commercial plans. Allowing States to direct plans to pay providers using a tiered payment rate structure based on different criteria, such as the hospital's payer mix, without limiting the total payment rate to the ACR specific to each tier (which would be considered a separate provider class), but rather at the broader service level would provide States with tools to further the goal of parity with commercial payments, which may have a positive impact on access to care and the quality of care delivered. We would still permit States to elect to provide a demonstration of the ACR at both the service and provider class level or just at the service level if the State chooses to provide the more detailed and extensive analysis, but this level of analysis would no longer be required. We remind States that the statutory requirements in sections 1902(a)(2), 1903(a), 1903(w), and 1905(b) of the Act concerning the non-Federal share contribution and financing requirements, including those implemented in 42 CFR part 433, subpart B concerning health care-related taxes, bona fide provider related donations, and IGTs, apply to all Medicaid expenditures regardless of delivery system (fee-for-service or managed care).

At § 438.6(c)(2)(iii)(B), we propose to specify the requirements for the comparison of the total payment rate for the services included in the SDP to the ACR for those services if a State seeks written prior approval for an SDP that includes inpatient hospital services, outpatient hospital services, qualified practitioner services at an academic medical center or nursing facility services. Under this proposal, the comparison must: (1) be specific to each managed care program that the SDP applies to; (2) be specific to each provider class to which the SDP applies; (3) be projected for the rating period for which written prior approval is sought; (4) use payment data that is specific to each service included in the SDP; and (5) include a description of each of the components of the total payment rate as defined in § 438.6(a) as a percentage of the average commercial rate, demonstrated pursuant to § 438.6(c)(2)(iii)(A), for each of the four categories of services (that is, inpatient hospital services, outpatient hospital services, nursing facility services or qualified practitioner services at an academic medical center) included in the SDP submitted to CMS for review and approval.

The proposed comparison of the total payment rate to the ACR would align with current practice with one exception. We are proposing to codify that the total payment rate comparison would be specific to each Medicaid managed care program to which the SDP under review would apply. Evaluating payment at the managed care program level would be consistent with the payment analysis described in section I.B.1.d. of this proposed rule. The total payment rate comparison proposed at § 438.6(c)(iii)(B) would be a more detailed analysis than is currently requested from States for SDP reviews. Under our proposal, these more detailed total payment rate comparisons would also have to be updated and submitted with each initial preprint, amendment and renewal per proposed § 438.6(c)(2)(iii)(C). In addition, we are proposing that the total payment rate comparison to ACR must be specific to both the service and the provider class; this is current practice today but differs from our proposal for the ACR demonstration, which is proposed to be service specific only.

We have proposed a set of standards and practices States must follow in conducting their ACR analysis. However, we are not proposing to require that States use a specific source of data for the ACR analysis. Further, at this time, we are not proposing to require States to use a specific template or format for the ACR analysis. In our experience working with States on conducting the analysis of the ACR, the availability of data differs by State and service. States are familiar with the process used for conducting a code-level analysis of the ACR for the qualified practitioner services at academic medical centers for Medicaid FFS.[84] Some States have continued to use this same process for documenting the ACR for SDPs as well, particularly when there is a limited number of providers from which to collect such data (for example, academic medical centers). However, code-level data analysis to determine the ACR has proven more challenging for other services, particularly when that service is provided by large numbers of providers. For example, the number of hospitals furnishing inpatient services in a given State can be hundreds of providers.

Data for inpatient and outpatient hospital service payment rates tend to be more readily available in both the Medicare and commercial markets. States with SDPs for hospital services have provided analyses using hospital cost reports and all-payer claims databases. Others have relied on actuaries and outside consultants, which may have access to private commercial databases, to produce an ACR analysis. At times, States have purchased access to private commercial databases to conduct these analyses. We believe each of these approaches, provided the data used for the analyses meet the proposed requirements in § 438.6(c)(2)(iii), would be acceptable to meet our proposed requirements.

4. Average Commercial Rate Demonstration and Total Payment Rate Comparison Compliance

We propose at § 438.6(c)(2)(iii)(C) to require States to submit the ACR demonstration and the total payment rate comparison for review as part of the documentation necessary for written prior approval for payment arrangements, initial submissions or renewals, starting with the first rating period beginning on or after the effective date of this rule. The total payment rate comparison will need to be updated with each subsequent preprint amendment and renewal.

In recognition of the additional State resources required to conduct an ACR analysis, we propose to require that States update the ACR demonstration once every 3 years as long as the State continues to seek to include the SDP in the MCO, PIHP, or PAHP contract. This time period aligns with existing policy for ACR demonstrations for qualified practitioners in Medicaid FFS programs; specifically, those that demonstrate payment at the Medicare equivalent of the ACR.

For discussion on the proposed applicability dates for the proposals outlined in this section, see section I.B.2.p. of this proposed rule.

We solicit public comments on our proposals.

Expenditure Limit for SDPs. The increasing use by States of SDPs has been cited as a key area of oversight risk for CMS. Several oversight bodies, including MACPAC, OIG, and GAO, have authored reports focused on CMS oversight of SDPs.[85] [86] [87] Both GAO and

[84] *https://www.medicaid.gov/medicaid/financial-management/payment-limit-demonstrations/index.html.*

[85] Medicaid and CHIP Payment and Access Commission, ''Oversight of Managed Care Directed Payments,'' June 2022, available at *https://www.macpac.gov/wp-content/uploads/2022/06/*

MACPAC have noted concerns about the growth of SDPs in terms of spending as well as fiscal oversight. Additionally, as States' use of SDPs in managed care programs continues to grow, some interested parties have raised concerns that the risk-based nature of capitation rates for managed care plans has diminished. Medicaid managed care plans generally have the responsibility under risk-based contracts to negotiate with its providers to set payment rates, except when a State believes the use of an SDP is a necessary tool to support the State's Medicaid program goals and objectives. In a risk contract, as defined in § 438.2, a managed care plan assumes risk for the cost of the services covered under the contract and incurs loss if the cost of furnishing the services exceeds the payments under the contract. States' use of SDPs and the portion of total costs for each managed care program varies widely and, in some cases, are a substantial portion of total program costs on an aggregate, rate cell, or category of service basis in a given managed care program or by managed care plan. For example, in one State, one SDP accounts for nine percent of the total projected capitation rates in a given managed care program, and as much as 43 percent of the capitation rates by rate cell for SFY 2023. In another State, SDPs accounted for over 50 percent of the projected Medicaid managed care hospital benefit component of the capitation rates in CY 2022. In a third State, the amount of SDP payments as a percentage of the capitation rates are between 12.5 percent and 40.3 percent by managed care plan and rate cell for SFY 2022. Some interested parties have raised concerns that such percentages are not reasonable in rate setting, and that States are potentially using SDP arrangements to circumvent Medicaid FFS UPLs by explicitly shifting costs from Medicaid FFS to managed care contracts.

CMS agrees with some of these concerns; and therefore, we are considering, and invite comment on, potentially imposing a limit on the amount of SDP expenditures in the final rule based on comments received. Imposing such a limit could help to address and improve program and fiscal protections to address the oversight risks identified by oversight bodies, ensure that risk-based contracts are used as intended, and that managed care plans that are ''at risk'' truly have the ability to manage how their revenue is used to cover all reasonable, appropriate, and attainable costs under the terms of the contract. Such an approach could have potential negative impacts on access to care that would need to be balanced with the need for improved program and fiscal integrity. We seek public comment on whether we should adopt a limit on SDP expenditures in the final rule.

To minimize burden on States, a limit on SDP expenditures could be structured similarly to the proposed 5 percent limit for ILOS expenditures, based on the ILOS cost percentage, proposed in § 438.16(c)(1) (see section I.B.4.b. of this proposed rule). However, we question whether the five percent limit proposed for ILOSs would be a reasonable limit for SDPs given the expansive nature of and associated services impacted by SDPs. Rather, we believe 10 to 25 percent of total costs could be more realistic for limiting SDP expenditures. Like with the ILOS cost percentage, CMS would not approve the related managed care contracts if the limit on SDP expenditures were exceeded. We seek public comment on both the overall approach of using a percent of total costs as well as on the appropriateness of 10 to 25 percent or what a reasonable percentage limit for SDP expenditures could be. We believe a limit on SDP expenditures could be structured in the following ways and invite comment on them as well as if the SDP expenditures limit should be imposed on a rate cell basis instead to inform our deliberative process.

One way to impose a limit on total SDP expenditures could be as a portion of the total costs for each Medicaid managed care program. Under such an approach, States would be required to produce the same type of calculation for the final State directed payment cost percentage (see section I.B.2.j. of this proposed rule) except that for the numerator, States would be required to account for all SDPs applicable to that managed care program instead of just one SDP. Otherwise, the numerator and denominator would be calculated in the same manner as described for the final State directed payment cost percentage.

A second way to impose a limit on total SDP expenditures could be as a portion of the total costs for each Medicaid managed care program, but only focus on the costs related to inpatient hospital services, outpatient hospital services, nursing facility services, and qualified practitioner services at academic medical centers. Under this second approach, States would be required to produce the same type of calculation for the final State directed payment cost percentage (see section I.B.2.j. of this proposed rule) except the numerator would include all SDPs for inpatient hospital services, outpatient hospital services, nursing facility services and qualified practitioner services at an academic medical center applicable to that managed care program instead of just one SDP. Similarly, the denominator would only include the portion of total Medicaid managed care payments made from the State to the plan related to these four service types.

If we finalize a limit on SDP expenditures, States would need to submit documentation to CMS to demonstrate compliance. We believe that requiring this documentation be submitted with one of these existing submission requirements rather than submitting separately would increase program efficiencies and reduce administrative burden. We are considering, and invite comment on, whether documentation to comply with a limit on the amount of SDP expenditures should be submitted with the associated managed care plan contract that includes the SDP contractual arrangement, the associated rate certification, or the SDP preprint.

We seek comment on these alternatives, including perspectives on how well the alternatives address the concerns we have identified and potential consequences of using overall expenditure limits for SDPs.

g. Financing (§ 438.6(c)(2)(ii)(G) and (H))

From our experience in working with States, it has become clear that SDPs provide an important tool for States in furthering the goals and objectives of their Medicaid programs within a managed care environment. In finalizing the standards and limits for SDPs and pass-through payments in the 2016 and 2017 final rules, we intended to ensure that the funding that was included in Medicaid managed care rate development was done so appropriately and in alignment with Federal statutory requirements applicable to the Medicaid program. This includes Federal requirements for the source(s) of the non-Federal share of SDPs.

Background on Medicaid Non-Federal Share Financing. Medicaid expenditures are jointly funded by the Federal and State governments. Section 1903(a)(1) of the Act provides for

Chapter-2-Oversight-of-Managed-Care-Directed-Payments-1.pdf.

[86] U.S. Department of Health and Human Services Office of the Inspector General, ''Aspects of Texas' Quality Incentive Payment Program Raise Questions About Its Ability To Promote Economy and Efficiency in the Medicaid Program,'' A–06–18–07001, December 21, 2020, available at *https://oig.hhs.gov/oas/reports/region6/61807001.asp.*

[87] U.S. Government Accountability Office, ''Medicaid: State Directed Payments in Managed Care,'' June 28, 2022, available at *https://www.gao.gov/assets/gao-22-105731.pdf.*

Federal payments to States of the Federal share of authorized Medicaid expenditures. The foundation of Federal-State shared responsibility for the Medicaid program is that the State must participate in the financial burdens and risks of the program, which provides the State with an interest in operating and monitoring its Medicaid program in the best interest of beneficiaries (see section 1902(a)(19) of the Act) and in a manner that results in receiving the best value for taxpayers for the funds expended. Sections 1902(a)(2), 1903(a), and 1905(b) of the Act require States to share in the cost of medical assistance and in the cost of administering the Medicaid program. FFP is not available for expenditures for services and activities that are not medical assistance authorized under a Medicaid authority or allowable State administrative activities. Additionally, FFP is not available to States for expenditures that do not conform to approved State plans, waiver, demonstration projects, or contracts, as applicable.

Section 1902(a)(2) of the Act and its implementing regulation in 42 CFR part 433, subpart B require States to share in the cost of medical assistance expenditures and permit other units of State or local government to contribute to the financing of the non-Federal share of medical assistance expenditures. These provisions are intended to safeguard the Federal-State partnership, irrespective of the Medicaid delivery system or authority (for example, FFS or managed care delivery system, and State plan, waiver, or demonstration authority), by ensuring that States are meaningfully engaged in identifying, assessing, mitigating, and sharing in the risks and responsibilities inherent in operating a program as complex and economically significant as Medicaid, and that States are accordingly motivated to administer their programs economically and efficiently (see, for example, section 1902(a)(4) of the Act).

There are several types of permissible means for financing the non-Federal share of Medicaid expenditures, including, but not limited to: (1) State general funds, typically derived from tax revenue appropriated directly to the Medicaid agency; (2) revenue derived from health care-related taxes when consistent with Federal statutory requirements at section 1903(w) of the Act and implementing regulations at 42 CFR part 433, subpart B; (3) provider-related donations to the State which must be ''bona fide'' in accordance with section 1903(w) of the Act and implementing regulations at 42 CFR part 433, subpart B; [88] and (4) intergovernmental transfers (IGTs) from units of State or local government that contribute funding for the non-Federal share of Medicaid expenditures by transferring their own funds to and for the unrestricted use of the Medicaid agency.[89] Regardless of the source or sources of financing used, the State must meet the requirements at section 1902(a)(2) of the Act and § 433.53 that obligate the State to fund at least 40 percent of the non-Federal share of total Medicaid expenditures (both medical assistance and administrative expenditures) with State funds.

Health care-related taxes and IGTs are a critical source of funding for many States' Medicaid programs, including for supporting the non-Federal share of many payments to safety net providers. Health care-related taxes made up approximately 17 percent ($37 billion) of all States' non-Federal share in 2018, the latest year for which data are available.[90] IGTs accounted for approximately 10 percent of all States' non-Federal share for that year. The Medicaid statute clearly permits certain health care-related taxes and IGTs to be used to support the non-Federal share of Medicaid expenditures, and CMS supports States' adoption of these non-Federal financing strategies where consistent with applicable Federal requirements. CMS approves hundreds of State payment proposals annually that are funded by health care-related taxes that appear to meet statutory requirements. The statute and regulations afford States flexibility to tailor health care-related taxes within certain parameters to suit their provider community, broader State tax policies, and the needs of State programs. However, all health care-related taxes must be imposed in a manner consistent with applicable Federal statutes and regulations, which prohibit direct or indirect ''hold harmless'' arrangements (see section 1903(w)(4) of the Act; 42 CFR 433.68(f)).

States first began to use health care-related taxes and provider-related donations in the mid-1980s as a way to finance the non-Federal share of Medicaid payments (Congressional Research Service, ''Medicaid Provider Taxes,'' August 5, 2016, page 2). Providers would agree to make a donation or would support (or not oppose) a tax on their activities or revenues, and these mechanisms (donations or taxes) would generate funds that could then be used to raise Medicaid payment rates to the providers. Frequently, these programs were designed to hold Medicaid providers ''harmless'' for the cost of their donation or tax payment. As a result, Federal expenditures rapidly increased without any corresponding increase in State expenditures, since the funds used to increase provider payments came from the providers themselves and were matched with Federal funds. In 1991, Congress passed the Medicaid Voluntary Contribution and Provider-Specific Tax Amendments (Pub. L. 102–234, enacted December 12, 1991) to establish limits for the use of provider-related donations and health care-related taxes to finance the non-Federal share of Medicaid expenditures. Statutory provisions relating to health care-related taxes and donations are in section 1903(w) of the Act.

Section 1903(w)(1)(A)(i)(II) requires that health care-related taxes be broad-based as defined in section 1903(w)(3)(B), which specifies that the tax must be imposed with respect to a permissible class of health care items or services (as described in section 1903(w)(7)(A)) or with respect to providers of such items or services and generally imposed at least with respect to all items or services in the class furnished by all non-Federal, nonpublic providers or with respect to all non-Federal, nonpublic providers; additionally, the tax must be imposed uniformly in accordance with section 1903(w)(3)(C) of the Act. However,

[88] ''Bona fide'' provider-related donations are truly voluntary and not part of a hold harmless arrangement that effectively repays the donation to the provider (or to providers furnishing the same class of items and services). As specified in § 433.54, a bona fide provider-related donation is made to the State or a unit of local government and has no direct or indirect relationship to Medicaid payments made to the provider, any related entity providing health care items or services, or other providers furnishing the same class of items or services as the provider or entity. This is satisfied where the donations are not returned to the individual provider, provider class, or a related entity under a hold harmless provision or practice. Circumstances in which a hold harmless practice exists are specified in § 433.54(c).

[89] Certified public expenditures (CPEs) also can be a permissible means of financing the non-Federal share of Medicaid expenditures. CPEs are financing that comes from units of State or local government where the units of State or local governmental entity contributes funding of the non-Federal share for Medicaid by certifying to the State Medicaid agency the amount of allowed expenditures incurred for allowable Medicaid activities, including the provision of allowable Medicaid services provided by enrolled Medicaid providers. States infrequently use CPEs as a financing source in a Medicaid managed care setting, as managed care plans need to be paid prospective capitation payments and CPEs by nature are a retrospective funding source, dependent on the amount of expenditures the unit of State or local government certifies that it already has made.

[90] U.S. Government Accountability Office, ''Medicaid: CMS Needs More Information on States' Financing and Payment Arrangements to Improve Oversight,'' GAO–21–98, December 7, 2020, available at *https://www.gao.gov/products/gao-21-98.*

section 1903(w)(1)(A)(iii) of the Act disallows the use of revenues from a broad-based health care related tax if there is in effect a hold harmless arrangement described in section 1903(w)(4) of the Act with respect to the tax. Section 1903(w)(4) of the Act specifies that, for purposes of section 1903(w)(1)(A)(iii) of the Act, there is in effect a hold harmless provision with respect to a broad-based health care related tax if the Secretary determines that any of the following applies: (A) the State or other unit of government imposing the tax provides (directly or indirectly) for a non-Medicaid payment to taxpayers and the amount of such payment is positively correlated either to the amount of the tax or to the difference between the amount of the tax and the amount of the Medicaid payment; (B) all or any portion of the Medicaid payment to the taxpayer varies based only upon the amount of the total tax paid; or (C) the State or other unit of government imposing the tax provides (directly or indirectly) for any payment, offset, or waiver that guarantees to hold taxpayers harmless for any portion of the costs of the tax. Section 1903(w)(1)(A) of the Act specifies that, for purposes of determining the Federal matching funds to be paid to a State, the total amount of the State's Medicaid expenditures must be reduced by the amount of revenue received the State (or by a unit of local government in the State) from impermissible health care-related taxes, including, as specified in section 1903(w)(1)(A)(iii) of the Act, from a broad-based health care related tax for which there is in effect a hold harmless provision described in section 1903(w)(4) of the Act.

In response to the Medicaid Voluntary Contribution and Provider-Specific Tax Amendments of 1991, we published the ''Medicaid Program; Limitations on Provider-Related Donations and Health Care-Related Taxes; Limitations on Payments to Disproportionate Share Hospitals'' interim final rule with comment period in the November 24, 1992 **Federal Register** (57 FR 55118) (November 1992 interim final rule) and the subsequent final rule published in the August 13, 1993 **Federal Register** (58 FR 43156) (August 1993 final rule) establishing when States may receive funds from provider-related donations and health care-related taxes without a reduction in medical assistance expenditures for the purposes of calculating FFP.

After the publication of the August 1993 final rule, we revisited the issue of health care-related taxes and provider-related donations in the ''Medicaid Program; Health-Care Related Taxes'' final rule (73 FR 9685) which published in the February 22, 2008 **Federal Register** (February 2008 final rule). The February 2008 final rule, in part, made explicit that certain practices would constitute a hold harmless arrangement, in response to certain State tax programs that we believed contained hold harmless provisions. For example, five States had imposed a tax on nursing homes and simultaneously created programs that awarded grants or tax credits to private pay residents of nursing facilities that enabled these residents to pay increased charges imposed by the facilities, which thereby recouped their own tax costs. We believed that these payments held the taxpayers (the nursing facilities) harmless for the cost of the tax, as the tax program repaid the facilities indirectly, through the intermediary of the nursing facility residents. However, in 2005, the Department of Health and Human (HHS) Departmental Appeals Board (the Board) (Decision No. 1981) ruled that such an arrangement did not constitute a hold harmless arrangement under the regulations then in place (73 FR 9686–9687). Accordingly, in discussing revisions to the hold harmless guarantee test in § 433.68(f)(3), the February 2008 final rule preamble explained that a State can provide a direct or indirect guarantee through a direct or indirect payment. We stated that a direct guarantee will be found when, ''a payment is made available to a taxpayer or party related to the taxpayer with the reasonable expectation that the payment would result in the taxpayer being held harmless for any part of the tax'' as a result of the payment (73 FR 9694). We noted parenthetically that such a direct guarantee can be made by the State through direct or indirect payments. *Id.* As an example of a party related to the taxpayer, the preamble cited the example of, ''as a nursing home resident is related to a nursing home'' (73 FR 9694). As discussed in this preamble to the February 2008 final rule, whenever there exists a ''reasonable expectation'' that the taxpayer will be held harmless for the cost of the tax by direct or indirect payments from the State, a hold harmless situation exists and the tax is impermissible for use to support the non-Federal share of Medicaid expenditures.

Non-Federal Share Financing and State Directed Payments. The statutory requirements in sections 1902(a)(2), 1903(a), 1903(w), and 1905(b) of the Act concerning the non-Federal share contribution and financing requirements, including those implemented in 42 CFR part 433, subpart B concerning health care-related taxes, bona fide provider related donations, and IGTs, apply to all Medicaid expenditures regardless of delivery system (fee-for-service or managed care). We employ various mechanisms for reviewing State methods for financing the non-Federal share of Medicaid expenditures. This includes, but is not limited to, reviews of fee-for-service SPAs, reviews of managed care SDPs, quarterly financial reviews of State expenditures reported on the Form CMS–64, focused financial management reviews, and reviews of State health care-related tax and provider-related donation proposals and waiver requests.

We reiterated this principle in the 2020 Medicaid managed care rule, noting ''certain financing requirements in statute and regulation are applicable across the Medicaid program irrespective of the delivery system (for example, fee-for-service, managed care, and demonstration authorities), and are similarly applicable whether a State elects to direct payments under § 438.6(c)'' (85 CFR 72765). Further, section 1903(m)(2)(A) of the Act limits FFP in prepaid capitation payments to MCOs for coverage of a defined minimum set of benefits to cases in which the prepaid payments are developed on an actuarially sound basis for assuming the cost of providing the benefits at issue to Medicaid managed care enrollees. CMS has extended this requirement, through rulemaking under section 1902(a)(4) of the Act, to the capitation rates paid to PIHPs and PAHPs under a risk contract as well.

As part of our review of SDP proposals, we are increasingly encountering issues with State financing of the non-Federal share of SDPs, including use of health care-related taxes and IGT arrangements that may not be in compliance with the underlying Medicaid requirements for non-Federal share financing. In January 2021, CMS released a revised preprint form that systematically collects documentation regarding the source(s) of the non-Federal share for each SDP and requires States to provide additional assurances and details specific to each financing mechanism, which has contributed to our increased awareness of non-Federal share financing issues associated with SDPs.[91] Concerns around the funding of the non-Federal share for SDPs have been

[91] *https://www.medicaid.gov/medicaid/managed-care/downloads/sdp-4386c-preprint-template.pdf.*

raised by oversight bodies,[92] [93] and the Department of Health and Human Services Office of Inspector General (OIG) is currently conducting an audit of States' use of what are often referred to as Local Provider Participation Funds to support the non-Federal share of Medicaid payments, for which CMS has evidence that appears to suggest the use of hold harmless arrangements in connection with health care-related taxes.[94]

In recent years, we have identified instances in which States appear to be funding the non-Federal share of Medicaid SDP payments through health care-related tax programs that appear to involve an impermissible hold harmless arrangement. In these arrangements, with varying degrees of State awareness and involvement, providers appear to have pre-arranged agreements to redistribute Medicaid payments (or other provider funds that are replenished by Medicaid payments). These redistribution arrangements are not described on the States' SDP applications; if an SDP preprint stated that Medicaid payments ultimately would be directed to a recipient without being based on the delivery of Medicaid-covered services, we could not approve the SDP, because section 1903(a) of the Act limits Federal financial participation to expenditures for medical assistance and qualifying administrative activities (otherwise stated, FFP is not available in expenditures for payments to third parties unrelated to the provision of covered services or conduct of allowable administrative activities). Similarly, under 1903(w), FFP is not permissible in payments that would otherwise be matchable as medical assistance if the State share being matched does not comply with the conditions in section 1903(w), such as in the case of the type of hold harmless arrangement described above. The fact that these apparent hold harmless arrangements are not made explicit on SDP preprints should not affect our ability to disapprove SDPs when we cannot verify they do not employ redistribution arrangements.

These arrangements appear designed to redirect Medicaid payments away from the providers that furnish the greatest volume of Medicaid-covered services toward providers that provide fewer, or even no, Medicaid-covered services, with the effect of ensuring that taxpaying providers are held harmless for all or a portion of their cost of the health care-related tax. In the arrangements, a State or other unit of government imposes a health-care related tax, then uses the tax revenue to fund the non-Federal share of SDPs that require Medicaid managed care plans to pay the provider taxpayers. The taxpayers appear to enter a pre-arranged agreement to redistribute the Medicaid payments to ensure that all taxpayers, when accounting for both their original Medicaid payment (from the State through a managed care plan) and any redistribution payment received from another taxpayer(s) or other entity, receive back (and are thereby held harmless for) all or at least a portion of their tax amount.

Providers that serve a relatively low percentage of Medicaid patients or no Medicaid patients often do not receive enough Medicaid payments funded by a health care-related tax to cover the provider's cost in paying the tax. Providers in this position are unlikely to support a State or locality establishing or continuing a health care-related tax because the tax would have a negative financial impact on them. Redistribution arrangements like those just described seek to eliminate this negative financial impact or turn it into a positive financial impact for taxpaying providers, likely leading to broader support among the provider class of taxpayers for legislation establishing or continuing the tax. Based on limited information we have been able to obtain from providers participating in such arrangements, we believe providers with relatively higher Medicaid volume agree to redistribute some of their Medicaid payments to ensure broad support for the tax program, which ultimately works to these providers' advantage since the tax supports increased Medicaid payments to them (even net of Medicaid payments that they redistribute to other providers) compared to payment amounts for delivering Medicaid-covered services they would receive in the absence of the tax program. These redistribution arrangements therefore help ensure that State or local governments are successful in enacting or continuing provider tax programs.

The Medicaid statute in 1903(w) does not permit us to provide FFP in expenditures under any State payment proposal that would distribute Medicaid payments to providers based on the cost of a health care-related tax instead of based on Medicaid services, so payment redistribution arrangements often occur without notice to CMS (and possibly States) and are not described as part of a State payment proposal submitted for CMS review and approval (see, section 1903(w)(4) of the Act). Given that we cannot knowingly approve awarding FFP under this scenario, we believe that it would be inconsistent with the proper and efficient operation of the Medicaid State plan to approve an SDP when we know the payments would be funded under such an arrangement. For example, we would not approve an SDP that would require payment from a Medicaid managed care plan to a hospital that did not participate in Medicaid, in any amount. Nor would we approve an SDP that would require payment from a Medicaid managed care plan (that is, a Medicaid payment) to a hospital with a low percentage of Medicaid revenue based on the difference between the hospital's total cost of a health care-related tax and other Medicaid payments received by the hospital. As a result, the redistribution arrangements seek to achieve what cannot be accomplished explicitly through a CMS-approved payment methodology (that is, redirecting Medicaid funds to hold taxpayer providers harmless for their tax cost, with a net effect of directing Medicaid payments to providers based on criteria other than their provision of Medicaid-covered services).

Redistribution arrangements undermine the fiscal integrity of the Medicaid program and are inconsistent with existing statutory and regulatory requirements prohibiting hold harmless arrangements. Currently, § 433.68(f)(3), implementing section 1903(w)(4)(C) of the Act, provides that a hold harmless arrangement exists where a State or other unit of government imposing a health care-related tax provides for any direct or indirect payment, offset, or waiver such that the provision of the payment, offset, or waiver directly or indirectly guarantees to hold taxpayers harmless for all or any portion of the tax amount. The February 2008 final rule on health care-related taxes specified that hold harmless arrangements prohibited by § 433.68(f)(3) exist ''[w]hen a State payment is made available to a taxpayer or a party related to the taxpayer (for example, as a nursing home resident is related to a nursing home), in the

[92] See U.S. Government Accountability Office, ''Medicaid: CMS Needs More Information on States' Financing and Payment Arrangements to Improve Oversight,'' GAO–21–98, December 7, 2020, available at *https://www.gao.gov/products/gao-21-98*.

[93] See Medicaid and CHIP Payment and Access Commission, ''Oversight of Managed Care Directed Payments,'' June 2022, available at *https://www.macpac.gov/wp-content/uploads/2022/06/Chapter-2-Oversight-of-Managed-Care-Directed-Payments-1.pdf*.

[94] U.S. Department of Health and Human Services Office of the Inspector General, ''States' Use of Local Provider Participation Funds as the State Share of Medicaid Payments'', W–00–22–31557, report expected 2023, work plan available at *https://www.oig.hhs.gov/reports-and-publications/workplan/summary/wp-summary-0000626.asp*.

reasonable expectation that the payment would result in the taxpayer being held harmless for any part of the tax'' (73 FR 9694, quoting preamble discussion from the proposed rule). Regardless of whether the taxpayers participate voluntarily, whether the taxpayers receive the Medicaid payments from a Medicaid managed care plan, or whether taxpayers themselves or another entity make redistribution payments using the very dollars received as Medicaid payments or with other provider funds that are replenished by the Medicaid payments, the taxpayers participating in these redistribution arrangements have a reasonable expectation that they will be held harmless for all or a portion of their tax amount.

We stated that the addition of the words ''or indirectly'' in the regulation indicates that the State itself need not be involved in the actual redistribution of Medicaid funds for the purpose of returning tax amounts to taxpayers in order for the arrangement to qualify as a hold harmless (73 FR 9694). We further explained in the same preamble that we used the term ''reasonable expectation'' because ''State laws were rarely overt in requiring that State payments be used to hold taxpayers harmless'' (73 FR 9694). Hold harmless arrangements need not be overtly established through State law or contracts, but can be based upon a reasonable expectation that certain actions will take place among participating entities to return to taxpaying providers all or any portion of their tax amounts. The redistribution arrangements detailed earlier constitute a hold harmless arrangement described in section 1903(w)(4) of the Act and implementing regulations in part 433. Such arrangements require a reduction of the State's medical assistance expenditures as specified by section 1903(w)(1)(A)(iii) of the Act and § 433.70(b).

Approving an SDP under which the State share is funded through an impermissible redistribution agreement would also be inconsistent with ''proper and efficient administration'' of the Medicaid program within the meaning of section 1902(a)(4) of the Act, as it would result in expenditures for which FFP would ultimately have to be disallowed, when it would be more efficient to not allow such expenditures to be made in the first place. We therefore also rely on our authority under section 1902(a)(4) of the Act to specify methods of administration that are necessary for proper and efficient administration in support of the authority we proposed to make explicit in § 438.6 to disapprove an SDP when we are aware the State share in the SDP would be based on an arrangement that violates section 1903(w) of the Act. We note that in addition to the foregoing, SDPs that are required by Medicaid managed care contracts must be limited to payments for services that are covered under the Medicaid managed care contract and meet the definition of medical assistance under section 1903(a) of the Act. Thus, to the extent the funds are not used for medical assistance, but diverted for another purpose, matching as medical assistance would not be permissible.

In the past, we have identified instances of impermissible redirection or redistribution of Medicaid payments and have taken action to enforce compliance with the statute. For example, the Board upheld our decision to disallow a payment redirection arrangement in a State under a FFS State plan amendment, citing section 1903(a)(1) of the Act, among other requirements (HHS, Board Decision No. 2103, July 31, 2007). Specifically, the Board found that written agreements among certain hospitals redirected Medicaid payments. The payments were not retained by the hospitals to offset their Medicaid costs, as required under the State plan. Instead, pre-arranged agreements redirected Medicaid payments to other entities to fund non-Medicaid costs. In its decision, the Board stated, ''Hence, they were not authorized by the State plan or Medicaid statute[.]'' When providers redistribute their Medicaid payments for purposes of holding taxpayers harmless or otherwise, in effect, the State's claim for FFP in these provider payments is not limited to the portion of the payment that the provider actually retains as payment for furnishing Medicaid-covered services, but also includes the portion that the provider diverts for a non-Medicaid activity ineligible for FFP (for example, holding other taxpayers harmless for their tax costs). This payment of FFP for non-qualifying activities also has the effect of impermissibly inflating the Federal matching rate that the State receives for qualifying Medicaid expenditures above the applicable, statutorily-specified matching rate (see, for example, sections 1903(a), 1905(b), 1905(y), and 1905(z) of the Act).

Ensuring permissible non-Federal share sources and ensuring that FFP is only paid to States for allowable Medicaid expenditures is critical to protecting Medicaid's sustainability through responsible stewardship of public funds. State use of impermissible non-Federal share sources often artificially inflates Federal Medicaid expenditures. Further, these arrangements reward providers based on their ability to fund the State share, and disconnect the Medicaid payment from Medicaid services, quality of care, health outcomes, or other Medicaid program goals. Of critical concern, it appears that the redistribution arrangements are specifically designed to redirect Medicaid payments away from Medicaid providers that serve a high percentage of Medicaid beneficiaries to providers that do not participate in Medicaid or that have relatively lower Medicaid utilization.

States have cited challenges with identifying and providing details on redistribution arrangements when we have requested such information during the review of SDPs. The current lack of transparency prevents both CMS and States from having information necessary for reviewing both the proposed non-Federal share financing source and the proposed payment methodology to ensure they meet Federal requirements. Some States have also expressed concerns with ongoing oversight activities in which CMS is attempting to obtain information that may involve arrangements to which only private entities are a party. We are only interested in any business arrangements among private entities that could result in a violation of Federal statutory and regulatory requirements.

As noted above, we recognize that health care-related taxes can be critical tools for financing payments that support the Medicaid safety net, but they must be implemented in accordance with applicable statutory and regulatory requirements. This proposed rule would ensure that CMS and States have necessary information about any arrangements in place that would redistribute Medicaid payments and make clear that we have the authority to disapprove proposed SDPs if States identify the existence of such an arrangement or do not provide required information or ensure the attestations are made and available as required under proposed paragraph (c)(2)(ii)(H). The proposed new attestation requirement would help ensure appropriate transparency regarding the use of Medicaid payments and any relationship to the non-Federal share source(s), and aims to do so without interfering with providers' normal business arrangements.

All Federal legal requirements for the financing of the non-Federal share, including but not limited to, 42 CFR part 433, subpart B, apply regardless of delivery system, although currently,

§ 438.6(c) does not explicitly state that compliance with statutory requirements and regulations outside of part 438 related to the financing of the non-Federal share is required for SDPs to be approvable or that CMS may deny written prior approval for an SDP based on a State's failure to demonstrate that the financing of the non-Federal share is fully compliant with applicable Federal law. The requirements applicable to health care-related taxes, bona fide provider related donations, and IGTs also apply to the non-Federal share of expenditures for payments under part 438. Currently, § 438.6(c)(1)(ii)(E) provides that a State must demonstrate to CMS, in writing, that an SDP does not condition provider participation in the SDP on the provider entering into or adhering to intergovernmental transfer agreement. We believe additional measures are necessary to ensure compliance with applicable Federal requirements for the source(s) of non-Federal share. We are concerned that the failure of the current regulations to explicitly condition written prior approval of an SDP on the State demonstrating compliance with applicable Federal requirements for the source(s) of non-Federal share potentially compromises our ability to disapprove an SDP where it appears the SDP arrangement is supported by impermissible non-Federal share financing arrangements. Given the growing number of SDPs that raise potential financing concerns, and the growing number of SDPs generally, we believe it is important to be explicit in the regulations governing SDPs that the same financing requirements governing the sources of the non-Federal share apply regardless of delivery system, and that CMS will scrutinize the source of the non-Federal share of SDPs during the preprint review process. We propose to revise § 438.6(c)(2)(ii) to add a new paragraph (c)(2)(ii)(G) that would explicitly require that an SDP comply with all Federal legal requirements for the financing of the non-Federal share, including but not limited to, 42 CFR part 433, subpart B, as part of the CMS review process.

We also propose to revise § 438.6(c)(2)(ii) to ensure transparency regarding the use of SDPs and to ensure that the non-Federal share of SDPs is funded with a permissible source. Under our proposal, States would be required to ensure that each participating provider in an SDP arrangement attests that it does not participate in any hold harmless arrangement with respect to any health care-related tax as specified in § 433.68(f)(3) in which the State or other unit of government imposing the tax provides for any direct or indirect payment, offset, or waiver such that the provision of the payment, offset, or waiver directly or indirectly guarantees to hold the provider harmless for all or any portion of the tax amount. Such hold harmless arrangements include those that produce a reasonable expectation that taxpaying providers would be held harmless for all or a portion of their cost of a health care-related tax. States would be required to note in the preprint their compliance with this requirement prior to our written prior approval of any contractual payment arrangement directing how Medicaid managed care plans pay providers. States would comply with this proposed requirement by obtaining each provider's attestation or requiring the Medicaid managed care plan to obtain each provider's attestation. We also propose, at § 438.6(c)(2)(ii)(H) to require that the State ensure that such attestations are available upon CMS request.

Under this proposal, CMS may deny written prior approval of an SDP if it does not comply with any of the standards in § 438.6(c)(2), including the financing of the non-Federal share is not fully compliant with all Federal legal requirements for the financing of the non-Federal share and/or the State does not require an attestation from each provider receiving a payment based on the SDP that it does not participate in any hold harmless arrangement. As part of our proposed restructuring of § 438.6(c)(2), these provisions would apply to all SDPs, regardless of whether written prior approval is required. We rely on our authority in section 1902(a)(4) of the Act to require methods of administration as are found by the Secretary to be necessary for the proper and efficient operation of the Medicaid State Plan to propose these requirements for ensuring that the source of the non-Federal share of the financing for SDPs is consistent with section 1903(w) of the Act. It is consistent with the economic and efficient operation of the Medicaid State Plan to ensure that State expenditures are consistent with the requirements to obtain FFP, and thereby avoid the process of recouping FFP when provided inappropriately, which is needlessly burdensome for States and CMS. Given that all Federal legal requirements for the financing of the non-Federal share, including but not limited to, 42 CFR part 433, subpart B, apply regardless of delivery system, we also solicit public comment on whether the proposed changes in § 438.6(c)(2)(ii)(G) and (H) should be incorporated more broadly into 42 CFR part 438.

For discussion on the proposed applicability dates for the proposals outlined in this section, see section I.B.2.p. of this proposed rule.

We solicit public comments on these proposals.

h. Tie to Utilization and Delivery of Services for Fee Schedule Arrangements (§ 438.6(c)(2)(vii))

A fundamental requirement of SDPs is that they are payments related to the delivery of services under the contract. In the 2016 final rule, we stated how we believe that actuarially sound payments, which are required under section 1903(m)(2)(A)(iii) for capitation payments to MCOs and under part 438 regulations for capitation payments to risk-based PIHPs and PAHPs, must be based on the provision of covered benefits and associated administrative obligations under the managed care contract (81 FR 27588). This requirement that SDPs be tied to the utilization and delivery of covered benefits differentiates SDPs from pass-through payments. We described the differences between pass-through payments and SDPs in the 2016 final rule and in the 2017 Pass-Through Payment Rule, where we noted, that pass-through payments are not consistent with our regulatory standards for actuarially sound rates because they do not tie provider payments with the provision of services (81 FR 27587 through 27592, 82 FR 5415).

The current regulations at § 438.6(c)(2)(ii)(A) require that States demonstrate in writing that SDPs that require prior written approval be based on the utilization and delivery of services to Medicaid enrollees covered under the managed care plan contract. We have interpreted this requirement to mean that SDPs must be conditioned upon the utilization or delivery of services during the rating period identified in the preprint for which the State is seeking written prior approval. Requiring SDPs to be based on the utilization and delivery of services is a fundamental and necessary requirement for ensuring the fiscal and program integrity of SDPs, but we believe further clarification is necessary due to the variety of payment mechanisms that States use in their SDP arrangements. In particular, ensuring that payments are based on the delivery of services in SDPs that are fee schedule requirements described in § 438.6(c)(1)(iii) is relatively straightforward since fee schedules explicitly link a rate to each

code (for example, CPT or HCPCS), compared to SDPs that are VBP initiatives described in § 438.6(c)(1)(i) and (ii). As discussed in further detail in the section I.B.2.i of this proposed rule, ensuring that payments in VBP initiatives are based on the delivery of services in ways that do not hinder States' ability to pursue VBP efforts is more difficult because, by their nature, VBP initiatives seek to move away from paying for volume in favor of paying for value and performance. We propose revising § 438.6(c) to address how different types of SDPs must be based on utilization and delivery of covered services; this section discusses these requirements for fee schedule arrangements and section I.B.2.i. of this proposed rule discusses the requirements for VBP initiatives.

For SDPs that are fee schedule requirements described in § 438.6(c)(1)(iii), the tie to utilization and delivery of services means that States require managed care plans to make payments when a particular service was delivered during the rating period for which the SDP was approved. Thus, the State could not, under our interpretation of the requirement, require managed care plans to make payments for services that were delivered outside of the approved rating period. However, in working with States, we found that this was not always understood. We therefore clarified this in SMDL #21–001,[95] and explained that SDPs need to be conditioned on the delivery and utilization of services covered under the managed care plan contract for the applicable rating period and that payment cannot be based solely on historical utilization.

We propose to codify this clarification in a new § 438.6(c)(2)(vii)(A) for SDPs described in § 438.6(c)(1)(iii)—that is, minimum fee schedules, maximum fee schedules, and uniform increases. As proposed, § 438.6(c)(2)(vii)(A) would require that any and all payments made under the SDP are conditioned on the utilization and delivery of services under the managed care plan contract for the applicable rating period only. This would preclude States from making any SDP payment based on historical or any other basis that is not tied to the delivery of services to the rating period itself.

Our proposal also addresses SDPs that require reconciliation. In SMDL #21–001,[96] we noted that in capitation rate development, States can use historical data to inform the capitation rates that will be paid to managed care plans for services under the rating period, and this is consistent with § 438.5(b)(1) and (c). However, in accordance with current requirements in § 438.6(c)(2)(ii)(A), payment to providers for an SDP must be made based on the delivery and utilization of covered services rendered to Medicaid beneficiaries during the rating period documented for the approved SDP. We have reviewed and approved SDPs, typically SDPs that establish uniform increases of a specific dollar amount, in which States require managed care plans to make interim payments based on historical utilization and then after the close of the rating period, reconcile the payments to actual utilization that occurred during the rating period approved in the SDP. For these SDPs, States will include the SDP in the rate certification and then once actual utilization for the current rating year is known, CMS has also seen in some instances, States have their actuaries submit an amendment to adjust the amount paid to plans (whether through a separate payment term or an adjustment to base rates) to account for this reconciliation. These amendments typically come near to or after the close of the rating period and are most common when the reconciliation would result in increased costs to the plan absent the adjustment. As a result, risk is essentially removed from the managed care plans participating in the SDP. We are concerned with this practice as we believe tying payments in an SDP, even interim payments, to utilization from a historical time period outside of the rating period approved for the SDP, is inconsistent with prospective risk-based capitation rates that are developed for the delivery of services in the rating period. Further, rate amendments that are submitted after the rating period concludes that adjust the capitation rates retroactively to reflect actual utilization under the SDP goes against the risk-based nature of managed care. To address this, we propose a new § 438.6(c)(2)(vii)(B) which would prohibit States from requiring managed care plans to make interim payments based on historical utilization and then to reconcile those interim payments to utilization and delivery of services covered under the contract after the end of the rating period for which the SDP was originally approved.

To illustrate our concern and need for the proposed regulatory requirement, we share the following example for a State that has an SDP approved to require a uniform increase to be paid for inpatient hospital services for CY 2020. During CY 2020, the State's contracted managed care plans pay the inpatient hospital claims at their negotiated rates for actual utilization and report that utilization to the State via encounter data. Concurrently, the State directs its managed care plans, via the SDP, to make a separate uniform increase in payment to the same inpatient hospital service providers, based on historical CY 2019 utilization. Under this example, the increase in January CY 2020 payment for the providers is made based on January CY 2019 data, the increase in February CY 2020 payment is based on February CY 2019 data, and so forth. This pattern of monthly payments continues throughout CY 2020. After the rating period ends in December 2020, and after a claims runout period that can be as long as 16 months, the State then in mid-CY 2021 or potentially early 2022, reconciles the amount of CY 2019-based uniform increase payments to the amount the payments should be based on CY 2020 claims. The State then requires its managed care plans to make additional payments to, or recoup payments from, the hospitals for under- or over-payment of the CY 2019-based uniform increase.

In the inpatient hospital uniform increase example above, the State may initially account for the SDP in the CY 2020 rate certification and, after the rating period is over, the State submits an amendment to their rate certification to revise the total dollar amount dedicated to the SDP and the capitation rates to reflect the SDP provider payments that were made based on actual utilization in the CY 2020 rating period—thereby, making the managed care plans ''whole'' and removing risk from the managed care plans participating in the SDP. We do not find these practices consistent with the nature of risk-based managed care.

Capitation rates must be actuarially sound as required by section 1903(m)(2)(A)(iii) of the Act[97] and in § 438.4. Specifically, § 438.4(a) requires that actuarially sound capitation rates are projected to provide for all reasonable, appropriate, and attainable costs that are required under the terms of the contract and for the operation of the MCO, PIHP, or PAHP for the time period and the population covered under the terms of the contract, and such capitation rates are developed in

[95] *https://www.medicaid.gov/Federal-Policy-Guidance/Downloads/smd21001.pdf.*

[96] *https://www.medicaid.gov/Federal-Policy-Guidance/Downloads/smd21001.pdf.*

[97] The actuarial soundness requirements apply statutorily to MCOs under section 1903(m)(2)(A)(ii) of the Act and were extended to PIHPs and PAHPs under our authority in section 1902(a)(4) of the Act in the 2002 final rule.

accordance with the requirements outlined in § 438.4(b). ''Rating Period'' is defined at § 438.2 as a period of 12 months selected by the State for which the actuarially sound capitation rates are developed and documented in the rate certification submitted to CMS as required by § 438.7(a). We believe SDPs that make payments based on retrospective utilization and include reconciliations to reflect actual utilization, while eventually tying final payment to utilization and delivery of services during the rating period approved in the SDP, are contrary to the nature of risk-based managed care. SDPs must tie to the utilization and delivery of services to Medicaid enrollees covered under the contract for the rating period approved in the SDP.

We have previously issued regulations and guidance in response to payments we found to be inconsistent with the statute concerning actuarial soundness. In the 2016 rule we noted our belief that the statutory requirement that capitation payments to managed care plans be actuarially sound requires that payments under the managed care contract align with the provision of services under the contract. We further noted that based on our review of capitation rates, we found pass-through payments being directed to specific providers that generally were not directly linked to the delivered services or the outcomes of those services; thereby noting that pass-through payments are not consistent with actuarially sound rates and do not tie provider payments with the provision of services [98] These concerns led CMS to phase out the ability of States to utilize pass-through payments as outlined in § 438.6(d). We reach a similar conclusion in our review of SDP proposals which use reconciliation of historical to actual utilization; if States are seeking to remove risk from managed care plans in connection with these types of SDPs, it is inconsistent with the nature of risk-based Medicaid managed care. As further noted in the 2016 rule, ''[t]he underlying concept of managed care and actuarial soundness is that the [S]tate is transferring the risk of providing services to the MCO and is paying the MCO an amount that is reasonable, appropriate, and attainable compared to the costs associated with providing the services in a free market. Inherent in the transfer of risk to the MCO is the concept that the MCO has both the ability and the responsibility to utilize the funding under that contract to manage the contractual requirements for the delivery of services.'' [99]

States use retrospective reconciliations even though there are less administratively burdensome ways to ensure payment rates for specific services are at or above a certain level. States could accomplish this through the establishment of a minimum fee schedule, which we propose to define in § 438.6(a) as any contract requirement where the State requires a MCO, PIHP, or PAHP to pay no less than a certain amount for a covered service(s). If a State's intent is to require that managed care plans pay an additional amount per service delivered, States could accomplish this through the establishment of a uniform increase, which we propose to define in § 438.6(a) as any contract requirement where the State requires a MCO, PIHP, or PAHP to pay the same amount (the same dollar or the same percentage increase) per covered service(s) in addition to the rates the managed care plan negotiated with providers. In addition to being less administratively burdensome, both options would provide more clarity to providers on payment rates and likely result in more timely payments than a retrospective reconciliation process. Both options would also allow States' actuaries to include the SDPs into the standard capitation rate development process using the same utilization projections used to develop the underlying capitation rates. States can require both minimum fee schedules and uniform increases under current regulations.

We believe requiring managed care plans to make interim payments based on historical utilization and then reconciling to actual utilization instead suggests an intent by State to ensure payment of a specific aggregate amount to certain providers or, in some cases, removal of all risk related to these SDPs from managed care plans. We believe prohibiting this practice and removing post-payment reconciliation processes as we propose in § 438.6(c)(2)(vii)(B) would alleviate actuarial and oversight concerns as well as restore program and fiscal integrity to these kinds of payment arrangements.

CMS is proposing to prohibit the use of post-payment reconciliation processes for SDPs; specifically, that States establishing fee schedules under § 438.6(c)(1)(iii) cannot require that plans pay providers using a post-payment reconciliation process. It is not uncommon for States to pair SDPs requiring plans to pay providers using a post-payment reconciliation process with a separate payment term described later in section I.B.2.l. However, post-payment reconciliation process and separate payment terms are not the same. Separate payment terms are payments made to the plan in addition to the capitation rates to account for any portion of the cost of complying with the SDP not already accounted for in the capitation rates. In contrast, the post-payment reconciliation process that we are proposing to prohibit here directs how the plans pay providers. In both cases, CMS has raised concerns about the removal of risk from the plan and their use by some States in ways that are contrary to the risk-based nature of Medicaid managed care. However, as discussed later, while CMS has a strong preference that SDPs be included as adjustments to the capitation rates since that method is most consistent with the nature of risk-based managed care, we believe separate payment terms can be a useful tool for States to be able to make targeted investments in response to acute concerns around access to care. In contrast, we do not see the same kind of benefit to the Medicaid program in allowing States to require that plans pay providers using a post-payment reconciliation process. We believe that there are methods for providing sufficient guardrails around the use of separate payment terms that lessen the risks associated with the use of separate payment terms as we have proposed and described in section I.B.2.1. of this proposed rule.

For discussion on the proposed applicability dates for the proposals outlined in this section, see section I.B.2.p. of this proposed rule.

We solicit public comments on our proposals.

i. Value-Based Payments and Delivery System Reform Initiatives (§ 438.6(c)(2)(vi))

We are also proposing several changes to § 438.6(c) to address how VBP initiatives, which include value-based purchasing, delivery system reform, and performance improvement initiatives as described in § 438.6(c)(1)(i) and (ii), can be tied to delivery of services under the Medicaid managed care contract as well as to remove barriers that prevent States from using SDPs to implement these initiatives. Currently § 438.6(c)(2)(ii)(A) requires SDPs to be based on the utilization and delivery of services, so SDPs that require use of VBP initiatives must base payment to providers on utilization and delivery of services. Further, § 438.6(c)(2)(iii)(A) requires States to demonstrate in writing that the SDP will make participation in the VBP initiative available, using the same

[98] 81 FR 27587 and 27588.

[99] 81 FR 27588.

terms of performance, to a class of providers providing services under the contract related to the initiative. Existing regulations at § 438.6(c)(1)(i) and (ii) allow States to direct Medicaid managed care plans to implement value-based purchasing models with providers or to participate in delivery system reform or performance improvement initiatives; these types of SDPs require written prior approval from CMS. These provisions were adopted as exceptions to the overall prohibition on States directing the payment arrangements used by Medicaid managed care plans to pay for covered services. Since the 2016 rule, States have used SDPs to strengthen their ability to use their managed care programs to promote innovative and cost-effective methods of delivering care to Medicaid enrollees, to incent managed care plans to engage in State activities that promote certain performance targets, and to identify strategies for VBP initiatives to link quality outcomes to provider reimbursement. As the number of SDPs for VBP initiatives continues to grow, we have found that the existing requirements at § 438.6(c)(2)(iii) can pose unnecessary barriers to implementation of these initiatives in some cases. Revisions to § 438.6(c) would address such barriers. First, we propose to redesignate current paragraph (c)(2)(iii) as paragraph (c)(2)(vi) with a revision to remove the phrase ''demonstrate in writing,'' and we propose to redesignate current paragraph (c)(2)(iii)(A) as paragraph (c)(2)(iv)(A).

In an effort to remove provisions that are barriers to implementation of VBP initiatives, add specificity to the types of arrangements that can be approved under § 438.6(c), and to strengthen the link between SDPs that are VBP initiatives and quality of care, we are proposing the following changes to the requirements that are specific to SDPs that involve VBP initiatives:

(1) Remove the existing requirements at § 438.6(c)(2)(iii)(C) that currently prohibit States from setting the amount or frequency of the plan's expenditures.

(2) Remove the existing requirements at § 438.6(c)(2)(iii)(D) that currently prohibit States from recouping unspent funds allocated for these SDPs.

(3) Redesignate § 438.6(c)(2)(iii)(B) with revisions and clarifications to § 438.6(c)(2)(vi)(B). The provision addresses how performance in these types of arrangements is measured for participating providers.

(4) Adopt a new § 438.6(c)(2)(vi)(C) to establish requirements for use of population-based and condition-based payments in these types of SDP arrangements. As discussed in section I.B.2.f of this proposed rule, we are proposing to adopt requirements for provider payment rates used in SDP arrangements through revisions to § 438.6(c)(2)(iii).

Currently, § 438.6(c)(2)(iii)(C) prohibits States from setting the amount or frequency of expenditures in SDPs that are VBP initiatives. In the 2015 proposed rule,[100] we reasoned that while capitation rates to the managed care plans would reflect an amount for incentive payments to providers for meeting performance targets, the plans should retain control over the amount and frequency of payments. We believed that this approach balanced the need to have a health plan participate in a multi-payer or community-wide initiative, while giving the health plan a measure of control to participate as an equal collaborator with other payers and participants. However, VBP initiatives often include, by design, specific payment amounts at specific times. As States began to design and implement VBP initiatives, sometimes across delivery systems or focused on broad population health goals, many found that allowing plans to retain such discretion undermined the State's ability to implement meaningful initiatives with clear, consistent operational parameters necessary to drive provider performance improvement and achieve the goals of the State's program. Also, because some VBP initiatives provide funding to providers on a bases other than ''per claim,'' these payment arrangements need to be designed and administered in a way that encourages providers to commit to meeting performance goals while trusting that they will receive the promised funding if they meet the performance targets. This is especially true for multi-delivery system arrangements or arrangements that do not make payments for long periods of time, such as annually. Inconsistencies in administration or payment can undermine providers' confidence in the arrangement. For example, States often direct their Medicaid managed care plans to distribute earned performance improvement payments to providers on a quarterly basis. Because these types of payment arrangements affect provider revenue differently than the usual per claim payment methodology, establishing strong parameters and operational details that define when and how providers will receive payment is critical for robust provider participation. While allowing States the flexibility to include the amount and frequency of payments when designing VBP and delivery system reform initiatives removes discretion from managed care plans, we believe this flexibility is necessary to ensure that States can achieve their quality goals and get value for the dollars and effort that they invest in these arrangements. Creating obstacles for States trying to implement VBP initiatives was not our intent in the 2016 final rule. Our goal then and now is to incent States to implement innovative initiatives that reward quality of care and improved health outcomes over volume of services. To accomplish this, we need to refine our regulations; we propose to remove the existing text at § 438.6(c)(2)(iii)(C) that prohibits States from setting the amount and frequency of payment. We believe this would enable States to design more effective VBP initiatives using more robust quality measures to help ensure provider uptake, boost providers' confidence in the efficiency and effectiveness of the arrangement, and enable States to use VBP initiatives to achieve critical program goals.

Currently, § 438.6(c)(2)(iii)(D) prohibits States from recouping any unspent funds allocated for SDP arrangements from managed care plans when the SDP arrangement is for VBP, delivery system reform, or performance improvement initiatives. In the 2015 proposed rule, we explained that because funds associated with delivery system reform or performance initiatives are part of the capitation payment, any unspent funds would remain with the MCO, PIHP, or PAHP. We believed this was important to ensure that the SDPs made to providers were associated with a value relative to innovation and Statewide reform goals and not simply an avenue for States to provide funding increases to specific providers. However, allowing managed care plans to retain unspent funds when providers fail to achieve performance targets can create perverse incentives for States and managed care plans. States have described to us that they are often not incentivized to establish VBP arrangements with ambitious performance or quality targets if those arrangements result in managed care plans profiting from weak provider performance. Although States attempt to balance setting performance targets high enough to improve care quality and health outcomes but not so high that providers are discouraged from participating or so low that they do not result in improved quality or outcomes,

[100] *https://www.federalregister.gov/documents/2015/06/01/2015-12965/medicaid-and-childrens-health-insurance-program-chip-programs-medicaid-managed-care-chip-delivered.*

many States struggle due to of lack experience and robust data. And unfortunately, failed attempts to implement VBP arrangements discourage States, plans, and providers from trying to use the arrangements again. It was never our intent to discourage States from adopting innovative VBP initiatives, so we seek to address the unintended consequence created in the 2016 final rule by proposing to remove the regulation text at § 438.6(c)(2)(iii)(D) that prohibits States from recouping unspent funds from the plans. We believe that removing this prohibition could enable States to reinvest these unspent funds to further promote VBP and delivery system innovation.

To expand the types of VBP initiatives that would be allowed under § 438.6(c)(1)(i) and (ii) and ensure a focus on value over volume, we are also proposing additional revisions in § 438.6(c)(2)(vi) to distinguish between performance-based payments and the use of proposed population-based or condition-based payments to providers.

The existing regulations at § 438.6(c)(1)(i) and (ii) were intended both to incent State activities that promote certain performance targets as well as to facilitate and support delivery system reform initiatives within the managed care environment to improve health care outcomes. We recognize that certain types of multi-payer or Medicaid-specific initiatives, such as patient-centered medical homes (PCMH), broad-based provider health information exchange projects, and delivery system reform projects to improve access to services, among others, may not lend themselves to being conditioned upon provider performance during the rating period.[101] Instead, these arrangements are conditioned upon other factors, such as the volume and characteristics of a provider's attributed population of patients or upon meeting a total cost of care (TCOC) benchmark, for example, through the provision of intense case management resulting in a reduction of chronic disease. Due to the diversity of VBP initiatives, we believe that the existing language at § 438.6(c)(2)(iii)(B), which requires that all SDPs that direct plan expenditures under § 438.6(c)(1)(i) and (ii) must use a common set of performance measures across all of the payers and providers, cannot be broadly applied to arrangements or initiatives under § 438.6(c)(1)(i) and (ii) that do not measure specific provider performance measures.

We believe the best way to address the limitations in current regulation text is to specify different requirements for VBP initiatives that condition payment upon performance from ones that are population or condition-based. Therefore, we propose to use new § 438.6(c)(2)(vi)(B) for requirements for SDPs that condition payment on performance. We are also proposing to adopt additional requirements in addition to redesignating the provision currently at § 438.6(c)(2)(iii)(B) to newly proposed § 438.6(c)(2)(vi)(B)(*2*). Additionally, we are proposing new requirements at new (c)(2)(vi)(B)(1) and (3) through (5) that are clarifications or extensions of the current requirement that SDPs use a common set of performance metrics.

We further propose to add new § 438.6(c)(2)(vi)(C) to describe the requirements for SDPs that are population-based payments and condition-based payments.

Performance-Based Payments. Under current § 438.6(c)(2)(ii)(A), SDPs that direct the MCO's, PIHP's, or PAHP's expenditures under paragraphs (c)(1)(i) and (ii) must be based on the utilization and delivery of services. Therefore, we have required that SDPs that are VBP initiatives be based on performance tied to the delivery of covered services to Medicaid beneficiaries covered under the Medicaid managed care contract for the rating period. This means that we have not allowed these types of SDPs to be based on ''pay-for-reporting'' because the act of reporting, alone, is an administrative activity and not a covered service. Instead, when States seek to design SDPs that pay providers for administrative activities rather than provider performance, we have encouraged States to use provider reporting or participation in learning collaboratives as a condition of provider eligibility for the SDPs and then tie payment under the SDP to utilization under § 438.6(c)(1)(iii). At § 438.6(c)(2)(vi)(B)(*1*), we propose to codify our interpretation of this policy by requiring that payments to providers under SDPs that are based on performance not be conditioned upon administrative activities, such as the reporting of data, nor upon the participation in learning collaboratives or similar administrative activities. The proposed regulation explicitly states our policy so that States have a clear understanding of how to design their SDPs appropriately. We recognize and understand the importance of establishing provider reporting requirements, learning collaboratives, and similar activities to help further States' goals for performance and quality improvement and want to support these activities; however, while these activities can be used as eligibility criteria for the provider class receiving payments, they cannot be the basis for receiving payment from the Medicaid managed care plan under an SDP described in § 438.6(c)(1)(i) or (ii) that is based on performance.

Currently, our policy is that the performance measurement period for SDPs that condition payment based upon performance must overlap with the rating period in which the payment for the SDP is made. However, we have found that States frequently experience delays in obtaining performance-based data due to claims run out time and the time needed for data analyses and validation of the data and the results. All of this can make it difficult, if not impossible, to comply with this requirement. Therefore, we propose to permit States to use a performance measurement period that precedes the start of the rating period in which payment is delivered by up to 12 months. Under this aspect of our proposal, States would be able to condition payment on performance measure data from time periods up to 12 months prior to the start of the rating period in which the SDP is paid to providers. We believe that this flexibility would allow States adequate time to collect and analyze performance data for use in the payment arrangement and may incentivize States to adopt more VBP initiatives. We solicit comment on whether 12 months is an appropriate time period to allow for claims runout and data analysis, or if the time period that the performance period may precede the rating period should be limited to 6 months or extended to 18 or 24 months, or if the performance period should remain consistent with the rating period. We also propose that the performance measurement period must not exceed the length of the rating period. We believe this would make it clear to States that although we propose to extend the length of time between provider performance and payment for administrative simplicity, we are not extending the performance measurement time. Finally, we are also proposing that all payments would need to be documented in the rate certification for the rating period in which the payment is delivered. We also believe identifying which rating period the payments should be reflected in is important since up to 2 rating periods may be involved between

[101] *http://hcp-lan.org/workproducts/apm-framework-onepager.pdf.*

performance and payment, and we want States to document these payments consistently. Specifically, we propose, at § 438.6(c)(2)(vi)(B)(*3*), that a payment arrangement that is based on performance must define and use a performance period that must not exceed the length of the rating period and must not precede the start of the rating period in which the payment is delivered by more than 12 months, and all payments must be documented in the rate certification for the rating period in which the payment is delivered.

In a December 2020 report,[102] the OIG found that a quality improvement incentive SDP implemented in one State resulted in incentive payments paid to providers whose performance declined during the measurement period. Other interested parties, such as MACPAC, have noted concerns with performance improvement SDPs that continue even when there has been a decline in quality or access. In alignment with our proposed evaluation policies at § 438.6(c)(2)(iv) (see section I.B.2.j. of this proposed rule) that seek to better monitor the impact of SDPs on quality and access to care, and in an effort to establish guardrails against payment for declining performance in VBP SDPs, we propose to add § 438.6(c)(2)(vi)(B)(*4*) and (*5*). Measurable performance targets that demonstrate performance relative to a baseline allow States (and CMS) to assess whether or not a provider's performance has improved. Therefore, at § 438.6(c)(2)(vi)(B)(*4*), we propose to require that all SDPs that condition payment on performance include a baseline statistic for all metrics that are used to measure the performance that is the basis for payment from the plan to the provider; these are the metrics (including, per proposed paragraph (c)(2)(iv)(A)(*2*), at least one performance measure, as that term is proposed to be defined in § 438.6(a)) that are specified by the States in order to comply with proposed § 438.6(c)(2)(vi)(B)(*2*). At § 438.6(c)(2)(vi)(B)(*5*), we propose to require that all SDPs that condition payment on performance use measurable performance targets, which are attributable to the performance by the providers in delivering services to enrollees in each of the State's managed care program(s) to which the payment arrangement applies, that demonstrate improvement over baseline data on all metrics selected in § 438.6(c)(2)(vi)(B)(*2*). We believe that these proposals would be consistent with how quality improvement is usually measured as well as be responsive to oversight bodies and help promote economy and efficiency in Medicaid managed care.

Population-Based Payments and Condition-Based Payments. As discussed previously in this preamble section, States often adopt VBP initiatives that are intended to further goals of improved population health and better care at lower cost. We support these efforts and encourage the use of methodologies or approaches to provider reimbursement that prioritize achieving improved health outcomes over volume of services. Therefore, we propose to add new § 438.6(c)(2)(vi)(C) to establish regulatory pathways for approval of VBP initiatives that may not be conditioned upon specific measures of performance.

We propose to define a ''population-based payment'' at § 438.6(a) as a prospective payment for a defined Medicaid service(s) for a population of Medicaid managed care enrollees covered under the contract attributed to a specific provider or provider group. We propose to define a ''condition-based payment'' as a prospective payment for a defined set of Medicaid service(s), that are tied to a specific condition and delivered to Medicaid managed care enrollees. One example of a population-based payment would be an SDP that is a primary care medical home (PCMH) and directs managed care plans to pay prospective per member per month (PMPM) payments for care management to primary care providers, where care management is the service being delivered under the contract and covered by the PMPM. An attributed population could also be condition-based. For example, States could direct managed care plans to pay a provider or provider group a PMPM for Medicaid enrollees with a specific condition when the enrollee is attributed to the provider or provider group for treatment for that condition.

At § 438.6(c)(2)(vi)(C)(*1*), we propose to require that population-based and condition-based payments be conditioned upon either the delivery by the provider of one or more specified Medicaid covered service(s) during the rating period or the attribution to the provider of a covered enrollee for the rating period for treatment. This proposed requirement aligns with the requirement, currently at § 438.6(c)(2)(ii)(A), that SDP arrangements base payments to providers on utilization and delivery of services under the Medicaid managed care contract. States, consistent with 1903(m)(2)(A)(xi), § 438.242(d), and 438.818, must collect, maintain, and submit to T–MSIS encounter data showing that covered service(s) have been delivered to the enrollees attributed to a provider that receives the population-based payment. Further, if the payment is conditioned upon the attribution of a covered enrollee to a provider, we propose § 438.6(c)(2)(vi)(C)(2) to require that the attribution methodology uses data that are no older than the 3 most recent and complete years of data; seeks to preserve existing provider-enrollee relationships; accounts for enrollee preference in choice of provider; and describes when patient panels are attributed, how frequently they are updated, and how those updates are communicated to providers.

We have seen States submit proposals for VBP initiatives that include prospective PMPM population-based payments with no direct tie to value or quality of care and paid in addition to the contractually negotiated rate. Because population-based payments should promote higher quality and coordination of care to result in improved health outcomes, we believe it is imperative that these type of PMPM payments are used to ensure that enrollees are receiving higher quality and coordinated services to increase the likelihood of enrollees experiencing better outcomes. Therefore, we propose to add § 438.6(c)(2)(vi)(C)(*3*) to require that population-based payments and condition-based payments replace the negotiated rate between a plan and providers for the Medicaid covered service(s) being delivered as a part of the SDP to prevent any duplicate payment(s) for the same service. Also, at § 438.6(c)(2)(vi)(C)(*2*), we propose to add a requirement that prevents payments from being made in addition to any other payments made by plans to the same provider on behalf of the same enrollee for the same services included in the population- or condition-based payment. We believe that the requirements in paragraph (c)(2)(vi)(C)(*2*) would prevent States from implementing SDPs under § 438.6(c)(2)(vi)(C) that are PMPM add-on payments made in addition to negotiated rates with no further tie to quality or value.

We recognize the importance of providing a regulatory pathway for States to implement SDPs that are VBP initiatives designed to promote higher quality care in more effective and efficient ways at a lower cost. Because quality of care and provider

[102] U.S. Department of Health and Human Services Office of the Inspector General, ''Aspects of Texas' Quality Incentive Payment Program Raise Questions About Its Ability To Promote Economy and Efficiency in the Medicaid Program,'' A–06–18–07001, December 21, 2020, available at *https://oig.hhs.gov/oas/reports/region6/61807001.asp.*

performance are integral and inherent to all types of VBP initiatives, we believe that SDPs under proposed § 438.6(c)(2)(vi)(C) that are designed to include population-based or condition-based payments must also include in their design and evaluation at least one performance measure and set the target for such a measure to demonstrate improvement over baseline at the provider class level for the provider class receiving the payment. As such, we propose new § 438.6(c)(2)(vi)(C)(*4*) to require that States include at least one performance measure that measures performance at the provider class level as a part of the evaluation plan outlined in proposed § 438.6(c)(2)(iv). We are also proposing that States would be required to set the target for such a performance measure to demonstrate improvement over baseline. We believe that this balances the need to provide States the flexibility to design VBP initiatives to meet their population health and other value-based care goals, while providing accountability by monitoring the effect of the initiatives on the performance of the provider class and the subsequent health outcomes of the enrollees.

Approval Period. In the 2020 Medicaid managed care rule, we finalized a revision to § 438.6(c)(2)(i) allowing that SDPs are VBP initiatives as defined in § 438.6(c)(1)(i) and (ii) meet additional criteria described in § 438.6(c)(3)(i)(A) through (C) would be eligible for multi-year approval if requested. Because of the tie to the managed care quality strategy, which in § 438.340 is required to be updated at least once every 3 years, CMS has never granted written prior approval of an SDP for more than 3 years. We are proposing to modify § 438.6(c)(3)(i) to add that a multi-year written prior approval may be for of up to three rating periods to codify our existing policy. Requiring States to renew multi-year SDPs every 3 years will allow us to monitor changes and ensure that SDPs remains aligned with States' most current managed care quality strategy. We are also proposing minor revisions in paragraphs (c)(3)(i)(A) through (C) to use the term ''State directed payment'' as appropriate and to revise paragraph (c)(3)(ii) to specify it is about written prior approvals. Finally, we are proposing to redesignate paragraph (c)(2)(F) to new paragraph (c)(3)(iii) to explicitly provide that State directed payments are not automatically renewed.

For discussion on the proposed applicability dates for the proposals outlined in this section, see section I.B.2.p. of this proposed rule.

We solicit public comments on these proposals.

j. Quality and Evaluation (§ 438.6(c)(2)(ii)(D) and (F), (c)(2)(iv) and (v), and (c)(7))

We are proposing several changes to the SDP regulations in § 438.6(c) to support more robust quality improvement and evaluation. Existing regulations at § 438.6(c)(2)(ii)(C) and (D) specify that to receive written prior approval, States must demonstrate in writing, amongst other requirements, that the State expects the SDP to advance at least one of the goals and objectives in the State's managed care quality strategy and has an evaluation plan that measures the degree to which the SDP advances the identified goals and objectives. We issued guidance in November 2017 [103] that provided further guidance on what evaluation plans should generally include: the identification of performance criteria which can be used to assess progress on the specified goal(s) and objective(s); baseline data for performance measure(s); and improvement targets for performance measure(s).

In order to monitor the extent to which an SDP advances the identified goals and objectives in a State's managed care quality strategy, we request that States submit their SDP evaluation results from prior rating periods to aid our review of preprint submissions that are renewals of an existing SDP. If an SDP proposal meets regulatory requirements but the State is unable to provide the requested evaluation results, we will usually approve a renewal of the SDP with a ''condition of concurrence'' that the State submit evaluation results with the following year's preprint submission for renewal of the SDP for the following rating period. For example, one common condition of concurrence for year two preprints is the provision of SDP evaluation results data for year one of the SDP with the year three preprint submission.

In 2021, CMS conducted an internal analysis to assess the effectiveness of SDP evaluation plans in measuring progress toward States' managed care quality strategy goals and objectives and whether SDP evaluation findings provided us with sufficient information to analyze whether an SDP facilitated quality improvement. We analyzed data from 228 renewal preprints submitted by 33 States between April 2018 and February 2021. Over half (63 percent) of the evaluation plans submitted were incomplete, and only 43 percent of the renewal preprints included any evaluation results. Our analysis also found only a 35 percent compliance rate with conditions of concurrence requesting States submit SDP evaluation results with the preprint for the following rating period. Our policy goals in this area are frustrated by the lack of a regulation requiring submission of these evaluation results. By adopting requirements for submission of evaluation plans and reports, we intend to increase compliance and improve our oversight in this area.

As the volume of SDP preprint submissions and total dollars flowing through SDPs continues to increase, we recognize the importance of ensuring that SDPs are contributing to Medicaid quality goals and objectives, and recognize that meaningful evaluation results are critical for ensuring that these payments further improvements in quality of care. Moreover, consistent submission of evaluation results is important for transparency and for responsiveness to oversight bodies. Consistent with our internal findings, other entities, including MACPAC [104] and GAO,[105] have noted concerns about the level of detail and quality of SDP evaluations. In MACPAC's June 2022 Report to Congress, the Commission noted concern about the lack of availability of information on evaluation results for SDPs, even when the arrangements had been renewed multiple times. The report also noted that examples of when evaluation results showed a decline in quality or access but the SDPs were renewed without changes. MACPAC recommended in its report that CMS require more rigorous evaluation requirements for SDPs, particularly for arrangements that substantially increase provider payments above Medicaid FFS reimbursement. The report also suggests that CMS provide written guidance on the types of measures that States should use to evaluate progress towards meeting quality and access goals and noted that we should clarify the extent to which evaluation results are used to inform approval and renewal decisions.

We are proposing a number of regulatory changes to enhance CMS's

[103] *https://www.medicaid.gov/federal-policy-guidance/downloads/cib11022017.pdf.*

[104] Medicaid and CHIP Payment and Access Commission, ''Oversight of Managed Care Directed Payments,'' June 2022, available at *https://www.macpac.gov/wp-content/uploads/2022/06/Chapter-2-Oversight-of-Managed-Care-Directed-Payments-1.pdf.*

[105] U.S. Government Accountability Office, ''Medicaid: State Directed Payments in Managed Care,'' June 28, 2022, available at *https://www.gao.gov/assets/gao-22-105731.pdf.*

ability to collect evaluations of SDPs and enhance the level of detail described in the evaluation. CMS' intent is to shine a spotlight on SDP evaluations and use evaluation results in determining future approvals of State directed payments. CMS also plans to issue additional technical assistance on this subject as well to assist States in the development of evaluation plans in alignment with the proposed regulatory requirements and preparing the subsequent evaluation reports.

In an effort to strengthen reporting and to better monitor the impact of SDPs on quality and access to care, we propose at § 438.6(c)(2)(iv) that the State must submit an evaluation plan for each SDP that requires written prior approval that includes four specific elements. We specify that our proposal is to establish minimum content requirements for SDP evaluation plans but is not intended to limit States in evaluating their SDP arrangements. Currently, § 438.6(c)(2)(ii)(D) requires that States develop an evaluation plan that measures the degree to which the arrangement advances at least one of the goals and objectives in the State's managed care quality strategy (which is required by § 438.340).

We propose at § 438.6(c)(2)(iv)(A) that the evaluation plan must identify at least two metrics that would be used to measure the effectiveness of the payment arrangement in advancing the identified goal(s) and objective(s) from the State's managed care quality strategy on an annual basis. In addition, proposed paragraph (c)(2)(vi)(C)(*4*) further specifies that at least one of those metrics must measure performance at the provider class level for SDPs that are population- or condition-based payments. Under § 438.6(c)(2)(iv)(A)(*1*), we propose that the metrics must be specific to the SDP and attributable to the performance by the providers for enrollees in all of the State's managed care program(s) to which the SDP applies, when practicable and relevant. We propose the standard ''when practicable and relevant'' to allow flexibility to account for situations in which contract or program level specificity may be either impossible to obtain or may be ineffective in measuring the identified quality goal(s) and objective(s). For example, States may implement a quality improvement initiative in both the Medicaid FFS program and Medicaid managed care program(s), but measuring the impact of that initiative on each program separately would not produce valid results due to the small sample sizes. Proposing this flexibility would allow States to produce an evaluation inclusive of both Medicaid managed care and FFS data and comprised of measures relevant to the approved SDP to demonstrate the effect the SDP arrangement is having on advancing the State's overall quality goals.

We propose at § 438.6(c)(2)(iv)(A)(*2*) to require that at least one of the selected metrics must be a performance measure, for which we propose a definition in § 438.6(a) as described in section I.B.2.i. of this proposed rule. We currently allow, and would continue to allow, States to select a metric with a goal of maintaining access to care when that is the goal of the SDP. While access metrics provide valuable information, they do not measure service delivery, quality of care, or outcomes, and they do not provide insight into the impact that these payment arrangements have on the quality of care delivered to Medicaid enrollees. Therefore, if a State elects to choose a metric that measures maintenance of access, our proposal would require States to choose at least one additional performance metric. Because we recognize that performance is a broad term and that the approach to evaluating quality in healthcare is evolving, and because we understand the importance of preserving States' flexibility to identify performance measure(s) that are most appropriate for evaluating the specific SDP, we are not proposing additional requirements for the other minimum metric so as not to preclude innovation. However, we would strongly recommend that States use existing measure sets which are in wide use across Medicaid and CHIP, including the Medicaid and CHIP Child and Adult Core Sets [106] and the Home and Community-Based Services Quality Measure Set,[107] to facilitate alignment and reduce administrative burden. In some cases, these existing measures may not be the most appropriate choice for States' Medicaid managed care goals; therefore, we will issue subregulatory guidance to provide best practices and recommendations for choosing appropriate performance measures when not using existing measure sets.

Concerns around access to primary care, maternal health, and behavioral health have been raised nationally. The current administration considers increasing access to care for these services to be a national priority. We encourage States to implement SDPs for these services and providers to improve access. We also encourage States to include measures that focus on primary care and behavioral health in their evaluation plans when relevant. This could include using existing measures from the Medicaid and CHIP Child and Adult Core Sets [108] or other standardized measure sets. CMS also expects that States consider examining parity in rates for primary care and behavioral health compared to other services, such as inpatient and outpatient hospital services, as part of their evaluation of SDPs.

It is crucial to monitor and evaluate the impact of SDP implementation, and as such we propose at § 438.6(c)(2)(iv)(B) to require States to include baseline performance statistics for all metrics that would be used in the evaluation since this data must be established in order to monitor changes in performance during the SDP performance period. We believe this proposal is particularly necessary since we found in our internal study that, among the SDP evaluation plan elements, a baseline statistic(s) was the most commonly missing element. We propose the requirements at § 438.6(c)(2)(iv)(B) in an effort to ensure that States' evaluation plans produce reliable results throughout the entirety of the SDP's implementation.

Measurable SDP evaluation performance targets that demonstrate performance relative to the baseline measurement allow States to determine whether the payment arrangement is having the intended effect and helping a State make progress toward its quality goals. Our internal analysis showed that nearly 20 percent of performance measures selected by States were not specific or measurable. Therefore, at § 438.6(c)(2)(iv)(C), we also propose to require that States include measurable performance targets relative to the baseline statistic for each of the selected measures in their evaluation plan.

Overall, we believe that the proposed regulations at § 438.6(c)(2)(iv) would ensure that States collect and use stronger data for developing and evaluating payment arrangements to meet the goals of their Medicaid programs and would also be responsive to recommendations for more clarity for SDP evaluation plans. However, we

[106] Medicaid and CHIP Child Core Set (*https://www.medicaid.gov/medicaid/quality-of-care/performance-measurement/child-core-set/index.html*), the Medicaid Adult Core Set (*https://www.medicaid.gov/medicaid/quality-of-care/performance-measurement/adult-core-set/index.html*).

[107] *https://www.medicaid.gov/federal-policy-guidance/downloads/smd22003.pdf.*

[108] Medicaid and CHIP Child Core Set (*https://www.medicaid.gov/medicaid/quality-of-care/performance-measurement/child-core-set/index.html*), the Medicaid Adult Core Set (*https://www.medicaid.gov/medicaid/quality-of-care/performance-measurement/adult-core-set/index.html*).

recognize and share the concerns raised by oversight bodies regarding the limited availability of SDP evaluation results for use in internal and external monitoring of the effect of SDPs on quality of care. While we ask States for evaluation results as part of the review process for SDP renewals, current regulations do not explicitly require submission of completed evaluation reports and results or use by CMS of prior evaluation reports and results in reviewing current SDPs for renewal or new SDPs. As a result, because most States do not comply with our request for evaluation data, we are proposing to revise § 438.6(c)(2) to ensure that SDPs further the goals and objectives identified in the State's managed care quality strategy. We propose at § 438.6(c)(2)(iv)(D) that States must provide commitment to submit an evaluation report in accordance with proposed § 438.6(c)(2)(v), which is discussed in the next paragraph of this section, if the final State directed payment cost percentage exceeds 1.5 percent.

Finally, we are proposing to amend § 438.6(c)(2)(ii)(D) to further require the evaluation plan include all the elements outlined in paragraph (c)(2)(iv). These proposed changes in § 438.6(c)(2)(ii)(D) and the new proposed requirements in § 438.6(c)(2)(iv) would further identify the necessary components of a State's evaluation plans for SDPs and make clear that we have the authority to disapprove proposed SDPs if States fail to provide in writing evaluation plans for their SDPs that comply with these regulatory requirements.

Section 1902(a)(6) of the Act requires that States provide reports, in such form and containing such information, as the Secretary may from time to time require. Our proposal to add new § 438.6(c)(2)(v) to require that States submit to CMS, for specified types of SDPs that have a final State directed payment cost percentage that exceeds 1.5 percent, an evaluation report using the evaluation plan the State outlined under proposed § 438.6(c)(2)(iv). As proposed in § 438.6(c)(2)(v), the proposed evaluation reporting requirement is limited to States with SDPs that require prior approval. We recognize that submitting an evaluation report would impose some additional burden on States, so we propose this risk-based approach to identify when an evaluation report must be submitted to CMS based on the actual total amount that is paid as a separate payment term described in § 438.6(c)(6) or portion of the actual total portion of capitation payments attributable to the SDP, as a percentage of the State's total Medicaid managed care program costs for each managed care program. This approach would allow States and CMS to focus resources on payment arrangements with the highest financial risk. We have selected the 1.5 percent as it aligns with existing Medicaid managed care policy for when rate amendments are necessary (often referred to as a *de minimis* threshold or *de minimis* changes) and with proposed policies for in lieu of services (see section I.B.3. of this proposed rule).

We propose to define ''final State directed payment cost percentage'' in § 438.6(a) as the annual amount calculated, in accordance with paragraph (c)(7)(iii) of this section, for each State directed payment and each managed care program. In § 438.6(c)(7)(iii)(A), we propose for SDPs requiring prior approval that the final SDP cost percentage numerator be calculated as the portion of the total capitation payments that is attributable to the State directed payment and, actual total amount that is paid as a separate payment term described in § 438.6(c)(6), for each managed care program. In § 438.6(c)(7)(iii)(B), we propose the final SDP cost percentage denominator be calculated as the actual total capitation payments, defined at § 438.2, for each managed care program, including all State directed payments in effect under § 438.6(c) and pass-through payments in effect under § 438.6(d), and the actual total amount of State directed payments that are paid as a separate payment term as described in paragraph (c)(6). To calculate the numerator for a minimum or maximum fee schedule type of SDP that is incorporated into capitation rates as an adjustment to base capitation rates, an actuary should calculate the absolute change that the SDP has on base capitation rates. Over time, as the SDP is reflected in the base data and incorporated into base capitation rates, it is possible that the absolute effect may decrease or no longer be apparent, and the numerator may decrease to zero. We solicit comment on whether the numerator for a minimum or maximum fee schedule SDP that is incorporated into capitation rates as an adjustment to base capitation rates should be calculated in a different manner (for example, estimating a portion of the capitation rates resulting from the SDP). We do not believe that it is necessary to propose regulation text to codify this approach as we intend to issue additional guidance in the Medicaid Managed Care Rate Development Guide in accordance with § 438.7(e). We also solicit comment on whether we should codify this in regulation text. We believe this proposed numerator and denominator would provide an accurate measurement of the final expenditures associated with a SDP and total program costs in each managed care program in a risk-based contract.

We believe the final SDP cost percentage should be measured distinctly for each managed care program and SDP, as reflected in the definition proposed for this term. This is appropriate because capitation rates are typically developed by program, SDPs may vary by program, and each managed care program may include differing populations, benefits, geographic areas, delivery models, or managed care plan types. For example, one State may have a behavioral health program that covers care to most Medicaid beneficiaries through PIHPs, a physical health program that covers physical health care to children and pregnant women through MCOs, and a program that covers physical health and MLTSS to adults with a disability through MCOs. Another State may have several different managed care programs that serve similar populations and provide similar benefits through MCOs, but the delivery model and geographic areas served by the managed care programs vary. We addressed managed care program variability within the 2016 final rule when we noted that ''This clarification in the regulatory text to reference ''managed care program'' in the regulatory text is to recognize that States may have more than one Medicaid managed care program—for example physical health and behavioral health . . .'' (81 FR 27571). Therefore, we believe it would be contrary to our intent if States were to develop a final SDP cost percentage by aggregating data from more than one managed care program since that would be inconsistent with rate development, the unique elements of separate managed care programs, and the SDPs that vary by managed care program. We note here that we intend to use this application of managed care program in other parts of this section of this proposed rule, including, but not limited to, the discussion of calculating the total payment rate in section I.B.2.f. of this proposed rule, measurement of performance for certain VBP arrangements discussed in section I.B.2.i. of this proposed rule and separate payment terms in section I.B.2.i. of this proposed rule.

With § 438.6(c)(7)(i), we propose that the final State directed payment cost percentage be calculated on an annual basis and recalculated annually to ensure consistent application across all States and managed care programs. To

ensure that final State directed payment cost percentage would be developed in a consistent manner with how the State directed payment costs would be included in rate development, we propose at § 438.6(c)(7)(ii) to require that the final SDP cost percentage would have to be certified by an actuary and developed in a reasonable and appropriate manner consistent with generally accepted actuarial principles and practices. An ''actuary'' is defined in § 438.2 as an individual who meets the qualification standards established by the American Academy of Actuaries for an actuary and follows the practice standards established by the Actuarial Standards Board, and who is acting on behalf of the State to develop and certify capitation rates.

Although all States would be required to develop and document evaluation plans in compliance with the provisions proposed in § 438.6(c)(2)(iv), the proposed regulation at § 438.6(c)(2)(v) requires submission of the evaluation report for an SDP based on whether the SDP results in a final SDP cost percentage greater than 1.5 percent. In recognition that the final SDP cost percentage report represents additional State burden and that many States may choose to evaluate their SDPs regardless of the final SDP cost percentage, we propose § 438.6(c)(7) which requires States to submit the final SDP cost percentage report, only if a State wishes to demonstrate that it is below 1.5 percent. With this proposed reporting requirement, States would be required to provide the final SDP cost percentage report to demonstrate that an SDP is exempt from the proposed evaluation report requirement. For SDP arrangements that do not exceed the threshold, States would not be required to submit evaluation results under proposed new paragraph § 438.6(c)(2)(v), but we would encourage States to monitor the evaluation results of all of their SDPs. We recognize that in order to monitor the 1.5 percent threshold, we would need a reporting mechanism by which States would be required to calculate and provide the final SDP cost percentage to CMS. Therefore, we propose a requirement (at new § 438.6(c)(7)(iv)) that the State submit the final State directed payment cost percentage annually to CMS for review, when the final State directed payment cost percentage does not exceed 1.5 percent and the State has not voluntarily submitted the evaluation report, as a separate report concurrent with the rate certification submission required in § 438.7(a) no later than 2 years after the completion of each 12-month rating period that included a State directed payment. We believe that it is appropriate for States' actuaries to develop a separate report to document that the final State directed payment cost percentage does not exceed 1.5 percent, rather than including it in a rate certification, because the final State directed payment cost percentage may require alternate data compared to the base data that were used for prospective rate development, given the timing of base data requirements as outlined in § 438.5(c)(2). We note that this proposal is similar to the concurrent submission for the proposed MLR reporting at § 438.74 and proposed ILOS projected and final cost percentage reporting at § 438.16(c). We considered proposing that States submit the final SDP report to CMS upon completion of the report, separately and apart from the rate certification. However, we believe there should be consistency across States for when this report is submitted to CMS for review, and we believe receiving this report and the rate certification at the same time would enable CMS to review them concurrently.

As the proposed denominator for the final SDP cost percentage would be based on the actual total capitation payments and the actual total State directed payments paid as a separate payment term (see section I.B.2.l. of this proposed rule for details on this proposal for separate payment terms) paid by States to managed care plans, we recognize that calculating the final SDP cost percentage would take States and actuaries some time. For example, changes to the eligibility file and revised rate certifications for rate amendments may impact the final capitation payments that are a component of the calculation. Given these factors, we believe that 2 years is an adequate amount of time to accurately perform the calculation. Under this proposal, for example, the final SDP cost percentage report for a managed care program that uses a calendar year 2024 rating period would be submitted to CMS with the calendar year 2027 rate certification.

For the evaluation reports, we propose to adopt three requirements in § 438.6 (c)(2)(v)(A). First, in § 438.6(c)(2)(v)(A)(*1*), we propose that evaluation reports must include all of the elements approved in the evaluation plan required in § 438.6(c)(2)(iv). In § 438.6(c)(2)(v)(A)(*2*), we propose to require that States include the 3 most recent and complete years of annual results for each metric as required in § 438.6(c)(2)(iv)(A). Lastly, at § 438.6(c)(2)(v)(A)(*3*), in acknowledgement of MACPAC's recommendation to enhance transparency of the use and effectiveness of SDP arrangements, we propose to require that States publish their evaluation reports on their public facing website as required under § 438.10(c)(3).

States consistently have difficulty providing evaluation results in the first few years after implementation of an SDP due to the time required for complete data collection. Our internal analysis found that States' ability to provide evaluation results improved over time. Although only 21 percent of proposals included evaluation results in year two, 55 percent of proposals included results data in year three, and 66 percent of year 4 proposals included the results of the evaluation. For this reason, we considered but ultimately did not propose that States submit an annual evaluation. Therefore, we propose at § 438.6(c)(2)(v)(B) to require States to submit the first evaluation report no later than 2 years after the conclusion of the 3-year evaluation period and that subsequent evaluation reports would have to be submitted to CMS every 3 years after.

In § 438.6(c)(2)(v)(A)(*2*), we propose to require that evaluation reports include the 3 most recent and complete years of annual results for each metric as approved under the evaluation plan approved as part of the preprint review. Therefore, the first evaluation report would be due no later than with the submission of the preprint for the sixth rating period after the applicability date for the evaluation plan; this evaluation plan would contain results from the first 3 years after the applicability date for the evaluation plan. We believe that this approach to implementation would allow adequate time for States to obtain final and validated encounter data and performance measurement data to compile and publish the first evaluation report. We also considered a 5 and 10-year period evaluation period, but we concluded that seemed to be an unreasonably long time to obtain actionable evaluation results. We concluded that a 3-year period would provide sufficient time to collect complete data and demonstrate evaluation trends over a period of time.

After submission of the initial evaluation report, States would be required to submit subsequent evaluation reports every 3 years. This means that States would submit the second evaluation report with the SDP preprint submission for the first rating period beginning 9 years after the applicability date for the evaluation plan; this evaluation report would contain results from years four through six after the applicability date for the

evaluation plan . States would be required to continue submitting evaluation reports with this frequency as long as the SDP is implemented. We acknowledge that some SDPs will have been operational for multiple years when these proposed regulations take effect. We are not proposing a different implementation timeline for SDP arrangements that predate the compliance deadline for this proposal. For these mature payment arrangements, States would be required to submit an evaluation report in the fifth year after the compliance date that includes the 3 most recent and complete years of annual results for the SDP. However, because these types of long-standing payment arrangements have been collecting evaluation data since implementation, we would expect States to include the evaluation history in the report in order to provide the most accurate picture.

We recognize and share the concerns that oversight bodies have expressed regarding the extent to which CMS uses evaluation results to inform SDP written prior approval decisions. In response to these concerns and as a part of the proposed revisions to § 438.6(c)(2)(ii), which include the standards that all SDPs must meet, we are proposing a new standard at § 438.6(c)(2)(ii)(F) requiring that all SDPs must result in achievement of the stated goals and objectives in alignment with the State's evaluation plan. We believe that the proposed changes would help us to better monitor the impact of SDPs on quality and access to care and would help standardize our review of SDP proposal submissions under § 438.6(c) while allowing us to disapprove SDPs that do not meet their stated quality goals and objectives.

We are also making a concurrent proposal at § 438.358(c)(7) to include a new optional EQR activity to support evaluation requirements, which would give States the option to leverage a CMS-developed protocol or their EQRO to assist with evaluating SDPs. We believe this proposed optional activity would reduce burden associated with these new requirements and is discussed in more detail in section I.B.5.c.3 of this proposed rule. we are considering, and invite public comment on, requiring that States procure an independent evaluator for SDP evaluations in the final rule based on comments received. In consideration of the myriad of new proposed requirements within this proposed rule, we weighed the value of independent evaluation with increased State burden. We are concerned that it would be overly burdensome for States to procure independent evaluators for SDPs due, in part, to the timing of the final SDP cost percentage submission. In section I.B.2. of this proposed rule, we are proposing that the final SDP cost percentage be submitted 2 years following completion of the applicable rating period, and we propose here that if the final SDP cost percentage exceeds the 1.5 percent, States would be required to submit an evaluation. While we encourage all States to evaluate their SDPs, it could be difficult and time consuming to procure an independent evaluator in a timely manner solely for the purpose of the SDP evaluation since States would not know definitely whether an evaluation is required until 2 years following the rating period. We solicit comment on whether we should consider a requirement that States use an independent evaluator for SDP evaluations.

For discussion on the proposed applicability dates for the proposals outlined in this section, see section I.B.2.p. of this proposed rule.

We solicit public comments on our proposals and the alternatives under consideration.

k. Contract Term Requirements (§ 438.6(c)(5))

SDPs are contractual obligations in which States direct Medicaid managed care plans on how or how much to pay specified provider classes for certain Medicaid-covered services. The current heading for § 438.6(c) describes paragraph (c) as being about delivery system and provider payment initiatives under MCO, PIHP, or PAHP contracts. Further, the regulation refers to SDPs throughout as provisions in the contract between the MCO, PIHP or PAHP and the State that direct expenditures by the managed care plan (that is, payments made by the managed care plan to providers). SDPs are to be included in a State's managed care rate certification per § 438.7(b)(6) and final capitation rates for each MCO, PIHP, and PAHP must be identified in the applicable contract submitted for CMS review and approval per § 438.3(c)(1)(i). Thus, every SDP must be documented in the managed care contract and actuarial rate certification.

Previous guidance issued to States, including in the January 2022 State Guide to CMS Criteria for Medicaid Managed Care Contract Review and Approval (State Guide), indicates that contractual requirements for SDPs should be sufficiently detailed for managed care plans to operationalize each payment arrangement in alignment with the approved preprint(s).[109] The State Guide includes examples of information that States could consider including in their managed care contracts for SDPs.[110] However, despite this guidance, there is a wide variety of ways States include these requirements into their contracts, many of which lack critical details to ensure that plans implement the contractual requirement consistent with the approved SDP. For example, some States have sought to include a broad contractual requirement that their plans must comply with all SDPs approved under § 438.6(c) with no further details in the contract to describe the specific payment arrangements that the State is directing the managed care plan to implement and follow. Other States have relied on broad contract requirements stating that plans must comply with all applicable State laws as a method of requiring compliance with State legislation requiring plans to pay no less than a particular fee schedule for some services. These types of vague contractual provisions represent significant oversight risk for both States and CMS.

To reduce this risk and improve the clarity of SDPs for managed care plans, we propose to codify at § 438.6(c)(5) minimum requirements for the content of a Medicaid managed care contract that includes one or more SDP contractual requirement(s). We believe these minimum requirements for SDP contract terms would assist States when developing their contracts, ensure that managed care plans receive necessary information on the State's intent and direction for the SDP, facilitate CMS' review of managed care contracts, and ensure compliance with the approved SDP preprint. At § 438.6(c)(5)(i) through (v), we propose to specify the information that must be documented in the managed care contract for each SDP. Proposed § 438.6(c)(5)(i) would require the State to identify the start date and, if applicable, the end date within the applicable rating period. While most SDPs, particularly long-standing contractual requirements, are in effect throughout the entire rating period, some SDPs begin in the middle of the rating period or are for a limited period of time within a rating period. This requirement would ensure that the time period for which the SDP applies is clear to the managed care plans.

Proposed § 438.6(c)(5)(ii) would require the managed care contract to

[109] *https://www.medicaid.gov/medicaid/downloads/mce-checklist-state-user-guide.pdf.*

[110] *https://www.medicaid.gov/medicaid/downloads/mce-checklist-state-user-guide.pdf.*

describe the provider class eligible for the payment arrangement and all eligibility requirements. This would ensure compliance with the scope of the written prior approval issued by CMS because we have implemented paragraph (c)(2)(ii)(B) by requiring States to provide a description of the class of providers eligible to participate and the eligibility criteria. In addition, a clear contract term will provide clear direction to plans regarding the provider class that is eligible for the SDPs.

Proposed § 438.6(c)(5)(iii) would require the State to include a description of each payment arrangement in the managed care contract. This will ensure compliance with the written prior approval issued by CMS and provide clear direction to plans while also assisting CMS in its review and approval of Medicaid managed care contracts. For each type of payment arrangement, we are proposing to require that specific elements be included in the contract at a minimum. For SDPs that are minimum fee schedule arrangements, we propose that the contract must include: in § 438.6(c)(5)(iii)(A)(1), the fee schedule the plan must ensure payments are at or above; in paragraph (c)(5)(iii)(A)(2), the procedure and diagnosis codes to which the fee schedule applies; and in paragraph (c)(5)(iii)(A)(3), the applicable dates of service within the rating period for which the fee schedule applies. We are proposing the requirement at paragraph (c)(5)(iii)(A)(3) so that it is clear that payment can only be triggered based on service delivery within the applicable rating period.

For minimum fee schedules set at the State plan approved rate as described in § 438.6(c)(1)(iii)(A), we propose to require at § 438.6(c)(5)(iii)(A)(4) that the contract reference the applicable State plan page, the date it was approved, and a link to where the currently approved State plan page is posted online when possible. For minimum fee schedules set at the Medicare rate as described in § 438.6(c)(1)(iii)(B), we propose to require at § 438.6(c)(5)(iii)(A)(5), that the contract include the Medicare fee schedule and any specific information necessary for implementing the payment arrangement. For example, Medicare updates their fee schedules annually using a calendar year but Medicaid managed care contracts may not be based on a calendar year, such as those that use a State fiscal year. Therefore, States would have to identify the publication year of the Medicare fee schedule being required by the SDP. As another example, the Medicare physician fee schedule includes factors for different geographic areas of the State to reflect higher cost areas; the Medicaid managed care contract would have to specify if the plans are required to apply those factors or use an average of those factors and pay the same rate irrespective of the provider's geographic region.

For uniform increases as described in paragraph (c)(1)(iii)(D), we propose at § 438.6(c)(5)(iii)(B)(1) through (5) to require the contract to include: (1) whether the uniform increase will be a specific dollar amount or a specific percentage increase over negotiated rates; (2) the procedure and diagnosis codes to which the uniform increase will be applied; (3) the specific dollar amount of the increase or percent of increase, or the methodology to establish the specific dollar amount or percentage increase; (4) the applicable dates of service within the rating period for which the uniform increase applies; and (5) the roles and responsibilities of the State and the plan, as well as the timing of payment(s), and any other significant relevant information.

For maximum fee schedules as described in paragraph (c)(1)(iii)(E), we propose at § 438.6(c)(5)(iii)(C)(1) through (4) to require the contract to include: (1) the maximum fee schedule the plan must ensure payments are below; (2) the procedure and diagnosis codes to which the fee schedule applies; (3) the applicable dates of service within the rating period for which the fee schedule applies; and (4) details of the State's exemption process for plans and providers to follow if they are under contract obligations that result in the need to pay more than the maximum fee schedule. We believe an exemption process is necessary for payment arrangements that limit how much a managed care plan can pay a provider to ensure that the MCO, PIHP, or PAHP retains the ability to reasonably manage risk and has discretion in accomplishing the goals of the contract.

For contractual obligations described in paragraph (c)(1)(i) and (ii) that condition payment based upon performance, we propose at § 438.6(c)(5)(iii)(D)(*1*) through (6) to require that managed care plan contracts must include a description of the following elements approved in the SDP arrangement: (1) the performance measures that payment will be conditioned upon; (2) the measurement period for those metrics; (3) the baseline statistics against which performance will be based; (4) the performance targets that must be achieved on each metric for the provider to obtain the performance-based payment; (5) the methodology to determine if the provider qualifies for the performance-based payment as well as the amount of the payment; and (6) the roles and responsibilities of the State and the plan, the timing of payment(s), what to do with any unearned payments if applicable, and other significant relevant information. Some States perform the calculations to determine if a provider has achieved the performance targets necessary to earn performance-based payments, while others delegate that function to their managed care plans. Adding this specificity to the contract would ensure clarity for both the States and the managed care plans.

For contractual obligations described in paragraphs (c)(1)(i) and (ii) that are population or condition-based payments as defined in § 438.6(a), we propose at § 438.6(c)(5)(iii)(E) to require the contract to describe: (1) the Medicaid covered service(s) that the population or condition-based payment is made for; (2) the time period that the population-based or condition-based payment covers; (3) when the population-based or condition-based payment is to be made and how frequently; (4) a description of the attribution methodology, if one is used, which must include at a minimum the data used, when the panels will be established, how frequently those panels will be updated, and how that attribution model will be communicated to providers; and (5) the roles and responsibilities of the State and the plan in operationalizing the attribution methodology if an attribution methodology is used.

Proposed § 438.6(c)(5)(iv) would require that the State include in the managed care contract any encounter reporting and separate reporting requirements that the State needs in order to audit the SDP and report provider-level payment amounts to CMS as required in § 438.6(c)(4).

Proposed § 438.6(c)(5)(v) would require that the State indicate in the contract whether the State would be using a separate payment term as defined in § 438.6(a) to implement the SDP. This information would provide additional clarity for oversight purposes for both States and CMS.

Finally, we propose to require in § 438.6(c)(5)(vi) that all SDPs must be specifically described and documented in MCO, PIHP, and PAHP contracts no later than 120 days after the start of the SDP or approval of the SDP under § 438.6(c)(2)(i), whichever is later. This timeframe is consistent with the timeframe being proposed for documenting separate payment terms in the managed care contract under § 438.6(c)(6)(v). We believe that

proposing to require States to document the SDP within these timeframes is reasonable given that the contract would only have to document the SDP and the contract action could be submitted to CMS in draft form so long as it included all of the required elements in § 438.6(c)(5)(i) through (v), as applicable. CMS would not require a final signed copy of the contract amendment within this proposed 120-day timeframe; however, States would still be required to submit a final signed contract action prior to CMS' approval of the managed care contract.

For discussion on the proposed applicability dates for the proposals outlined in this section, see section I.B.2.p. of this proposed rule.

We solicit public comments on our proposals.

l. Including SDPs in Rate Certifications and Separate Payment Terms (§§ 438.6(c)(2)(ii)(J), (c)(6) and 438.7(f))

Including SDPs in rate certifications. Under current regulations, all SDPs must be included in all applicable managed care contract(s) and described in all applicable rate certification(s) as noted in § 438.7(b)(6). As part of our proposed amendment and redesignation of current § 438.6(c)(2)(i), we are proposing to re-designate the existing regulatory requirement at § 438.6(c)(2)(i) as § 438.6(c)(2)(ii)(J) to require that each SDP must be developed in accordance with § 438.4 and the standards specified in §§ 438.5, 438.7, and 438.8. We are also proposing to remove the current provision that SDPs must be developed in accordance with generally accepted actuarial principles and practices. We are proposing this edit because inclusion of the language ''generally accepted actuarial principles and practices'' is duplicative of the language included in § 438.4. establishment of SDPs is a State decision. We are concerned that inclusion of the duplicative language that SDPs must be developed in accordance with generally accepted actuarial principles and practices could be interpreted as a requirement for an actuary to be involved in the development of the SDP arrangement and adherence to actuarial standards of practice (ASOPs), potentially creating unnecessary State administrative burden associated with the preprint development process. However, we note the proposed rule maintains the existing requirement that SDPs must be developed in accordance with § 438.4 and the standards specified in §§ 438.5, 438.7, and 438.8. While we believe that an actuary, as defined in § 438.2, must develop the capitation rates to ensure they are actuarially sound and account for all SDPs when doing so, but we believe States should have the flexibility to determine if they wish to involve actuaries in the development of each specific SDP arrangement. Because actuaries must account for all SDPs approved by CMS and included in the State's approved managed care contract in the applicable rate certifications, providing all documentation required by CMS, we do recommend that States consult with and keep actuaries apprised of SDPs to facilitate their development of actuarially sound capitation rates. We also believe that for certain SDPs, specifically bundled payments, episode-based payments, population-based payments and accountable care organizations, it would be beneficial for actuaries to assist States in the development of these arrangements.

In accordance with § 438.4(a), actuarially sound capitation rates are projected to provide for all reasonable, appropriate and attainable costs that are required under the terms of the contract and for the operation of the managed care plan for the time period and the population covered under the terms of the contract, and capitation rates are developed in accordance with the requirements in § 438.4(b) to be approved by CMS. This includes the requirement in § 438.4(b)(1) that the capitation rates must be developed with generally accepted actuarial principles and practices and in § 438.4(b)(7) they must meet any applicable special contract provisions as specified in § 438.6, to ensure that all SDPs, which are contractual arrangements, are considered as the actuary develops actuarially sound capitation rates. (Similarly, withhold and incentive arrangements and pass-through payments must be taken into account when capitation rates are developed.) We are not proposing changes to the requirements for actuarially sound capitation rates; therefore, we will retain and reaffirm here applicability of the requirements of that SDPs must be developed in such a way as to ensure compliance with § 438.4 and the standards specified in § 438.5 and specify further that SDPs must also be developed in such a way to ensure compliance with § 438.7 and § 438.8.

We solicit public comments on our proposal.

Separate Payment Terms. Under current regulations, all SDPs must be included in all applicable managed care contract(s) and described in all applicable rate certification(s) as noted in § 438.7(b)(6). As part of the Medicaid Managed Care Rate Development Guide, CMS has historically provided guidance on two ways that States could make payment to cover SDP obligations in Medicaid managed care contracts: through adjustments to the base capitation rates [111] in alignment with the standards described in § 438.5(f) or through a ''separate payment term'' [112] which was described in guidance applicable to rating periods beginning between July 1, 2019 and June 30, 2021. Separate payment terms are unique to Medicaid managed care SDPs. CMS has not previously formally defined separate payment terms in regulation.

The most common structure for separate payment terms is a State first establishes a finite and predetermined pool of funding that is paid by the State to the plan(s) separately and in addition to the capitation payments for a specific SDP. The pool of funds is then disbursed regularly throughout the rating period (for example, quarterly) based on the services provided in that portion of the rating period (for example, quarter) to increase total provider payments or reach a specific payment rate target. Typically, States divide the dedicated funding pool into equal allotments (for example, four if making quarterly payments to their plans). They then review the encounter data for the service(s) and provider class identified in the approved preprint for the quarter that has just ended and divide the allotment by the total service utilization across all providers in the defined class (for example, inpatient discharges for all rural hospitals) to determine a uniform dollar amount to be paid in addition to the initial payment by the managed care plan for rendered services. The State will then pay the quarterly allotment to the managed care plans, separate from the capitation rate payment, and direct them to use that allotment for additional retroactive payments to providers for the utilization that occurred in the quarter that just ended. The State will repeat this process each quarter, with the uniform increase changing for each quarter depending on utilization but being paid uniformly to providers in the defined class for the services within that quarter (for example, inpatient discharges for rural hospitals). Other

[111] As defined in § 438.2, capitation payments are a payment the State makes periodically to a contractor on behalf of each beneficiary enrolled under a contract and based on the actuarially sound capitation rate for the provision of services under the State plan.

[112] This guidance has appeared in the Medicaid Managed Care Rate Development Guide for rating periods starting between July 1, 2019 and June 30, 2021. Medicaid Managed Care Rate Development Guides for every rating period are located at *https://www.medicaid.gov/medicaid/managed-care/guidance/rate-review-and-rate-guides/index.html.*

States have chosen to make payments semi-annually, annually, or monthly. States have also utilized separate payment terms for SDPs that are performance-based payments rather than uniform increases (for example, pay for performance under which payment is conditioned upon provider performance).

As noted earlier, separate payment terms are paid separate and apart from capitation rate payments; they are not included in capitation rates. The development of the separate payment term is frequently done by the State rather than the State's actuaries; CMS has never required actuaries to certify the reasonableness of the amount of the separate payment term, but only that the separate payment term is consistent with what was approved in the SDP preprint. However, CMS has always required that separate payment terms be documented in the State's rate certification and that SDPs, including those that utilize separate payment terms, must be developed in accordance with § 438.4 and the standards in §§ 438.5, 438.7 and 438.8. CMS has asked actuaries to document the separate payment terms in the State's rate certification because they are required payments for services under the risk-based contract.

Depending on the size and scope of the SDP and the provider payment rates assumed in the capitation rate development, separate payment terms can have a significant impact on the assessment of the actuarial soundness of the rates. In some cases, capitation rates may not be sufficient without taking separate payment terms into account. When examined in conjunction with the capitation rates, CMS has found that amounts included in separate payment terms can, when combined with capitation payment amounts, represent a significant portion of the total payment made under the Medicaid managed care contract. For example, in one State, the separate payment term for an SDP for inpatient hospital services represented 40 percent of the total amount paid in certain rate cells.

In some cases, the provider payment rates assumed in the development of the capitation rates, absent the SDP paid through a separate payment term to the plan(s), are so low that the capitation rates would likely not be actuarially sound. In the example above, considering how low the payment rates were absent the SDP paid to the plans through a separate payment term in this State, it would be difficult for an actuary to determine that the capitation rates are actuarially sound. However, the additional payments made as part of the SDP for these providers raise the effective provider payment rates, and after considering all payments made to the plan (the base capitation rates and the separate payment term payments for the SDP) the actuary may be able to determine that the capitation rates are actuarially sound. This is not the case for all States and for all SDPs; however, this example highlights the need to account for the impact of separate payment terms on the assessment of the actuarial soundness of the capitation rates. Additionally, since the contract requires that the managed care plans pay the SDP to providers, the separate payment term must be included within the actuarial certification for the rates to be considered actuarially sound as defined in § 438.4(a). For this reason, we consider separate payment terms part of the contract with the managed care plans that is subject to the requirements of section 1903(m)(2)(A) of the Act, and a necessary part of certifying the actuarial soundness of capitation rates under this provision. As such, we propose to regulate them under this authority.

Over time, the number of SDPs approved by CMS using separate payment terms has increased substantially. According to our internal analysis, 41.5 percent of all SDPs that CMS has reviewed and approved from May 2016 through March 2022 were included in the State's rate certification submission as a separate payment term. While there has been some fluctuation over time in this trend, the share of SDPs that use separate payment terms has increased from 42 percent of all SDPs that began in calendar year 2020 to 55 percent of all SDPs that began in calendar year 2021.[113]

In our January 2021 SMDL, we published additional guidance on SDPs, and expressed our growing concern with the increased use of separate payment terms.[114] We noted, ''[a]s CMS has reviewed State directed payments and the related rate certifications, CMS has identified a number of concerns around the use of separate payment terms. Frequently, while there is risk for the providers, there is often little or no risk for the plans related to the directed payment, which is contrary to the nature of risk-based managed care. This can also result in perverse incentives for plans that can result in shifting utilization to providers in ways that are not consistent with Medicaid program goals.''

To better understand why States choose to pay plans for their SDPs through a separate payment term, we started collecting information from States as part of the revised preprint form published in January 2021. States were required to start using this revised preprint for SDP requests for rating periods beginning on or after July 1, 2021. In the revised preprint form, States must identify if any portion of the SDP would be included in the rate certification as a separate payment term and if so, to provide additional justification as to why this is necessary and what precludes the State from covering the costs of SDPs as an adjustment to the capitation rates paid to managed care plans.

From the data we have collected as well as discussions with States, we have noted that there are a number of reasons why States use separate payment terms. For example, States have noted particular challenges with including VBP arrangements in capitation rates. They have asserted that it is difficult to project individual provider level performance in a way that lends itself to inclusion in standard rate development practices. Additionally, performance measurement often does not align with States' rating periods, further complicating the standard rate development process.

Several States also noted that even for fee schedule-based SDPs, such as uniform payment increases, incorporation into standard rate development practices presents challenges. States assert that using a separate payment term offers administrative simplicity to the State agency in administering the SDPs because distributing a pre-determined amount of funding among the plans is much easier than relying on actuarial projections. Further, the use of a separate payment term also promotes the ease of tracking and verification of accurate payment to providers from the managed care plans required under the SDP. This is particularly important when States are implementing legislative directives that require an appropriation of funding be dedicated to a specific purpose. State legislatures, in some instances, have identified a specific dollar amount that they want to invest in increasing reimbursement for a particular service, potentially to respond to an acute concern around

[113] Our internal analysis examines trends based upon when a payment arrangement began. Since States have different rating periods, this can refer to different time frames for different States. For example, payment arrangements that began in calendar year 2020 would include payment arrangements that were in effect for CY 2020 rating periods, which operated between January 1, 2020 through December 31, 2020, as well as SFY 2021 rating periods, which for most States were operated between July 1, 2020 through June 30, 2021.

[114] *https://www.medicaid.gov/Federal-Policy-Guidance/Downloads/smd21001.pdf.*

access. Incorporating this funding into the State's capitation rates through standard rate development would not ensure that plans did not use this funding, or portions of this funding, for other purposes. Additionally, even with the proper tracking, States would have to specify a particular minimum fee schedule or uniform increase at the start of the rating period to include in rate development and ensure it went to the appropriate providers for the appropriate services. While such a methodology is permissible and used effectively by a number of States today, some States have noted challenges in utilizing such an approach, particularly if the SDP is targeting a narrow set of providers.

States have also noted that utilization often cannot be predicted adequately; thus, including dedicated funding into base rates may not always result in the funding being distributed as intended by the legislature. Absent the ability to use separate payment terms, States are likely to resort to requiring plans to make interim payments based on historical utilization and then reconciling to current utilization, often after the end of the rating period, to ensure that all of the funding was used as directed by the legislature. As noted in section I.B.2.h. of this proposed rule, we have significant concerns with this practice in States that already require plans to make interim payments based on historical utilization and then reconcile to current utilization. As part of this proposed rulemaking, we have proposed to prohibit such payment methodologies in § 438.6(c)(2)(vii).

States also stated that separate payment terms reduce the burden on managed care plans by limiting the need to update claims systems. In fact, one State noted that they shifted from incorporating a particular SDP as an adjustment to capitation rates to implementing the SDP through a separate payment term because their managed care plans did not have the ability to update or modify their claims payment systems in a manner that would ensure accurate payment of the increases required under the State's SDP if the funding was built into the capitation payment. The State noted that the managed care plans had dedicated significant technical resources and still could not implement the changes needed accurately.

As noted earlier, CMS has a strong preference that SDPs be included as adjustments to the capitation rates since that method is most consistent with the nature of risk-based managed care. However, we recognize that States believe there is utility in the use of separate payment terms for specific programmatic or policy goals. We believe separate payment terms are one tool for States to be able to make targeted investments in response to acute concerns around access to care. However, we continue to believe that, while separate payment terms often retain risk for the providers as opposed to guaranteeing them payment irrespective of the Medicaid services they deliver to Medicaid managed care enrollees, there is often little or no risk for the plans related to separate payment terms under an SDP, which is contrary to the nature of risk-based managed care.

Therefore, we believe that it is necessary to establish regulatory requirements regarding the use of separate payment terms to fulfill our obligations for fiscal and programmatic oversight. Because the use of separate payment terms is limited to SDPs that must be tied to utilization and delivery of services to Medicaid enrollees under the managed care contract and the potential impact of separate payment terms on the assessment of actuarial soundness and certification of capitation rates, we consider separate payment terms part of the contract with the a managed care plan that is subject to 1903(m)(2)(A) requirements, and we propose to regulate them under this authority. States are generally not permitted to direct the expenditures of a Medicaid managed care plan under the contract between the State and the plan or to make payments to providers for services covered under the contract between the State and the plan (§§ 438.6 and 438.60) unless SDP requirements are satisfied.

Proposed Regulatory Changes—Contract Requirements

First, we propose to amend § 438.6(a) to define ''separate payment term'' as a pre-determined and finite funding pool that the State establishes and documents in the Medicaid managed care contract for a specific SDP for which the State has received written prior approval. Payments made from this funding pool are made by the State to the MCOs, PIHPs or PAHPs exclusively for SDPs for which the State has received written prior approval and are made separately and in addition to the capitation rates identified in the contract as required under § 438.3(c)(1)(i).

CMS recognizes that some separate payment terms in the past may not have fit this definition. For example, one State makes one payment monthly that is inclusive of both the capitation payment and the separate payment term. The State then contractually requires the managed care plans to hold a portion of the monthly payment in a reserve that the State later directs the plans how to pay to providers under an approved SDP. In this example, the State initially indicated to CMS that the SDP was accounted for through adjustments to base data in capitation rates. However, the State later agreed with CMS that the contractual requirement to hold a portion of the monthly payment in a reserve that the State later directed was more in alignment with separate payment terms. To be clear, such a practice would not be considered an adjustment to base rates or part of capitation rate development under this proposed rule; instead it would, under our proposed rule, fall under the proposed definition of a separate payment term and would have to comply with all proposed requirements for SDPs and separate payment terms in the proposed revisions to § 438.6(c).

We propose a new § 438.6(c)(6) that would specify requirements for the use of separate payment terms. First, we propose a new § 438.6(c)(6)(i) to require that all separate payment terms are reviewed and approved as part of the review of the SDP in § 438.6(c)(2). This is effectively current practice today; when a State indicates that an SDP is included in the applicable rate certification(s) through a separate payment term, the approved preprint is checked to ensure that it also indicates that the SDP utilizes a separate payment term. This requirement would codify this operational practice. We believe reviewing and approving the separate payment term as part of the SDP review and approval process would be mutually beneficial for CMS and States because they are inextricably linked given the proposed definition of a separate payment term. We believe this would also enable us to track of the use of separate payment terms more quickly and accurately.

Because we are proposing to require that separate payment terms are approved as part of the review and approval of the SDPs in § 438.6(c)(2)(i) (redesignated from 438.6(c)(2)(ii)), we believe we should explicitly address those SDPs that do not require written prior approval to ensure clarity for States. Therefore, we propose a new requirement at § 438.6(c)(6)(ii) that would expressly prohibit States from using separate payment terms to fund SDPs that are exempted from the written prior approval process—specifically, minimum fee schedules using State plan approved rates in § 438.6(c)(1)(iii)(A) and minimum fee schedules using approved Medicare fee schedules, as

proposed in § 438.6(c)(1)(iii)(B). Such payment arrangements must be included as an adjustment to the capitation rates identified in the contract, as required under § 438.3(c)(1)(i).

At § 438.6(c)(6)(iii), we propose to require that each separate payment term be specific to both an individual SDP approved under § 438.6(c)(2)(i) (redesignated from 438.6(c)(2)(ii)) and to each Medicaid managed care program to provide clarity in the contract for the plan and facilitate State and Federal oversight of such terms. SDPs approved under § 438.6(c)(2) can apply to more than one Medicaid managed care program. Requiring that each separate payment term be specific to both the SDP approved under § 438.6(c)(2)(i) (redesignated from 438.6(c)(2)(ii)) and each Medicaid managed care program would facilitate monitoring and oversight help ensure clarity and consistency between the approval of the separate payment term and the SDP, the managed care plan contract, and the rate certification.

Additionally, we are proposing a new requirement at § 438.6(c)(6)(iv) that the separate payment term would not exceed the total amount documented in the written prior approval for each SDP for which we have granted written prior approval. Under current practice, the total dollar amount for the separate payment term has acted as a threshold to ensure alignment between the rate certification and the SDP; States that documented more for the separate payment term in the rate certification(s) than the total dollars documented in the preprint under current practice have to either revise the rate amendment so that the total dollars for the separate payment term does not exceed what was captured in the preprint or submit an amendment to the preprint. If States choose to amend the preprint under current practice, the State is required to explain the cause of the increase (for example, a change in payment methodology, or expansion of the provider class); and then verify that the payment analysis has not changed or if it has, then update the payment analysis to ensure that the total payment rate is still reasonable, appropriate and attainable.[115] This proposed requirement would strengthen this practice by requiring that the amount included in both the rate certification(s) and contract(s) for each separate payment term cannot exceed the amount documented as part of the SDP review and approval. The total dollar amount documented in the written prior approval for the State directed payment would instead act as a maximum that could not be exceeded in the Medicaid managed care contract(s) and rate certification(s) that include the SDP without first obtaining written CMS approval of an amendment to the SDP as noted below. We emphasize that we currently review rate certifications to verify that the total dollars across all applicable Medicaid managed care programs do not exceed the total dollars identified in the State directed payment documentation approved by CMS. If the total dollars included in rate certifications exceed the total dollars identified in the State directed payment documentation, the State then has to either reduce the total dollars included in the rate certification for the separate payment term or, most commonly, submit an amendment to the preprint for review and approval by CMS. This process causes significant delays and administrative burden for both the State and the Federal government, and therefore, we believe a regulation prohibiting States from exceeding the total dollars for the separate payment term identified in the State directed payment documentation is appropriate and important.

We have also considered requiring that the separate payment term must equal exactly the total amount documented for each SDP for which we have granted written prior approval. Instead of acting as a maximum, the total dollar amount for the separate payment term would act as both a minimum and a maximum; the State's contract and rate certifications would have to include exactly the total dollar amount identified in the SDP approved by CMS. We did not propose this alternative as we are concerned that requiring the total amount for the separate payment term to act as both a minimum and maximum could be too administratively burdensome; however, we solicit comments on both our proposal to require that the total dollars documented in the SDP approved by CMS under (c)(2) would act as a maximum as well as this alternative option of the total dollars documented in the SDP approved by CMS under (c)(2)(i) as both a minimum and a maximum.

Historically, separate payment terms have only been documented in the State's preprint review and in the State's rate certifications; the details of when and how these payments would be made by the State to the plans was often not clear to CMS or the plans. This lack of clarity presents significant oversight concerns for these separate payment terms because it makes tracking the payments made from the State to the plan difficult to identify, particularly on the CMS–64 form on which States claim FFP. It also presents challenges for ensuring timely payment to plans and, ultimately, providers. CMS believes that just as the final capitation rates must be specifically identified in the applicable contract submitted for CMS review and approval, so too should separate payment terms associated with SDPs.

As previously noted in this section, CMS maintains that while there is risk for the providers as opposed to guaranteeing them payment irrespective of the Medicaid services they deliver to Medicaid managed care enrollees, there is often little or no risk for the plans related to the SDP to the extent it is included in contracts as a separate payment term, which is contrary to the nature of risk-based managed care. This becomes even more concerning when States retroactively amend the separate payment term, sometimes even after the end of the rating period.

To illustrate this, we provide the following examples. Example 1: States that include SDPs into their contracts and rate certifications through separate payment terms must have the total dollars for the separate payment term certified in the rate certification(s). The State would then look at the utilization over a defined period, for example, one quarter, and divide one-fourth of the total dollars certified in the separate payment term by the utilization during that quarter to determine a uniform dollar amount increase. Example 1 illustrates a common practice for SDPs that use separate payment terms: it allows the uniform dollar amount applied to utilization to vary from one quarter to another, but it ensures that the total dollars dedicated to the State directed payment are fully expended.

Example 2: Some States have used this same methodology in example 1, but instead of having their actuaries certify the total dollar amount prospectively, they would have their actuaries certify an estimate of the total dollars and then have their actuaries recertify a higher amount later, often after all the payments under the separate payment term have been made.

Example 2 not only removes all risk from the plans for the SDP, but also removes all risk from the providers when the actuary recertifies a total dollar amount later, often after all the payments under the separate payment

[115] As noted in section I.B.2.f. of this proposed rule, CMS requires States to demonstrate that SDPs result in provider payment rates that are reasonable, appropriate, and attainable as part of the preprint review process in alignment with the guidance published in State Medicaid Director Letter #21–001 published on January 8, 2021. We are proposing to codify this requirement in § 438.6(c)(2(ii)(I).

term have been made. Such practices are contradictory to the prospective nature of risk-based managed care. In our experience, such payment arrangements are not driven by furthering particular goals and objectives identified in the State's managed care quality strategy, but rather by the underlying financing of the non-Federal share associated with the SDPs. We note financing requirements in statute and regulation are applicable across the Medicaid program irrespective of the delivery system (for example, fee-for-service, managed care, and demonstration authorities), and are similarly applicable whether a State elects to direct payments under § 438.6(c) or not.

To curtail these concerning practices, we propose to require as part of § 438.6(c)(6)(v) that States must document the separate payment term in the State's managed care contracts no later than 120 days after the start of the payment arrangement or written prior approval of the SDP, whichever is later. We believe that proposing to require States to document the separate payment term within these timeframes is reasonable given that the contract amendment would only have to document the separate payment term and the related SDP; the contract action could be submitted to CMS in draft form so long as it included all of the required elements. CMS would not require a final signed copy of the amendment within this proposed 120-day timeframe; however, States would still be required to submit a final signed contract action prior to CMS' approval of the managed care contract.

To further the fiscal and programmatic integrity of separate payment terms, we propose in § 438.6(c)(6)(v)(A) to prohibit States from amending the separate payment term after CMS approval except to account for an amendment to the payment methodology that is first approved by CMS as an amendment to the approved State directed payment. We recognize that a change in payment methodology would potentially result in the need to amend the separate payment term as it could impact the total dollar amount. However, to avoid the current practice where States include a total dollar amount in the rate certification(s) other than what is in the approved SDP preprint, CMS is proposing to require that CMS first approve the amendment to the preprint before the separate payment term can be amended. We believe this proposal would also ensure that some level of risk is maintained and that States do not retroactively add additional funding with the goal of removing all risk from the SDP arrangement. Such actions do not align with the fundamental principles of Medicaid managed care.

Alternatively, we are also considering including a proposal to permit amendments to the separate payment term to account for a change in the total aggregate dollars to be paid by the State to the plan where there is no change in the non-Federal portion of the total aggregate dollars. We are considering this alternative in recognition that the Federal portion of the total aggregate dollars may fluctuate due to Federal statute changes that are outside the State's control. We acknowledge that due to this, the total dollars, which includes the Federal share, cannot be perfectly predicted by States at the start of a State's rating period. We did not include this alternative proposal out of concern that it may have negative unintended consequences. We solicit comment on both the exception we are proposing and this alternative additional exception that we are considering.

To improve transparency of States' use of separate payment terms and to ensure that managed care plans have clear information on the contractual requirements associated to State directed payments linked to a separate payment term, in § 438.6(c)(6)(v)(B)(*1*) through (*4*), we propose four pieces of information that would be documented in the State's Medicaid managed care plan contracts: (1) the total dollars that the State would pay to the plans for the individual SDP that CMS gave written prior approval; (2) the timing and frequency of payments that would be made under the separate payment term from the State to the plans; (3) a description or reference to the contract requirement for the specific SDP for which the separate payment term would be used; and (4) any reporting that the State requires to ensure appropriate reporting of the separate payment term for purposes of MLR reporting under § 438.8.

Proposed Regulatory Changes—Rate Certification for Separate Payment Terms

To reflect our proposals discussed above that would require States to document separate payment terms in their managed care rate certifications, we propose changes to § 438.7. Specifically, we propose to add a new § 438.7(f) that would require the State, through its actuary, to certify the total dollar amount for each separate payment term as detailed in the State's Medicaid managed care contract, consistent with the requirements of § 438.6(c)(6). Requiring that all separate payment terms be included in the rate certification to plans is also current practice today and provides a complete picture of all payments made by States to plans under risk contracts.

We also propose to codify many existing practices that we currently employ when reviewing State directed payments that use separate payment terms. In § 438.7(f)(1), we propose that the State may pay each MCO, PIHP, or PAHP a different amount under the separate payment term compared to other MCOs, PIHPs, or PAHPs so long as the aggregate total dollars paid to all MCOs, PIHPs, and PAHPs does not exceed the total dollars of the separate payment term for each respective Medicaid managed care program included in the Medicaid managed care contract. In § 438.7(f)(2), we propose that the State, through its actuary, would have to provide an estimate of the impact of the separate payment term on a rate cell basis, as paid out per the SDP approved by CMS under § 438.6(c)(2)(i). Both of these proposed regulatory requirements are part of current operational practice today as documented in the Medicaid Managed Care Rate Development Guide.[116] Having the estimated impact of the separate payment term on a rate cell basis helps to evaluate the actuarial soundness of the capitation rates. In § 438.7(f)(3), we propose that no later than 12 months following the end of the rating period, the State would have to submit documentation to CMS that includes the total amount of the separate payment term in the rate certification consistent with the distribution methodology described in the State directed payment for which the State obtained written prior approval to facilitate oversight and monitoring of the separate payment term.

Finally, we are proposing at § 438.7(f)(4) to require States to submit a rate certification or rate certification amendment incorporating the separate payment term within 120 days of either the start of the payment arrangement or written prior approval of the SDP, whichever is later. This proposal is aligned with the proposed contract requirement in § 438.6(c)(6)(v).

As previously noted we strongly prefer that SDPs be included as adjustments to capitation rates since that method is most consistent with the nature of risk-based managed care. Our

[116] Medicaid Managed Care Rate Development Guides for every rating period are located at *https://www.medicaid.gov/medicaid/managed-care/guidance/rate-review-and-rate-guides/index.html.*

proposals to amend § 438.6(a) to add a new definition for separate payment term, the addition of §§ 438.6(c)(6) and 438.7(f) are intended to maintain the State's ability to use separate payment terms while implementing necessary guardrails for fiscal and programmatic oversight. However, given our longstanding concern with separate payment terms, CMS is considering, and invites comment on, requiring all SDPs to be included only through risk-based adjustments to capitation rates and eliminate the State's ability to use separate payment terms altogether in the final rule based on comments received. Prohibiting the use of separate payment terms would align with CMS' stated preference and would be most consistent with the nature of risk-based managed care. However, many States currently use separate payment terms for existing SDPs; prohibiting their use could cause some disruptions for States.

Another alternative CMS is considering, and invites comment on, is further prohibiting the use of separate payment terms not only to SDPs described in paragraphs (c)(1)(iii)(A) and (B), but to all SDPs described in paragraph (c)(1)(iii). Under this alternative, States would only be able to use separate payment terms for value-based initiatives described in paragraphs (c)(1)(i) and (ii). This alternative would still allow States to use separate payment terms for some payment arrangements and could incentivize States to consider quality-based payment models that can better improve health outcomes for Medicaid managed care enrollees. this proposal recognizes the difficulties that States and their actuaries may face in incorporating some value-based payment initiatives into capitation rate development as compared to fee schedules as described in paragraph (c)(1)(iii).

For each of these two alternatives, we acknowledge that some States currently use separate payment terms. Therefore, these alternative proposals could cause some disruptions as States evaluate changes to SDPs. If CMS adopts one of the alternatives for a total payment rate limit on SDP expenditures in the final rule, we also seek public comment on whether or not CMS should consider a transition period in order to mitigate any disruptions.

We seek public comment on whether either of these alternative approaches we are considering should be adopted in the final rule, as well as comments on our proposals.

For discussion on the proposed applicability dates for the proposals outlined in this section, see section I.B.2.p. of this proposed rule.

We solicit public comment on our proposals.

m. SDPs Included Through Adjustments to Base Capitation Rates (§ 438.7(c)(4) Through (6))

We also propose three additional changes to § 438.7(c) to address adjustments to managed care capitation rates that are used for SDPs. Specifically, we propose to add a new regulatory requirement at § 438.7(c)(5) specifying that retroactive adjustments to capitation rates resulting from an SDP must be the result of an approved SDP being added to the contract, an amendment to an already approved SDP, a State directed payment described in § 438.6(c)(1)(iii)(A) or (B), or a material error in the data, assumptions, or methodologies used to develop the initial rate adjustment such that modifications are necessary to correct the error. This requirement would align with the proposed requirement at § 438.6(c)(6)(v)(A). We believe this proposed regulatory requirement is necessary to ensure the fiscal integrity of SDPs and their impact on rate development. While not as frequent, we have also observed States, through their actuaries, submitting amendments to rates for SDPs included through adjustments to base rates that do not reflect changes in payment methodology, changes in benefit design, or general actuarial practices, but instead appear to be related to financing of the non-Federal share. We do not view such actions as consistent with the prospective and risk-based nature of Medicaid managed care. It also creates significant administrative burden for both States and the Federal government, by delaying review of associated rate certifications.

Additionally, we propose a new regulatory requirement at § 438.7(c)(4) that States must submit a revised rate certification for any changes in the capitation rate per rate cell, as required under § 438.7(a) for any special contract provisions related to payment in § 438.6 not already described in the rate certification, regardless of the size of the change in the capitation rate per rate cell. States are permitted the flexibility under § 438.7(c)(3) to increase or decrease the capitation rate per rate cell up to 1.5 percent during the rating period without submitting a revised rate certification for rate changes unrelated to special contract provisions, including SDPs, and ILOSs as proposed in section I.B.4.e. of this proposed rule. We believe that providing this same flexibility for changes to rates for special contract provisions, including SDPs, is incongruent with the existing requirement at § 438.7(b)(6) that the rate certification include a description of any of the special contract provisions related to payment in § 438.6 that are applied in the contract. In addition, we believe it is also inconsistent with ensuring appropriate program integrity, such as the 105 percent threshold in 438.6(b)(2) and existing and proposed SDP standards. Therefore, our proposal here addresses and clarifies this requirement.

Finally, we propose a new regulatory requirement at § 438.7(c)(6) to require that States must submit the required rate certification documentation for SDPs incorporated through adjustments to base rates (either the initial rate certification or a revised rate certification) no later than 120 days after either the start date of the SDP approved under § 438.6(c)(2)(i) (redesignated from § 438.6(c)(2)(ii)) or 120 days after the date CMS issued written prior approval of the SDP, whichever is later.

For discussion on the proposed applicability dates for the proposals outlined in this section, see section I.B.2.p. of this proposed rule.

We solicit public comment on our proposals.

n. Appeals (§ 430.3(d))

As outlined under § 438.6(c), SDPs are arrangements that allow States to require managed care plans to make specified payments to healthcare providers when the payments support overall Medicaid program goals and objectives (for example, funding to ensure certain minimum payments are made to safety net providers to ensure access or quality payments to ensure providers are appropriately rewarded for meeting certain program goals). Section 438.6(c) was issued by CMS because this type of State direction of managed care payment goes against the general premise of managed care in which a contracted organization assumes risk from the State for the delivery of care to its beneficiaries. As a result, we established a process whereby States must submit a ''preprint'' form to CMS to document how the SDP complies with the Federal requirements outlined in § 438.6(c). If the proposal does comply, we issue written prior approval. Subsequent to written prior approval, the SDP is permitted to be included in the relevant managed care organization contract and rate certification documents. This process is required by CMS for most SDPs.

As discussed throughout this proposed rule, the volume of State

requests for written approval to implement State directed payment arrangements has grown significantly in both number and total dollars included in managed care plan capitation rates since § 438.6(c) was promulgated in the 2016 final rule.

Based on our review of SDP prior approval requests, we have observed that States use SDPs not only as routine payment mechanisms, such as to set minimum fee schedules or provide uniform increases, but also for more complex payment arrangements, such as to implement Total Cost of Care (TCOC) programs, and multi-metric and multi-year VBPs. CMS provides technical assistance to States at all stages of SDP development to help States develop SDP arrangements that meet their programmatic goals and comply with § 438.6(c). This technical assistance can involve both verbal and written assistance, as well as the exchange of CMS-generated question sets and State responses. The State responses are shared internally with Federal review partners who provide subject matter expertise, which may include those representing managed care policy and operations, quality, and actuarial science, which is then shared with the State to inform SDP revisions and ensure compliance with the regulations.

Providing this technical assistance has become increasingly challenging as the number and complexity of States' SDP requests has increased. To date, when CMS and States have found themselves unable to reach agreement on an SDP proposal and we are unable to issue prior written approval, States have agreed to withdraw the submission. However, as SDPs have matured as a State tool, they have outgrown this informal process of State rescission. The proposals in this rule would further specify and strengthen the SDP regulations and we believe it is appropriate to begin formally disapproving proposals that cannot comply with the regulations.

A disapproval for an SDP could be issued for many reasons, including impermissible financing of the non-Federal share, failure to show improvement in the proposed quality evaluation report in the timeframe required, or non-compliance with the controlling regulations in part 438. To be consistent with other CMS processes which issue formal disapprovals, such as those for SPA submissions and disallowances of State Medicaid claims, there should be a formal process for States to appeal should CMS issue disapproval of written prior approval for a State's SDP proposal. The alternative is that a State may seek redress in the courts, which can be costly and slow for both CMS and the States. We believe that States will benefit from and appreciate an established, consistent administrative process with which they are familiar.

Under our authority under section 1902(a)(4) of the Act to establish methods for proper and effective operations in Medicaid, we propose to add a new § 430.3(d) that would explicitly permit disputes that pertain to written disapprovals of SDPs under § 438.6(c) to be heard by the Health and Human Services (HHS) Department Appeals Board (the Board) in accordance with procedures set forth in 45 CFR part 16. As described in that section, the Board is comprised of members appointed by the HHS Secretary it conducts *de novo* review of certain agency decisions under the procedures at 45 CFR part 16 and its corresponding appendix A. The Board has a robust administrative adjudication process as well experience resolving disputes between CMS and States involving the Medicaid program, as it already reviews Medicaid disallowances under Title XIX of the Act using the procedures set forth at 45 CFR part 16.

Applying those procedures to CMS's decision to deny a State's SDP request, the State would have 30 days to appeal to the Board after an appellant receives a final written decision from CMS communicating a disapproval of a State directed payment. The case would then be assigned a presiding Board member who would preside over procedural matters and conduct record development in the case. Within 10 days of receiving the notice of appeal, the Board would assess the filing for completeness and jurisdiction. If it is found to be appropriately filed, the Board would acknowledge the notice and outline the next steps in the case. Under existing 45 CFR 16.16, the Board may even allow additional parties to participate if there is a ''clearly identifiable and substantial interest in the outcome of the dispute'' in the discretion of the Board. The State would then have 30 days to file its appeal brief, which would contain its argument for why the final decision of CMS was in error, and its appeal file, which would include the documents on which its arguments are based. Then, CMS would have 30 days to submit its brief in response to the State's brief as well as any additional supporting documentation not already contained in the record. The State would be given fifteen days to submit its optional reply.

Under the Board's process, parties would be encouraged to work cooperatively to develop a joint appeal file and stipulate to facts alleviating the need to submit documentation. At any time, the Board may request additional documentation or information, request additional briefings, hold conferences, set schedules, issue orders to show cause, and take other steps as appropriate to ''develop a prompt, sound decision'' per existing 45 CFR 16.9. Although there is no general right to a hearing in cases heard under 45 CFR part 16, States appealing a CMS disapproval of a proposed State directed payment under this proposed process could request a hearing or oral argument, or the Board may call for one *sua sponte* should it determine its decision-making would be enhanced by such proceedings. Generally, the Board's proceedings are held in Washington, DC, but may be held in an HHS Regional Office or ''other convenient facility near the appellant.'' Decisions are issued by the Board in three-member panels. Under 45 CFR 16.23, the Board has established general goals for its consideration of cases within 6 to 9 months; however, the paramount concern of the Board is to take the time needed to review a record fairly and adequately in order to produce a sound decision. Mediation may be used under 45 CFR 16.18 as an alternative or preliminary process to resolve the issues between the parties.

As an alternative to our proposal described above to use the Board for such decisions, we also considered permitting appeals of SDP written disapprovals to be heard by the CMS Offices of Hearings and Inquiries (OHI) and the CMS Administrator for final agency action, as governed by part 430, subpart D. The current jurisdiction of OHI stems from section 1902 of the Act, under which it hears appeals arising from decisions to disapprove Medicaid State Plan material under § 430.18 or to withhold Federal funds under § 430.35 for noncompliance of a State Plan. The OHI process is overseen by a presiding officer who makes a recommendation to the Administrator, who issues the final decision. The process is initiated upon issuance of a written disapproval.

If we were to use this process for disapproval of SDPs, the hearing officer would mail the State a notice of hearing or opportunity for hearing related to an SDP disapproval that is also published in the **Federal Register**. The hearing would be scheduled either in the CMS Regional Office or another place designated by the hearing officer for convenience and necessity of the parties between 30 and 60 days after notice. Before the hearing, issues may be added, removed, or modified, to also be published in the **Federal Register** and

with twenty days' notice to the State before the hearing, unless all issues have been resolved, in which case the hearing is terminated.

Under this process, the State and CMS would be given 15 days to provide comment and information regarding the removal of an issue. Before the hearing, other individuals or groups would be able to petition to join the matter as a party within 15 days after notice is posted in the **Federal Register**. The State and CMS would be able to file comments on these petitions within five days from receipt. The presiding officer would determine whether to recognize additional parties. Alternatively, any person or organization would be able to file an *amicus curiae* (friend of the court) as a non-party, should their petition to do so be granted. The parties would have the right to conduct discovery before the hearing under § 430.86 and to participate in prehearing conferences under § 430.83.

At the hearing, parties would make opening statements, submit evidence, present and cross-examine witnesses, and present oral arguments.[117] The transcript of the hearing along with stipulations, briefs, and memoranda would be filed with CMS and may be inspected and copied in the office of the CMS Docket Clerk. After the expiration of the period for post hearing brief, the presiding officer would certify the record and recommendation to the Administrator. The Administrator would serve a copy to the parties who have 20 days to file exceptions or support to the recommendation. The Administrator would then issue its final decision within 60 days. The decision of the Administrator under this section is the final decision of the Secretary and constitutes ''final agency action'' within the meaning of 5 U.S.C. 704 and a ''final determination'' within the meaning of section 1116(a)(3) of the Act and § 430.38. Should the Administrator preside directly, they will issue a decision within 60 days after expiration of the period for submission of post hearing briefs. Hearings using this CMS/OHI and Administrator review process most often take over 1 year to reach final resolution.

We believe the Board would be the most appropriate entity to hear appeals of disapprovals of SDPs proposals for the following reasons. Foremost, while both the Board's and OHI's processes can resolve disputes, we believe the Board's shorter goal resolution time of 6 to 9 months would better facilitate timely approval of managed care plan contracts and the payment of capitation payments. Medicaid managed care uses a prospective payment system of capitation payments and anything that delays approval of the managed care plans' contracts can have a significant adverse impact on a State's managed care program. Additionally, the Board's processes have the added flexibilities of allowing for mediation under 45 CFR 16.18, as well as not requiring, but allowing, a hearing, as described in 45 CFR 16.11. These differences in the Board regulations give additional options and possible efficiencies to the parties. Therefore, while we believe both processes would be adequate for appeals of any disapproval of a State directed payment, for the reasons described above, we believe the processes under the Board would be the most appropriate proposal for inclusion in § 430.3(d).

We seek public comment on whether the Board or OHI appeals processes would best serve the purposes of resolving disputes fairly and efficiently.

o. Reporting Requirements To Support Oversight (§ 438.6(c)(4))

Many States with managed care programs are using the authority in § 438.6(c) to direct managed care plans' payments to certain providers. States' increasing use of these arrangements has been cited as a key area of oversight risk for CMS. Several oversight bodies, including MACPAC, OIG, and GAO, have authored reports focused on CMS oversight of SDPs.[118] [119] [120] Both GAO and MACPAC have recommended that we collect and make available provider-specific information about Medicaid payments to providers, including SDPs.

As discussed in section I.B.3. of this proposed rule, CMS' current review and approval process for SDPs is prospective; that is, we do not consistently nor systematically review the actual amounts that States provide to managed care plans for these SDPs [121] nor the actual amounts that managed care plans pay to providers. CMS published a revised preprint form in January 2021 that requires States to provide an estimated total dollar amount that will be included in the capitation rates for the SDP arrangement; [122] however, States are not required to report to CMS on the actual expenditures associated with these arrangements in any separate or identifiable way. On a limited basis, we perform in-depth State-level medical loss ratio (MLR) reviews and Financial Management Reviews (FMRs) that include the actual amounts paid through SDPs. But without the systematic collection of actual payment amounts, we cannot determine exactly how much is being paid under these arrangements, to what extent actual expenditures differ from the estimated dollar amounts approved by CMS under a State's proposal, and whether Federal funds are at risk for impermissible or inappropriate payments.

We concur with the oversight bodies that it is important that we gain more information and insight into actual SDP spending to help us fulfill our oversight and monitoring obligations. We propose two approaches, one near term and one longer term, for collecting both aggregate and provider-level information. The first proposal would use existing MLR reporting as a vehicle to collect actual expenditure data associated with SDPs. Specifically, in § 438.8(k), we propose to require that managed care plans include SDPs and associated revenue as separate lines in their MLR reports to States; specifically, the amount of payments to providers made under SDPs that direct the managed care plan's expenditures as specified in § 438.6(c) and the payments from the State to the managed care plans for expenditures related to these SDPs. In turn, we propose to require that managed care plan-level SDP expenditure reporting be explicitly reflected in States' annual summary MLR reporting to CMS, as required under § 438.74. See section I.B.3. of this proposed rule for more information about these proposals.

We also propose to establish a new requirement at § 438.6(c)(4) for States to annually submit data, no later than 180

[117] 42 CFR 430.83.

[118] Medicaid and CHIP Payment and Access Commission, ''Oversight of Managed Care Directed Payments,'' June 2022, available at *https://www.macpac.gov/wp-content/uploads/2022/06/Chapter-2-Oversight-of-Managed-Care-Directed-Payments-1.pdf.*

[119] U.S. Department of Health and Human Services Office of the Inspector General, ''Aspects of Texas' Quality Incentive Payment Program Raise Questions About Its Ability To Promote Economy and Efficiency in the Medicaid Program,'' A–06–18–07001, December 21, 2020, available at *https://oig.hhs.gov/oas/reports/region6/61807001.asp.*

[120] U.S. Government Accountability Office, ''Medicaid: State Directed Payments in Managed Care,'' June 28, 2022, available at *https://www.gao.gov/assets/gao-22-105731.pdf.*

[121] Consistent with the requirements for separate payment terms outlined in the Medicaid managed care rate guide, CMS requires States to (1) submit documentation to CMS includes the total amount of the payment into the rate certification's rate cells consistent with the distribution methodology included in the approved State directed payment preprint, as if the payment information had been known when the rates were initially developed; and (2) submit a rate amendment to CMS if the total amount of the payment or distribution methodology is changed from the initial rate certification.

[122] *https://www.medicaid.gov/medicaid/managed-care/downloads/sdp-4386c-preprint-template.pdf.*

days after each rating period, to CMS' Transformed Medicaid Statistical Information System (T–MSIS), and in any successor format or system designated by CMS, specifying the total dollars expended by each MCO, PIHP, and PAHP for SDPs that were in effect for the rating period, including amounts paid to individual providers. The purpose of this reporting would be to gain more information and insight into actual SDP spending at the individual provider-level. As MACPAC noted in their June 2022 Report to Congress, ''[State directed payments] are a large and rapidly growing form of Medicaid payments to providers, but we do not have provider-level data on how billions of dollars in directed payments are being spent''.[123] The Commission noted that SDPs are larger than Disproportionate Share Hospital (DSH) and Upper Payment Limit (UPL) supplemental payments, but there is much less data on who is receiving them.[124] Currently, States must provide CMS with specific information for FFS supplemental payments that are made to individual providers; however, there is no such requirement for States or managed care plans to provide this type of quantitative, provider-specific data separately for SDPs. We believe implementing a provider-level SDP reporting requirement would facilitate our understanding of provider-level Medicaid reimbursement across delivery systems.

We propose to develop and provide the form through which the reporting would occur so that there would be one uniform template for all States to use. We propose in § 438.6(c)(4) the minimum data fields that would need to be collected to provide the data needed to perform proper oversight of SDPs. Proposed § 438.6(c)(4)(i) through (v) outlines the minimum data fields: provider identifiers, enrollee identifiers, managed care plan identifiers, procedure and diagnosis codes, and allowed, billed, and paid amounts. Paid amounts would include the amount that represents the managed care plan's negotiated payment amount, the amount of the State directed payments, the amount for any pass-through payments under § 438.6(d), and any other amounts included in the total paid to the provider. When contemplating the FFS supplemental payment reporting, we considered how States should have the information being requested readily available, ''[i]ncluding the provider-specific payment amounts when approved supplemental payments are actually made and claimed for FFP, as the aggregate expenditures reported on the CMS–64 comprise the individual, provider-specific payment amounts''.[125] Similarly, we believe States and their managed care plans already collect provider-level SDP data, including the negotiated rate between the plan and provider and any additional SDPs (or pass-through payments specified at § 438.6(d)) that are made to the provider. We seek comment on whether these are the appropriate minimum data fields to require and what provider-level SDP data States currently collect as part of their monitoring and oversight of SDPs.

We recognize that there are existing data collection processes and systems established between CMS and States that could likely support this SDP reporting, and would like to rely on these systems to the extent they could help minimize additional or duplicative reporting by States. For instance, we considered the existing system and reporting structure that States are using for FFS supplemental payment reporting. The Consolidated Appropriations Act (CAA) of 2021 established new reporting requirements for Medicaid FFS supplemental payments under both State plan or demonstration authorities consistent with section 1902(a)(30)(A) of the Act.[126] [127] We issued guidance in December 2021 outlining the information that States must report to CMS as a condition of approval for a State plan or SPA that would provide for a supplemental payment, beginning with supplemental payments data about payments made on or after October 1, 2021.

Under these FFS requirements, each quarter, each State must submit reports on supplemental payment data through the Medicaid Budget and Expenditure System (MBES), as a requirement for a State plan or State plan amendment that would provide for a supplemental payment. The data collection involves both narrative information, as well as quantitative, provider-specific data on supplemental payments. The narrative information includes descriptions of the supplemental payment methodology, determination of eligible providers, description of the timing of the payments, and justification for compliance with section 1902(a)(30)(A) of the Act. The quantitative, provider-specific data collection includes detailed provider-specific accounting of supplemental payments made within the quarter, including: provider name, provider ID number, and other provider identifiers; Medicaid authority (FFS or demonstration authority); Medicaid service category for the supplemental payments; aggregate base payments made to the provider; and aggregate supplemental payments made to the provider, which will reflect the State's claim for Federal financial participation.

This supplemental payment reporting is included in the MBES to capture the entire set of data reporting elements required in section 1903(bb)(1)(B) of the Act in one central location. MBES is familiar to States, in part because of State's quarterly expenditure reporting on the CMS–64 form. We can view additional reporting of provider-specific base and supplemental FFS payment amount information in MBES in the context of actual State expenditures for Medicaid. We could consider taking a similar approach for SDPs by adding reporting in MBES to capture provider-specific SDP data.

As another option, we considered encounter data reported through T–MSIS as the method for collecting SDP provider-specific payment amounts. Specifically, T–MSIS could work well for SDPs that are specifically tied to an encounter or claim, such as minimum fee schedules or uniform dollar or percentage increases. Current regulations at § 438.242(c)(3) require States to submit all enrollee encounter data, including the allowed amount and paid amounts, and these paid amounts should be inclusive of State directed payments that are tied to an encounter or claim. We could build additional data fields in T–MSIS to capture more details about the paid amount, including the amount that was the managed care plan's negotiated payment amount, the amount of the State directed payments, the amount for any pass-through payments under § 438.6(d), and any other amounts included in the total payment amount paid to the provider. This level of detail would provide the information we need for analysis and

[123] Medicaid and CHIP Payment and Access Commission, ''Oversight of Managed Care Directed Payments,'' June 2022, available at *https://www.macpac.gov/wp-content/uploads/2022/06/Chapter-2-Oversight-of-Managed-Care-Directed-Payments-1.pdf.*

[124] Medicaid and CHIP Payment and Access Commission, ''Oversight of Managed Care Directed Payments,'' June 2022, available at *https://www.macpac.gov/wp-content/uploads/2022/06/Chapter-2-Oversight-of-Managed-Care-Directed-Payments-1.pdf.*

[125] *https://www.medicaid.gov/federal-policy-guidance/downloads/smd21006.pdf.*

[126] The CAA included Division CC, Title II, Section 202 (section 202), which added section 1903(bb) of the Act to specify new supplemental payment reporting requirements.

[127] Demonstration authority includes uncompensated care (UC) pool payments, delivery system reform incentive payments (DSRIP), and possibly designated State health program (DSHP) payments to the extent that such payments meet the definition of supplemental payment as specified in section 1903(bb)(2) of the Act.

oversight of SDP spending, and it would be consistent with the managed care plan payment analysis proposed in § 438.207(b)(3) (see section I.B.1.d. of this proposed rule). There are various fields currently captured in T–MSIS via monthly encounter submissions (for example, national provider identifier, enrollee identifiers, managed care plan identifiers, procedure and diagnosis codes, billed, allowed, and paid amounts) that could help us determine provider-specific SDP reimbursement. We believe utilizing T–MSIS in this manner would substantially reduce unnecessary or duplicative reporting from States, would be an effective method to collect the data with minimal additional burden on managed care plans and States, and it would enable comprehensive analyses since the data would be included with all other T–MSIS data.

Lastly, we considered whether to utilize a separate reporting mechanism for this new reporting of SDP provider-level data. For example, we could explore building a new reporting portal, similar to the one developed for the submission of the Managed Care Program Annual Report. However, this would take considerable time and resources to develop and would be separate and distinct from all other SDP data, making it more difficult to perform comprehensive analyses. We also considered whether to permit States to submit the proposed reporting using a Word or Excel template sent to a CMS mailbox. While this would be the fastest way to collect the data, it too presents challenges for integrating the data with other data collected by CMS for analyses.

Because we believe T–MSIS to be the most efficient option, we propose in § 438.6(c)(4) to require States to submit data to T–MSIS as the method for collecting provider-specific payment amounts under SDPs. As specified in proposed § 438.6(c)(4)(i)(E), provider-specific paid amounts would include a plan's negotiated payment amount, the amount of the State directed payments, the amount for any pass-through payments under § 438.6(d), and any other amounts included in the total paid to the provider. States would submit this data to CMS no later than 180 days after each rating period. We believe 180 days permits adequate time for claims run out, submission of the necessary data to the State, and for the State to format the data for submission to CMS. We also propose in § 438.6(c)(4) that States would have to comply with this new reporting requirement after the rating period that begins after we release reporting instructions for submitting the information required by this proposal. We seek public comment on our proposal to use T–MSIS for this new reporting, or whether another reporting vehicle such as MBES, or other alternatives described in this proposed rulemaking would be better suited for SDP reporting. We also seek comment on how T–MSIS or another reporting vehicle could support capturing value-based payment arrangements in which payment is not triggered by an encounter or claim.

We also propose a conforming requirement at § 438.6(c)(5)(iv) to align with the proposal in § 438.6(c)(4); proposed paragraph (c)(5)(iv) would require States to document any reporting requirements necessary to comply with § 438.6(c)(4) in their managed care contracts.

We consider these data reporting proposals to be a two-prong approach, with the MLR proposed requirements explained in section I.B.3. of this proposed rule serving as a short-term step and the provider-specific data reporting proposed here being a longer-term initiative. We believe this would ensure the appropriate content and reporting while also giving States sufficient time to prepare for each proposal based on the level of new burden. While some managed care plans and States may assert that these proposals increase administrative burden unnecessarily, we believe that the increased transparency associated with these enhanced standards would benefit both State and Federal government oversight of SDPs. Implementing these proposals for State and managed care plan reporting of actual SDP expenditures would provide CMS more complete information when evaluating, developing, and implementing possible changes to Medicaid payment policy and fiscal integrity policy.

For discussion on the proposed applicability dates for the proposals outlined in this section, see section I.B.2.p. of this proposed rule.

We solicit public comment on these proposals.

p. Applicability and Compliance Dates (§§ 438.6(c)(4) and (c)(8), and 438.7(g)(2))

We propose that States and managed care plans would have to comply with § 438.6(a), (c)(1)(iii), (c)(2)(i), (c)(2)(ii)(A) through (C), (c)(2)(ii)(E), (c)(2)(ii)(G), (c)(2)(ii)(I) through (J), (c)(2)(vi)(A), (c)(3), (c)(6)(i) through (iv), and 438.7(c)(4), (c)(5), and (f)(1) through (3) upon the effective date of the final rule, as these proposals are either technical corrections or clarifications of existing policies and standards. We propose that States and managed care plans would have to comply with § 438.6(c)(2)(iii), (vi)(B), (vi)(C)(*1*) and (*2*) no later than the first rating period for contracts with MCOs, PIHPs and PAHPs beginning on or after the effective date of the final rule as these newly proposed requirements will provide States with increased flexibility and not require States to make changes to existing arrangements. We propose that States and managed care plans would have to comply with § 438.6(c)(2)(ii)(H), (c)(2)(vi)(C)(*3*) and (*4*), (c)(2)(vii), (c)(2)(viii) and (ix), and (c)(5)(i) through (v) no later than the first rating period for contracts with MCOs, PIHPs and PAHPs beginning on or after 2 years after the effective date of the final rule. We believe this is a reasonable timeframe for compliance because it allows States sufficient time to operationalize the timelines and requirements for preprint submissions that are newly established in these proposals while balancing the need to strengthen CMS oversight.

We further propose that States and managed care plans would have to comply with § 438.6(c)(2)(ii)(D), (F), (c)(2)(iv), (c)(2)(v), and (c)(7) no later than the first rating period for contracts with MCOs, PIHPs and PAHPs beginning on or after 3 years after the effective date of the final rule as we believe States will need a sufficient period of time to address the policy elements within these proposals and operationalize them via various reporting, documentation and submission processes. For § 438.6(c)(2)(ii)(D) and (F), (c)(2)(iv) and (v), and (c)(7), we are considering requiring compliance for the first rating period beginning on or after 1 year, or 2 years after the effective date of the final rule, but we are proposing the first rating period beginning on or after 3 years after the effective date of the final rule because we believe it strikes a balance between the work States would need to do to comply with these proposals and the urgency with which we believe these proposals should be implemented in order to strengthen and ensure appropriate and efficient operation of the Medicaid program. We solicit comment on the proposal and alternatives.

We propose that States and managed care plans would have to comply with §§ 438.6 (c)(5)(vi), and (c)(6)(v), and 438.7(c)(6) and (f)(4) no later than the first rating period for contracts with MCOs, PIHPs and PAHPs beginning on or after 4 years after the effective date of the final rule. Because these proposals establish new submission

timelines and new requirements for contract and rate certification documentation, and because States could view the new requirements as substantial changes to the SDP process, we are proposing a longer timeline for compliance. We are considering requiring compliance no later than the first rating period beginning on or after 3 years after effective date of the final rule to align with the compliance dates in the proposals described in the paragraph above; however, to provide States adequate time to implement strong policies and procedures to address the newly proposed requirements before submitting the relevant contract and rate certification documentation, we are proposing the longer period for States to adjust and come into compliance. We solicit comment on the proposal and alternative.

Finally, as outlined in proposed § 438.6(c)(4), States would be required to submit the initial TMSIS report subsequent to the first rating period following the release of CMS guidance on the content and form of the report.

We have proposed these applicability dates in §§ 438.6(c)(4) and (c)(8), and 438.7(g).

We solicit public comment on these proposals.

3. Medical Loss Ratio (MLR) Standards (§§ 438.8, 438.3, and 457.1203)

In the 2016 final rule, we finalized Medicaid and CHIP managed care regulations in §§ 438.8(k) and 457.1203(f) respectively, that require managed care plans to annually submit reports of their MLR to States, and, at §§ 438.74 and 457.1203(e) respectively, we require States to submit annually a summary of those reports to CMS. These sections were issued based on our authority under sections 1903(m)(2)(A)(iii), 1902(a)(4), and 2101(a) of the Act based on the rationale that actuarially sound capitation rates must be utilized for MCOs, PIHPs, and PAHPs. Additionally, actuarial soundness requires that capitation payments cover reasonable, appropriate, and attainable costs in providing covered services to enrollees in Medicaid managed care programs. We propose to amend our requirements under the same authority and rationale that we describe below.

Medical loss ratios are one tool that CMS and States can use to assess whether capitation rates are appropriately set by generally illustrating how capitation funds are spent on claims and quality improvement activities as compared to administrative expenses. More specifically, MLR calculation and reporting can be used to demonstrate that adequate amounts of the capitation payments are spent on services for enrollees. With MLR reporting, States have more information to understand how the capitation payments made for enrollees in managed care programs are expended, resulting in responsible fiscal stewardship of total Medicaid and CHIP expenditures.

Medicaid and CHIP managed care MLR reporting requirements align, generally, with Marketplace standards for Qualified Health Plans (QHPs) and Medicare Advantage standards for Medicare Advantage organizations (MAOs). As we noted in the preamble to the 2015 managed care proposed rule,[128] alignment with Marketplace or Medicare Advantage standards supports administrative simplicity for States and health plans to manage health care delivery across different product lines and eases the administrative burden on issuers and regulators that work in all of those contexts and markets (80 FR 31101). We also noted that a consistent methodology across multiple markets (private, Medicare, Medicaid, and CHIP) would allow for administrative efficiency for the States in their roles regulating insurance and Medicaid/CHIP, and for issuers and managed care plans to collect and measure data necessary to calculate an MLR and provide reports. In addition, a consistent standard would allow comparison of MLR outcomes consistently from State to State and among commercial, Medicare, and Medicaid/CHIP managed care plans (80 FR 31107).

In general, Medicaid and CHIP managed care MLR reporting requirements have remained aligned over time with the Marketplace MLR requirements; however, CMS finalized some regulatory changes for QHP MLR reporting in 45 CFR 158.140, 158.150, and 158.170 effective July 1, 2022.[129] To keep the Medicaid and CHIP managed care regulations aligned with these new Marketplace provisions, we propose several revisions to our requirements in the following areas:

- Requirements for clinical or quality improvement standards for provider incentive arrangements;
- Prohibited administrative costs in quality improvement activity (QIA) reporting; and
- Additional requirements for expense allocation methodology reporting.

In addition, we propose changes to specify timing of updates to credibility adjustment factors; when Medicaid and CHIP managed care plans are required to resubmit MLR reports to the State; the level of data aggregation required for State MLR summary reports to CMS; contract requirements related to reporting of overpayments; and new reporting requirements for SDPs.

a. Standards for Provider Incentives (§§ 438.3(i), 438.8(e)(2), 457.1201, and 457.1203)

We are revising standards for provider incentives to remain consistent with our goals of alignment with the Marketplace when appropriate, and to ensure that capitation rates are actuarially sound and based on reasonable expenditures for covered services under the contract. Under section 1903(m)(2)(A)(iii) of the Act and implementing regulations, FFP is not available for State expenditures incurred for payment (as determined under a prepaid capitation basis or under any other risk basis) for services provided by a managed care plan unless the prepaid payments are made on an actuarially sound basis. This requirement is made applicable to PIHPs and PAHPs under authority in section 1902(a)(4) of the Act. As specified in current regulations at § 438.4(a), actuarially sound Medicaid capitation rates are projected to provide for all reasonable, appropriate, and attainable costs as well as the operation of the MCO, PIHP, or PAHP required under the terms of the contract.

While Medicaid managed care plans are required to calculate and report an MLR to the State, States are not required to establish a minimum MLR requirement; although under current regulations at § 438.4(b)(9), capitation rates must be developed in a way that the managed care plan would reasonably achieve an MLR of at least 85 percent. Under current regulations at § 438.8(c), if a State elects to require that their managed care plans meet a minimum MLR requirement, the minimum must be set to at least 85 percent. Further, under § 438.8(j), States may establish a remittance arrangement based on an MLR requirement of 85 percent or higher. As a general matter, remittance arrangements based on minimum MLRs may provide value to States by requiring managed care plans to remit a portion of their capitation payments to States when spending on covered services and QIAs is less than the minimum MLR requirements.

[128] *https://www.govinfo.gov/content/pkg/FR-2015-06-01/pdf/2015-12965.pdf.*

[129] *https://www.federalregister.gov/documents/2022/05/06/2022-09438/patient-protection-and-affordable-care-act-hhs-notice-of-benefit-and-payment-parameters-for-2023.*

At existing §§ 438.3(i)(1) and 457.1201(h), respectively, Medicaid and CHIP managed care plan contracts must require compliance with the provider plan incentive requirements in §§ 422.208 and 422.210.[130] In this section, we refer to the term ''incentive'' to mean both incentive and bonus payments to providers. Under § 422.208(c), managed care plans may enter into a physician incentive plan with a health care provider, but plans must meet requirements applicable to those arrangements in § 422.208(c) through (g), and under § 422.208(c)(1) plans cannot make a payment, directly or indirectly, as an inducement to reduce or limit medically necessary services. A Medicaid and CHIP managed care plan may make incentive payments to a provider if the provider agrees to participate in the plan's provider network. These payment arrangements may be based solely on an amount negotiated between the plan and the provider. Medicaid and CHIP managed care plans can implement provider incentive arrangements that are not based on quality improvement standards or metrics; however, provider incentive payments must be included as incurred claims when managed care plans calculate their MLR, per §§ 438.8(e)(2)(iii)(A) and 457.1203(c) respectively. Further, provider incentive payments may influence the development of future capitation rates, and Medicaid managed care plans may have a financial incentive to inappropriately pay provider incentives when the plans are unlikely to meet minimum MLR requirements. Additionally, these payments may inappropriately inflate the numerator of the MLR calculation and reduce or eliminate remittances, if applicable. Additionally, including such data in the base data used for rate development may inappropriately inflate future capitation rates.

Vulnerabilities With Managed Care Plans' Provider Incentive Contracting Practices

As part of our Medicaid managed care program integrity oversight efforts, CMS recently conducted several in-depth reviews of States' oversight of managed care plan MLR reporting. These reviews included examinations of the contract language for provider incentive arrangements between managed care plans and network providers. As part of these reviews, CMS identified several examples of managed care plan practices that could make an incentive payment inappropriate to include in the numerator. For example, there were inconsistent documentation and contracting practices for incentive payments in contracts between some Medicaid managed care plans and their network providers, including State acceptance of attestations of these arrangements from senior managed care plan leadership when contract documentation was lacking. These reviews also noted that many managed care plans' contracts with network providers did not base the incentive payments on a requirement for the providers to meet quantitative clinical or quality improvement standards or metrics. In fact, examination of these contracts between managed care plans and their network providers revealed that some managed care plans did not require a provider to improve their performance in any way to receive an incentive payment. Additionally, many of the incentive arrangements were not developed prospectively with clear expectations for provider performance. Finally, we identified provider incentive performance periods that did not align with the MLR reporting period and provider incentive contracts that were signed after the performance period ended.

Contract Requirements for Provider Incentive Payment Arrangements

Based on these reviews, we are concerned that if a provider incentive arrangement is not based on basic core contracting practices (including sufficient supporting documentation and clear, prospective quantitative quality or performance metrics), it may create an opportunity for a managed care plan to more easily pay network providers solely to expend excess funds to increase their MLR numerator under the guise of paying incentives. This potential loophole could also be used to help managed care plans avoid paying remittances. Also, this practice could artificially inflate future capitation rates. To address these concerns, we are proposing additional requirements on provider incentive arrangements in § 438.3(i).

In a new § 438.3(i)(3) and (4) for Medicaid, and included in separate CHIP regulations through an existing cross-reference at § 457.1201(h), we propose to require that the State, through its contract(s) with a managed care plan, must include specific provisions related to provider incentive contracts. Specifically, the proposed changes would require in § 438.3(i)(3)(i) and (ii) that incentive payment contracts between managed care plans and network providers have a defined performance period that can be tied to the applicable MLR reporting period(s), and such contracts must be signed and dated by all appropriate parties before the commencement of the applicable performance period. We also propose, in § 438.3(i)(3)(iii), that all incentive payment contracts must include well-defined quality improvement or performance metrics that the provider must meet to receive the incentive payment. In addition, in § 438.3(i)(3)(iv), we propose that incentive payment contracts must specify a dollar amount that can be clearly linked to successful completion of these metrics as well as a date of payment. We note that managed care plans would continue to have flexibility to determine the appropriate quality improvement or quantitative performance metrics to include in the incentive payment contracts. In addition, the proposed changes would also require in § 438.3(i)(4)(i) that the State's contracts must define the documentation that the managed care plan must maintain to support these arrangements. In § 438.3(i)(4)(ii), we propose that the State must prohibit managed care plans from using attestations as documentation to support the provider incentive payments. In § 438.3(i)(4)(iii), we propose that the State's contracts require that managed care plans must make the incentive payment contracts and supporting documentation available to the State both upon request and at any routine frequency that the State establishes. Finally, we propose that States and managed care plans would have to comply with § 438.3(i)(3) and (4) no later than the rating period for contracts with MCOs, PIHPs, and PAHPs beginning on or after 60 days following the effective date of the final rule as we believe this is a reasonable timeframe for compliance. Therefore, we have proposed this applicability date in § 438.3(v) for Medicaid, and through a proposed cross-reference at § 457.1200(d) for separate CHIPs, and we seek public comment on this proposal. Other changes proposed to § 438.3(v) are outlined in section I.B.4.i. of this proposed rule.

We also propose to amend § 438.608 to cross-reference these requirements in the program integrity contract requirements section. Specifically, we propose to add a new § 438.608(e) that notes the requirements for provider incentives in § 438.3(i)(3) and (4). This proposed requirement is equally

[130] As specified in § 438.3(i)(2), in applying the provisions of §§ 422.208 and 422.210 of this chapter, references to ''MA organization,'' ''CMS,'' and ''Medicare beneficiaries'' must be read as references to ''MCO, PIHP, or PAHP,'' ''State,'' and ''Medicaid beneficiaries,'' respectively.

applicable for separate CHIPs through an existing cross-reference at § 457.1285.

Alignment With Marketplace Regulations for Provider Incentive Arrangements [131]

Effective July 1, 2022, the Marketplace regulations at 45 CFR 158.140(b)(2)(iii) were revised to require issuers to tie provider bonuses and incentives payments to clearly-defined, objectively measurable, and well-documented clinical or quality improvement standards for these costs to qualify as expenditures in the MLR numerator. In contrast, current Medicaid and CHIP managed care regulations for provider incentive arrangements do not require these payments to be based on quality or performance metrics. This inconsistency hinders the comparison of MLR data between the Marketplace issuers and Medicaid and CHIP managed care plans, which is important given the high number of health plans that are both sold in the Marketplace and Medicaid managed care plans as well as the frequent churn of individuals between Marketplace, Medicaid, and CHIP coverage. To address the potential for inappropriate inflation of the MLR numerator as well as facilitate data comparability, we propose in § 438.8(e)(2)(iii)(A) for Medicaid, which is included in separate CHIP regulations through an existing cross-reference at § 457.1203(c), to require that for a provider bonus or incentive payment to be included in the MLR numerator, the provider bonus or incentive arrangement would have to require providers to meet clearly-defined, objectively measurable, and well-documented clinical or quality improvement standards to receive the bonus or incentive payment. This change would prohibit Medicaid and CHIP managed care plans from including provider bonus or incentive payments that are not based on clinical or quality improvement standards in their MLR numerator, which would improve the accuracy of their MLR, as well as other components of managed care programs that rely on reported MLRs, such as capitation rate development and remittances. Further, a consistent methodology across multiple markets would allow for administrative efficiency for the States as they monitor their Medicaid and CHIP programs, and for issuers and managed care plans to collect and measure data necessary to calculate an MLR and provide reports.

We believe that by requiring States' contracts with managed care plans to specify how provider bonus or incentive payment arrangements would be structured in managed care plans' provider contracts, transparency around these arrangements would improve. In addition, by requiring the contracts to include more specific documentation requirements, CMS and States would be better able to ensure that provider bonus or incentive payments are not being used either to inappropriately increase the MLR to avoid paying potential remittances, inflate future capitation rates, or to simply move funds from a Medicaid managed care plan to an affiliated company. The proposals would increase transparency into provider bonuses and incentives, improve the quality of care provided by ensuring that bonuses and incentives are paid to providers that demonstrated furnishing high-quality care, and protect Medicaid and CHIP programs against fraud and other improper payments. We are seeking comment on these proposed requirements, including whether any additional documentation requirements should be specified in regulation. We propose that States and managed care plans would be required to comply with these requirements 60 days after the effective date of this final rule as we believe these proposals are critical for fiscal integrity in Medicaid and CHIP. We considered an alternative compliance date of no later than the rating period for contracts with MCOs, PIHPs and PAHPs beginning on or after 60 days following the effective date of the final rule; however, we are concerned this is not soon enough. We seek comment on this proposal.

b. Prohibited Costs in Quality Improvement Activities (§§ 438.8(e)(3) and 457.1203(c))

The preamble to the Marketplace regulations that took effect on July 1, 2022 indicated that examinations of MLR reporting of issuers found ''wide discrepancies in the types of expenses that issuers include in QIA expenses'' and that inconsistency ''creates an unequal playing field among issuers'' (87 FR 692). Therefore, to provide further clarity on the types of costs that may be included in MLR calculations in the future, CMS modified Marketplace regulations for QIA expenditures in 45 CFR 158.150(a), effective July 1, 2022, to prohibit the inclusion of indirect or overhead expenses that do not directly improve health care quality when reporting QIAs.

In Medicaid and separate CHIP regulations at §§ 438.8(e)(3) and 457.1203(c) respectively, we included QIA activities that meet the Marketplace MLR requirements, but we did not explicitly include a prohibition on managed care plans including indirect or overhead expenses when reporting QIA costs in the MLR because the commercial regulations did not have this exclusion at the time. As a result, the current Medicaid MLR regulations do not require managed care plans to exclude indirect or overhead QIA expenditures. For example, expenditures for facility maintenance, utilities, or marketing may be included in the MLR even though these expenses do not directly improve health care quality. As a result, Medicaid or CHIP managed care plans may include these types of costs as QIA costs in the MLR numerator, which could result in inappropriately inflated MLRs, and a different standard existing in the Marketplace and Medicaid and CHIP markets. This difference in standards could pose a potential administrative burden for managed care plans that participate in both Medicaid and CHIP and the Marketplace because managed care plans may include different types of expenses in reporting QIA.

To align Medicaid and CHIP MLR QIA reporting requirements with the Marketplace requirements and to improve clarity on the types of QIA expenditures that should be included in the MLR numerator, we propose to amend § 438.8(e)(3)(i) for Medicaid, which is included in separate CHIP regulations through an existing cross-reference at § 457.1203(c), to add a reference to the Marketplace regulation that prohibits the inclusion of overhead or indirect expenses that are not directly related to health care quality improvement. This change would provide States with more detailed QIA information to improve MLR reporting consistency, allow for better MLR data comparisons between the Marketplace and Medicaid and CHIP markets, and reduce administrative burden for managed care plans that participate in both Medicaid and CHIP and the Marketplace. We propose that these requirements would be effective 60 days after the effective date of this final rule as we believe these proposals are critical for fiscal integrity in Medicaid and CHIP. We considered an alternative effective date of no later than the rating period for contracts with MCOs, PIHPs and PAHPs beginning on or after 60 days following the effective date of the final rule; however, we are concerned this is not soon enough. We seek

[131] *https://www.federalregister.gov/documents/2022/05/06/2022-09438/patient-protection-and-affordable-care-act-hhs-notice-of-benefit-and-payment-parameters-for-2023.*

comment on the applicability date for these proposals.

c. Additional Requirements for Expense Allocation Methodology (§§ 438.8(k)(1)(vii) and 457.1203(f))

As specified in current regulations at §§ 438.8(k)(1)(vii) and 457.1203(f) respectively, Medicaid and CHIP managed care plans must provide a report of the methodology or methodologies that they used to allocate certain types of expenditures for calculating their MLR. Examples of these types of expenditures include overhead expenses such as facility costs or direct expenses such as employee salaries. If a plan operates multiple lines of business, for example in both Medicaid and the Marketplace, it must indicate in the Medicaid MLR report how the share of certain types of costs were attributed to the Medicaid line of business. However, the Medicaid MLR regulations in § 438.8(g) and (k)(1)(vii) do not require managed care plans to submit information about the types of expenditures allocated to the Medicaid line of business and do not require managed care plans to specify how each type of expenditure was allocated to the Medicaid MLR.

Recent CMS State-level Medicaid MLR reviews noted a lack of expense allocation information in managed care plans' MLR reports to States. Specifically, CMS determined that several plans operated in multiple markets, for example, Medicaid and Medicare Advantage, and failed to adequately describe how certain costs that may apply across multiple lines of business were allocated to the Medicaid MLR report. Examples of these expenses include: quality improvement expenses, taxes, licensing or regulatory fees, and non-claims costs. The impact of this lack of transparency is that it may be impossible for a State to determine if the managed care plan's allocation of the applicable expenses to the Medicaid line of business was reasonable. For example, if a managed care plan operating in multiple markets does not provide information on how quality improvement activity expenses were allocated to the Medicaid MLR, the State will be unable to determine if the MLR numerator is inappropriately inflated.

The Marketplace regulations in 45 CFR 158.170(b) require significantly more detail for expense allocation in QHPs' MLR reporting. Specifically, § 158.170(b) requires a description of the types of expenditures that were allocated, how the expenses met the criteria for inclusion in the MLR, and the method(s) used to aggregate these expenses. We propose to require in § 438.8(k)(1)(vii) for Medicaid, which is included in CHIP regulations through an existing cross-reference at § 457.1203(f), that managed care plans must include information that reflects the same information required under Marketplace requirements in the MLR report that they submit to the State. Specifically, in § 438.8(k)(1)(vii), we propose to add to the existing text that plans' descriptions of their methodology must include a detailed description of the methods used to allocate expenses, including incurred claims, quality improvement expenses, Federal and State taxes and licensing or regulatory fees, and other non-claims costs, as described § 158.170(b). These revisions would improve State MLR oversight by providing States with more detailed information to ensure the appropriateness of managed care plans' expense allocation. These proposed requirements would align with Marketplace regulations and reduce administrative burden for managed care plans. We propose that States and managed care plans would be required to comply with these requirements 60 days after the effective date of this final rule as we believe these proposals are critical for fiscal integrity in Medicaid and CHIP. We considered an alternative compliance date of no later than the rating period for contracts with MCOs, PIHPs and PAHPs beginning on or after 60 days following the effective date of the final rule; however, we are concerned that is not soon enough. We seek comment on this proposal.

d. Credibility Factor Adjustment to Publication Frequency (§§ 438.8(h)(4) and 457.1203(c))

Section 2718(c) of the Public Health Service Act charged the National Association of Insurance Commissioners (NAIC) with developing uniform methodologies for calculating measures of the expenditures that make up the MLR calculation, and to address the special circumstances of smaller plans. The NAIC model regulation allows smaller plans to adjust their MLR calculations by applying a ''credibility adjustment.'' Under §§ 438.8(h) and 457.1203(c) respectively, Medicaid and CHIP managed care calculated MLRs may be adjusted using credibility factors to account for potential variability in claims due to random statistical variation. These factors are applied to plans with fewer enrollees to adjust for the higher impact of claims variability on smaller plans. As stated in § 438.8(h)(4), CMS is responsible for developing and publishing these factors annually for States and managed care plans to use when reporting MLRs for plans with fewer enrollees. In the 2015 Medicaid and CHIP managed care proposed rule (80 FR 31111), we proposed adopting a credibility adjustment methodology along with assurances to monitor and reevaluate credibility factors ''in light of developing experience with the Affordable Care Act reforms.'' In the 2015 proposed rule (80 FR 31111), we also proposed to update the credibility adjustment method within the parameters of the methodology proposed in that proposed rule. We finalized this proposal without revision in the 2016 final rule (81 FR 27864). The Medicaid managed care credibility adjustment factors were published on July 31, 2017 at *https://www.medicaid.gov/federal-policy-guidance/downloads/cib073117.pdf.*

Since this publication of the credibility adjustment factors in 2017, the factors have not changed. The factors were originally developed using a statistical model applying the Central Limit Theorem (80 FR 31111). This model produced credibility factors that were not expected to change annually. Therefore, we believe that annual updates to these factors are not required, and we propose to modify § 438.8(h)(4) for Medicaid, which is included in separate CHIP regulations through an existing cross-reference at § 457.1203(c), to remove ''On an annual basis.'' If we determine that the factors need to be updated, we would use the methodology specified at § 438.8(h)(4)(i) through (vi). We are not proposing any revisions to § 438.8(h)(4)(i) through (vi) in this rule. We propose that these changes would be effective 60 days after the effective date of this final rule as we believe this timeframe is reasonable. We seek comment on this proposal.

e. MCO, PIHP, or PAHP MLR Reporting Resubmission Requirements (§§ 438.8(m) and 457.1203(f))

Medicaid and CHIP managed care plans are required to resubmit MLR reports to States under certain circumstances. In the 2015 managed care proposed rule preamble, we noted that States may make retroactive changes to capitation rates that could affect the MLR calculation for a given MLR reporting year and that when that occurred, the MCO, PIHP, or PAHP would need to recalculate the MLR and provide a new report with the updated figures (80 FR 31113). We also indicated that ''In any instance where a State makes a retroactive change to the capitation payments for an MLR reporting year where the report has already been submitted to the State, the

MCO, PIHP, or PAHP must re-calculate the MLR for all MLR reporting years affected by the change and submit a new report meeting the requirements in paragraph (k) of this section.'' This regulation was finalized in 2016 without changes (81 FR 27864). However, the reference in the regulation to changes to capitation ''payments'' rather than ''rates'' has caused confusion about when managed care plans should resubmit MLR reports to the State, and has contributed to additional administrative burden by requiring plans to resubmit MLR reports to the State and by requiring States to review multiple MLR report submissions from managed care plans.

As part of our Medicaid MLR report compliance reviews, we have heard from several States that MLR reports from MCOs, PIHPs, or PAHPs are often resubmitted to the State. These resubmissions usually resulted from payments the State made to the managed care plan as part of the retroactive eligibility review process. As part of this process in these States, the State reviews beneficiary eligibility records to determine if an individual qualifies for retroactive eligibility. If an enrollee qualifies for retroactive eligibility, the State modifies the number of capitation payments that were made to a plan; however, the State does not retroactively modify the capitation rate for a group of members. When a State modifies the number of payments, but not the rate of payment to a managed care plan, we believe that it is unnecessary for a plan to resubmit the MLR to the State. For separate payment terms, only used for SDPs, the proposed regulation changes would require the State to document in the managed care plan contracts the total dollars that the State would pay to the plans for the individual State directed payment; the timing and frequency of payments that would be made under the separate payment term from the State to the plans; a description or reference to the contract requirement for the specific State directed payment for which the separate payment term would be used; and any reporting that the State requires to ensure appropriate reporting of the separate payment term for purposes of MLR reporting under § 438.8. If the State modifies a separate payment term, the MLR would need to be resubmitted to the State. See further details in section I.B.2.l. of this proposed rule.

We propose to amend § 438.8(m) for Medicaid, which is included in separate CHIP regulations through an existing cross-reference at § 457.1203(f), to specify that an MCO, PIHP, or PAHP would only be required to resubmit an MLR report to the State when the State makes a retroactive change to capitation rates. Specifically, we propose to replace ''payments'' with ''rates'' and to insert ''retroactive rate'' before the word ''change.'' These changes would decrease administrative burden for both managed care plans and States by reducing the number of MLR report submissions while retaining our original intent. We propose that these changes would be effective 60 days after the effective date of this final rule as we believe this timeframe is reasonable to alleviate State and plan administrative burden. We considered an alternative effective date no later than the rating period for contracts with MCOs, PIHPs and PAHPs beginning on or after 60 days following the effective date of the final rule; however, we do not believe additional time is necessary. We seek comment on this proposal.

f. Level of MLR Data Aggregation (§§ 438.74 and 457.1203(e))

As specified in existing requirements at §§ 438.8(k) and 457.1203(f) respectively, Medicaid and CHIP managed care plans are required to submit detailed MLR reports to States, and States, as required in § 438.74 for Medicaid and § 457.1203(e) for separate CHIP, must submit a summary description of those reports to CMS. In the preamble to the 2015 managed care proposed rule (80 FR 31113), we described the term ''summary'' as meaning an abbreviated version of the more detailed reports required from managed care plans in § 438.8(k), but did not refer to a Statewide aggregation of data across managed care plans. The proposed regulatory text for § 438.74 did not include the words ''for each'' and was finalized as proposed. In our compliance reviews of State summary MLR reports, several States provided MLR data aggregated over the entire State and neglected to provide the abbreviated MLR report for each plan. These submissions of MLR summary reports that omitted information by plan indicate States' confusion with what is required for these reports.

To correct this issue, we propose to amend § 438.74(a) for Medicaid, which is included in separate CHIP regulations through an existing cross-reference at § 457.1203(e), to note explicitly that State MLR summary reports must include the required elements for each MCO, PIHP, or PAHP that is contracted with the State. To specify that the MLR information would have to be reported for each managed care plan, we propose in § 438.74(a)(1) to replace ''the'' with ''each'' before ''report(s).'' In addition, in § 438.74(a)(2), we propose to add language to specify that the information listed as required in the summary description must be provided for each MCO, PIHP, or PAHP under contract with the State. These changes would specify that States must provide MLR information for each managed care plan in their annual summary reports to CMS. We propose that States and managed care plans would be required to comply with these changes 60 days after the effective date of this final rule as we believe these proposals are critical for fiscal integrity in Medicaid and CHIP. We considered an alternative compliance date of no later than the rating period for MCO, PIHP and PAHP contracts beginning on or after 60 days following the effective date of the final rule; however, we are concerned this is not soon enough. We seek comment on this proposal.

g. Contract Requirements for Overpayments (§§ 438.608(a)(2) and(d)(3), and 457.1285)

In the 2016 final rule, we aimed to strengthen State and Medicaid and CHIP managed care plan responsibilities to protect against fraud and other overpayments in State Medicaid and CHIP programs, in part, by enhancing reporting requirements to support actuarial soundness payment provisions and program integrity efforts (81 FR 27606). Overpayments are defined in § 438.2 as any payment made to a network provider by a MCO, PIHP, or PAHP to which the network provider is not entitled under Title XIX of the Act or any payment to a MCO, PIHP, or PAHP by a State to which the MCO, PIHP, or PAHP is not entitled under Title XIX of the Act. These overpayments may be the result of fraud, waste, abuse, or other billing errors. Regardless of cause, overpayments should be excluded from the capitation rate because they do not represent reasonable, appropriate, or attainable costs.

The 2016 final rule also enhanced the integrity of capitation payments, in part, by requiring at § 438.608(d)(3) for Medicaid, and included in separate CHIP regulations through an existing cross-reference at § 457.1285, that State contracts with managed care plans include provisions specifying that managed care plans must report the recoveries of overpayments annually. This reporting to the State is critical to the actuarial soundness of capitation rates because managed care plans must exclude overpayments from their incurred claims, which is also a key element in the numerator of the MLR calculation. As required in § 438.5(b)(5), States must consider Medicaid managed

care plans' past reported MLR and the projected MLR in the development of capitation rates. If a managed care plan's MLR numerator does not exclude overpayments, the MLR may be inappropriately inflated. Section 438.608(d)(4) requires that the State use the results of the information and documentation collected under § 438.608(d)(3) for setting actuarially sound Medicaid capitation rates consistent with the requirements in § 438.4.

This proposed rule seeks to modify § 438.608(a)(2), which requires managed care plan contracts to include a provision for the prompt reporting of all overpayments identified or recovered (specifying those due to potential fraud) to the State; and § 438.608(d)(3), which requires managed care plan contracts to include annual reports on plan recoveries of overpayments. Both proposed changes are included in separate CHIP regulations through an existing cross-reference at § 457.1285. The proposed changes aim to ensure that Medicaid and CHIP managed care plans report comprehensive overpayment data to States in a timely manner, which would better position States to execute program integrity efforts and develop actuarially sound capitation rates.

Defining ''Prompt'' Reporting (§§ 438.608(a)(2) and 457.1285))

Current regulations at § 438.608(a)(2) require that States include a provision in their contracts with managed care plans for the prompt reporting to the State of all overpayments identified or recovered, specifying the overpayments due to potential fraud. However, the term ''prompt'' is not defined. Although a time period is not defined, prompt reporting of identified or recovered overpayments is important because it can enable a State to expeditiously take action against a provider to prevent further inappropriate activity, including potential fraud. With prompt reporting of managed care plan overpayments, the State is better equipped to identify similar overpayments and prevent future overpayments across its networks and managed care programs.

CMS' oversight efforts and other program integrity reviews have revealed that States interpret the promptness requirement under § 438.608(a)(2) inconsistently. For example, some States do not define ''prompt'' in managed care plan contracts, instead deferring to managed care plans' interpretation of the timeframe to report overpayments; this lack of definition can result in inconsistent overpayment reporting among managed care plans and States. Our reviews also revealed that some States do not use a consistent timeframe across managed care plan contracts when requiring the reporting of overpayments. As a result, managed care plans may not report identified or recovered overpayments within a timeframe that enables States to effectively and swiftly investigate and take appropriate administrative action against providers that may be committing fraudulent activities across networks and managed care programs.

We believe that establishing a uniform definition of the term ''prompt'' would provide clarity to States and managed care plans, thereby enhancing ongoing communication between managed care plans and States, particularly as it relates to program integrity practices. Therefore, we propose to amend § 438.608(a)(2) for Medicaid, and included in separate CHIP regulations through an existing cross-reference at § 457.1285, to define ''prompt'' as within 10 business days of identifying or recovering an overpayment. We believe 10 business days would provide a managed care plan sufficient time to investigate overpayments and determine whether they are due to potential fraud or other causes, such as billing errors, and also quickly provide the State with awareness to mitigate other potential overpayments across its networks and managed care programs. With a clear and consistent overpayment reporting requirement, States would be better equipped to: direct managed care plans to look for specific network provider issues, identify and recover managed care plan and fee-for-service claims that are known to be unallowable, take corrective actions to correct erroneous billing practices, or consider a potential law enforcement referral. We are seeking public comment on the proposed 10 business day timeframe and whether reporting should be from date of identification or recovery, or instead on a routine basis, such as monthly. We propose that States and managed care plans would be required to comply with these requirements 60 days after the effective date of this final rule as we believe these proposals are critical for fiscal integrity in Medicaid and CHIP. We considered an alternative effective date of no later than the rating period for contracts with MCOs, PIHPs and PAHPs beginning on or after 60 days following the effective date of the final rule; however, we do not believe additional time is necessary. We seek comment on this proposal.

Identifying Overpayment Reporting Requirements (§§ 438.608(d)(3) and 457.1285)

The overpayment reporting provisions in 42 CFR part 438, subpart H require managed care plans to recover the overpayments they identify, and in turn, report those identified overpayments to the State for purpose of setting actuarially sound capitation rates. In the 2015 proposed rule, we stated that ''MCOs, PIHPs, and PAHPs must report improper payments and recover overpayments they identify from network providers. States must take such recoveries into account when developing capitation rates. Therefore, capitation rates that include the amount of improper payments recovered by an MCO, PIHP, or PAHP as projected costs would not be considered actuarially sound.'' (80 FR 31119). It was our expectation that ''such recoveries'' include recoveries of all identified overpayments. This intent is also reflected in § 438.608(a)(2), which states that managed care plans must report both ''identified or recovered'' overpayments to the State. However, the words ''identified or'' were omitted from the related regulatory text at § 438.608(d)(3). Program integrity reviews and investigations conducted since the 2016 final rule have found that language in § 438.608(d)(3) providing that managed care plans only report ''recovered overpayments'' has created an unintentional effect of managed care plans' reporting partial overpayment data for capitation rate calculations. This omission may have also disincentivized managed care plans from investing in the resources necessary to recover identified overpayments in the interest of maintaining a higher MLR. For example, we have identified instances in which managed care plans identified an overpayment, but did not recover the entire overpayment from the provider due to negotiating or settling the overpayment to a lesser amount. In other cases, managed care plans identified an overpayment that was resolved by applying an offset to future payments to the provider instead of recovering the full overpayment in the impacted rating period. These situations resulted in the managed care plans only reporting a relatively small or no overpayment recovery amount to the State in the impacted rating period, instead of the full amount of the identified overpayment. This inconsistent reporting does not reflect our original intent in imposing the current requirements in § 438.608(d)(3), and prevents the State from accounting

for the full amount of the identified overpayment in the impacted rating period when developing capitation rates as required under § 438.608(d)(4).

To address these issues, we propose to revise § 438.608(d)(3) for Medicaid and separate CHIP regulations through an existing cross-reference at § 457.1285, to specify our original intent that any overpayment (whether identified or recovered) must be reported by Medicaid or CHIP managed care plans to the State. Through this proposed change, we believe that managed care plans and States would have more consistency in the overpayment reporting requirements at § 438.608(a)(2) and (d)(3) by requiring reporting to the State all overpayments, whether identified or recovered. By ensuring that both identified and recovered overpayments are reported, States and CMS would be more assured that capitation rates account for only reasonable, appropriate, and attainable costs covered under the contract. We propose that States and managed care plans would be required to comply with these requirements 60 days after the effective date of this final rule as we believe these proposals are critical for fiscal integrity in Medicaid and CHIP. We considered an alternative effective date no later than the rating period for contracts with MCOs, PIHPs and PAHPs beginning on or after 60 days following the effective date of the final rule; however, we are concerned that is not soon enough. We seek comment on this proposal.

h. Reporting of SDPs in the Medical Loss Ratio (MLR) (§§ 438.8(e)(2)(iii) and (f)(2), 438.74, 457.1203(e) and (f))

Many States are using the authority in § 438.6(c) to direct Medicaid managed care plans' payments to certain providers. See section I.B.2.e. of this proposed rule for more information. States' increasing use of SDP arrangements has been cited as a key area of oversight risk for CMS. Several advisory and oversight bodies, including MACPAC, the HHS OIG, and GAO, have authored reports focused on CMS oversight of SDPs.[132] [133] [134] The scope, size, and complexity of the SDP arrangements being submitted by States for approval has also grown steadily and quickly. For calendar year 2022, CMS received 298 preprints from States. In total, as of December 2022, CMS has reviewed more than 1,100 SDP proposals and approved 993 proposals since the 2016 final rule was issued.

SDPs also represent a notable amount of spending. MACPAC reported that CMS approved SDP arrangements in 37 States, with spending exceeding more than $25 billion for SDPs through 2020.[135] GAO also reported that at least $20 billion has been approved by CMS for preprints with payments to be made on or after July 1, 2021, across 79 proposals.[136]

Under our current review and approval process for SDPs we ask States to estimate projected SDP expenditures, but we do not review the actual amounts that States provide to Medicaid managed care plans for these payment arrangements, and we do not review the actual amounts that Medicaid managed care plans pay to providers. We retrospectively review SDP actual amounts as part of State-level MLR reviews and in-depth reviews of State expenditures where Federal dollars are at risk, known as Financial Management Reviews; however, these reviews are limited to only a few States each year. We do not conduct other formal retrospective reviews of actual SDP expenditures. Thus, we rarely confirm with States that SDP actual spending amounts were reasonably consistent with the CMS-approved estimated amounts. Instead, we require States to provide the estimated total payment amounts for these arrangements as part of the current approval process. We are also aware that some States are permitting managed care plans to retain a portion of SDPs for administrative costs when plans make these payments to providers. Because States are not required to provide the actual expenditures associated with these arrangements in any separate or identifiable way, we cannot determine exactly how much is being paid under these arrangements and whether Federal funds are at risk for impermissible or inappropriate payment.

We propose new reporting requirements for Medicaid SDPs in §§ 438.8 and 438.74 to align with the reporting that is currently required for Medicaid FFS supplemental payments. CMS FFS supplemental payment guidance notes that ''[i]nformation about all supplemental payments under the State plan and under demonstration is necessary to provide a full picture of Medicaid payments.'' [137] While States must provide CMS with the amounts for FFS supplemental payments, there is no requirement for States or managed care plans to provide actual payment data separately for SDPs. Implementing a new requirement for both State and managed care plan reporting of actual SDP expenditures would support CMS oversight activities to better understand provider-based payments across delivery systems.

To address the need for additional information on the actual amounts paid as SDPs, we propose to require Medicaid managed care plans to include SDPs and associated revenue as separate lines in the MLR reports required at § 438.8(k). The managed care MLR reporting requirements at § 438.8(k) were codified in the 2016 final rule, and States have substantial experience in obtaining and reviewing MLR reports from their managed care plans. To date, our MLR guidance has not addressed the inclusion of SDPs in the MLR; this proposal would specify these requirements by amending § 438.8(k) to ensure that Medicaid SDPs would be separately identified in annual MLR reporting.

Specifically, at § 438.8(e)(2)(iii)(C), we propose to require that managed care plan expenditures to providers that are directed by the State under § 438.6(c), including those that do and do not require prior CMS approval, must be included in the MLR numerator. In § 438.8(f)(2)(vii), we propose to require that State payments made to Medicaid MCOs, PIHPs, or PAHPs for approved arrangements under § 438.6(c) be included in the MLR denominator as premium revenue. We propose that States and managed care plans are required to comply with these changes in § 438.8(e)(2)(iii)(C) and (f)(2)(vii) 60 days after the effective date of the final rule as we believe these proposals are critical for fiscal integrity in Medicaid. We considered an alternative compliance date of no later than the rating period for contracts with MCOs, PIHPs and PAHPs beginning on or after 60 days following the effective date of the final rule; however, we are concerned this is not soon enough, given the fiscal integrity risks that are involved. We seek comment on this proposal.

We also propose to require that the managed care plans' MLR reports to States as required in § 438.8(k) include two additional line items. The first item at § 438.8(k)(1)(xiv) requires reporting of Medicaid managed care plan

[132] *https://www.macpac.gov/publication/june-2022-report-to-congress-on-medicaid-and-chip/ June 2022 Report to Congress on Medicaid and CHIP, Chapter 2.*

[133] *https://oig.hhs.gov/oas/reports/region6/61807001.asp.*

[134] *https://www.gao.gov/products/gao-22-105731.*

[135] *https://www.macpac.gov/wp-content/uploads/2022/06/MACPAC_June2022-WEB-Full-Booklet_FINAL-508-1.pdf.*

[136] *https://www.gao.gov/assets/gao-22-105731.pdf.*

[137] *https://www.medicaid.gov/federal-policy-guidance/downloads/smd21006.pdf.*

expenditures to providers that are directed by the State under § 438.6(c). The second item at § 438.8(k)(1)(xv) requires reporting of Medicaid managed care plan revenue from the State to make these payments. We propose, in § 438.8(k)(xvi), that States and managed care plans would be required to comply with § 438.8(k)(1)(xiv) and (xv) no later than the first rating period for contracts with MCOs, PIHPs, and PAHPs beginning on or after the effective date of the final rule. We considered an alternative effective date where States and plan would comply with these requirements 60 days after the effective date of this final rule. However, we were concerned this may not be a reasonable timeframe for compliance as the new reporting requirements may require State and managed care plans to make changes to financial reporting systems and processes. We seek public comment on this proposal.

For separate CHIPs, we do not propose to adopt the new reporting requirements at § 438.8(k)(1)(xiv) and (xv) because SDPs are not applicable to separate CHIP managed care plans. For this reason, we propose to amend § 457.1203(f) to exclude any references to SDPs for managed care plan MLR reporting. For clarity, we also propose to make a technical change at § 457.1203(f) to include the word ''in'' before the cross-reference to § 438.8.

To assist in CMS oversight of these arrangements, the plan-level SDP expenditure reporting should be reflected in States' annual summary MLR reports to CMS. As part of States' annual summary MLR reporting that is required under § 438.74, we propose to require two additional line items. The first item at § 438.74(a)(3)(i) requires State reporting of the amount of payments made to providers that direct Medicaid MCO, PIHP, or PAHP expenditures under § 438.6(c). The second item at § 438.74(a)(3)(ii) requires State reporting of the amount of payments, including amounts included in capitation payments, that the State makes to Medicaid MCOs, PIHPs, or PAHPs for approved SDPs under § 438.6(c). We propose, in § 438.74(a)(4), that States would be required to comply with § 438.74(a)(3) no later than the rating period for contracts with MCOs, PIHPs, and PAHPs beginning on or after 60 days following the effective date of the final rule as we believe this is a reasonable timeframe for compliance. We considered an alternative effective date where States would comply with the new requirement 60 days after the effective date of this final rule. However, we were concerned this may not be a reasonable timeline for compliance as these changes may require States to make changes to financial reporting systems and processes. We seek public comment on this proposal.

We do not propose to adopt the new SDP reporting requirements for separate CHIPs at § 438.74 since expenditures under § 438.6(c) are not applicable to separate CHIP managed care plans. However, since existing separate CHIP regulations at § 457.1203(e) currently cross-reference to the reporting requirements at § 438.74, we propose to amend § 457.1203(e) to exclude any references to SDPs in State MLR reporting.

While some managed care plans and States may oppose these proposals as increasing administrative burden, we believe that the increased transparency associated with these enhanced standards would benefit both State and Federal government oversight of SDPs. Implementing these new requirements for both State and managed care plan reporting of actual SDP expenditures would support CMS' understanding of provider-based payment across delivery systems.

4. In Lieu of Services and Settings (ILOSs) (§§ 438.2, 438.3, 438.7, 438.16, 438.66, 457.1201, 457.1207)

a. Overview of ILOS Requirements (§§ 438.2, 438.3(e), 438.16, 457.1201(e))

In the 2016 final rule, we finalized § 438.3(e) for Medicaid, which was included in separate CHIP regulations through cross-reference at § 457.1201(e), and specified in § 438.3(e)(2) that managed care plans have flexibility under risk contracts to provide a substitute service or setting for a service or setting covered under the State plan, when medically appropriate and cost effective, to enrollees at the managed care plan and enrollee option (81 FR 27538 and 27539). A substitute service or setting provided in lieu of a covered State plan service or setting under these parameters is known as an ''in lieu of service or setting'' (ILOS). In the 2015 notice of proposed rulemaking, we stated that, under risk contracts, managed care plans have historically had the flexibility to offer an ILOS that meets an enrollee's needs (80 FR 31116). Within the 2016 final rule, we clarified that this ILOS authority continues to exist for States and managed care plans, subject to § 438.3(e)(2). We believe ILOS authority is inherent in a risk contract in accordance with section 1903(m)(2)(A) of the Act which addresses risk-based capitation payments, which are defined in § 438.2. Additionally, we rely on the authority in section 1902(a)(4) of the Act to establish methods for proper and effective operations in Medicaid with respect to PIHPs and PAHPs. ILOSs are incorporated into the applicable States' contracts with its managed care plans and associated capitation rates, and are subject to CMS review and approval in accordance with § 438.3(a) and § 438.7(a) respectively.

ILOSs are utilized by States and their managed care plans to strengthen access to, and availability of, covered services and settings, or reduce or prevent the need for covered services and settings. As outlined in the guidance issued on January 7, 2021 [138] and January 4, 2023 [139] respectively, ILOSs can be an innovative option States may consider employing in Medicaid and CHIP managed care programs to address social determinants of health (SDOHs) and health-related social needs (HRSNs). The use of ILOSs can also improve population health, reduce health inequities, and lower overall health care costs in Medicaid. We further believe that ILOSs can be used, at the option of the managed care plan and the enrollee, as immediate or longer term substitutes for State plan-covered services and settings, or when the ILOSs can be expected to reduce or prevent the future need to utilize the State plan-covered services and settings. The investments and interventions implemented through ILOSs may also offset potential future acute and institutional care, and improve quality, health outcomes, and enrollee experience. For example, offering medically tailored meals as an ILOS may improve health outcomes and facilitate greater access to care to HCBS, thereby preventing or delaying enrollees' need for nursing facility care. We encourage managed care plans to leverage existing State and community level resources, including through contracting with community-based organizations and other providers that are already providing such services and settings and that have expertise working with Medicaid and CHIP enrollees. We believe there is a great deal of State and managed care plan interest in utilizing ILOSs to help address many of the unmet physical, behavioral, developmental, long-term care, and other needs of Medicaid and CHIP enrollees. We expect that States' and managed care plans' use of ILOSs, as well as associated Federal expenditures for these services and settings, will

[138] *https://www.medicaid.gov/federal-policy-guidance/downloads/sho21001.pdf.*

[139] *https://www.medicaid.gov/federal-policy-guidance/downloads/smd23001.pdf.*

continue to increase. We acknowledge that ILOSs can offer many benefits for enrollees, but we also believe it is necessary to ensure adequate assessment of these substitute services and settings prior to approval, and ongoing monitoring for appropriate utilization of ILOSs and beneficiary protections. Additionally, we believe there must be appropriate fiscal protections and accountability of expenditures on these ILOSs which are alternative services and settings not covered in the State plan. Therefore, we propose to revise the regulatory requirements for ILOSs to specify the nature of the ILOSs that can be offered and ensure appropriate and efficient use of Medicaid and CHIP resources, and that these investments advance the objectives of the Medicaid and CHIP programs.

To ensure clarity on the use of the term ''in lieu of service or setting'' and the associated acronym ''ILOS,'' we propose to add a definition in § 438.2 for Medicaid to define an ''in lieu of service or setting (ILOS)'' as a service or setting that is provided to an enrollee as a substitute for a covered service or setting under the State plan in accordance with § 438.3(e)(2) and acknowledge that an ILOS can be used as an immediate or longer term substitute for a covered service or setting under the State plan, or when the ILOS can be expected to reduce or prevent the future need to utilize State plan-covered service or setting. For separate CHIP, we propose to align by adding ''In lieu of service or setting (ILOS) is defined as provided in § 438.2 of this chapter'' to the definitions at § 457.10. Given this proposed definition and associated acronym, we also propose several conforming changes in § 438.3(e)(2). We propose to revise § 438.3(e)(2) to remove ''services or settings that are in lieu of services or settings covered under the State plan'' and replace it with ''an ILOS''. We propose to revise § 438.3(e)(2)(i) and (ii) to remove ''alternative service or setting'' and replace it with ''ILOS.'' In § 438.3(e)(2)(iii), we propose to remove ''in lieu of services'' and replace it with ''ILOS is'', and remove the ''and'' at the end of this requirement given new requirements that will be proposed. We propose to revise § 438.3(e)(2)(iv) to remove ''in lieu of services are'' and replace it with ''the ILOS is, and add the term ''and settings'' after ''covered State plan covered services'' to accurately reflect that ILOSs are substitute services and settings for State plan services and settings. Additionally, we added an ''and'' at the end of this requirement given a new proposed addition of § 438.3(e)(2)(v) that is described later in this section. The proposed changes at § 438.3(e) are equally applicable to separate CHIP managed care plan contract requirements through the existing cross-reference at § 457.1201(e).

Because we are making numerous proposals related to ILOSs, we believe adding a cross reference in § 438.3(e)(2)(v) to a new section would make it easier for readers to locate all of the provisions in one place and the designation flexibility of a new section would enable us to better organize the provisions for readability. To do this, we propose to create a new § 438.16 titled *ILOS requirements* for Medicaid, and we propose to amend § 457.1201(c) and (e) to include cross-references to § 438.16 to adopt for separate CHIP. Our proposals in § 438.16 would be based on several key principles, described in further detail in sections I.B.4.b. through I.B.4.h. of this proposed rule. These principles include that ILOSs would have to: (1) meet general parameters; (2) be provided in a manner that preserves enrollee rights and protections; (3) be medically appropriate and cost effective substitutes for State plan services and settings, (4) be subject to monitoring and oversight; and (5) undergo a retrospective evaluation, when applicable. We also propose parameters and limitations for ILOSs, including our proposed requirements for ILOSs to be appropriately documented in managed care plan contracts and considered in the development of capitation rates, and our proposed risk-based approach for State documentation and evaluation requirements of any managed care plan contracts that include ILOSs. CMS intends to continue our review of ILOSs as part of our review of the States' managed care plan contracts in accordance with § 438.3(a), and associated capitation rates in accordance with § 438.7(a). CMS has the authority to deny approval of any ILOS that does not meet standards in regulatory requirements, and thereby does not advance the objectives of the Medicaid program, as part of our review of the associated Medicaid managed care plan contracts and capitation rates.

We acknowledge that one of the most commonly utilized ILOSs is inpatient mental health or substance use disorder treatment provided during a short term stay (no more than 15 days during the period of the monthly capitation payment) in an institution for mental diseases (IMD). Due to the statutory limitation on coverage of services provided in an IMD in accordance with language in section 1905(a) of the Act following section 1905(a)(30) of the Act, our ability to permit States to make a monthly Medicaid capitation payment for an enrollee who receives services in an IMD is limited as outlined in § 438.6(e), and uniquely based on the nature of risk-based payment (see 80 FR 31116 for further details on this policy). Other than as an ILOS, in accordance with §§ 438.3(e)(2) and 438.6(e), FFP is not available for any medical assistance under Title XIX for services provided to an individual, ages 21 to 64, who is a patient in an IMD facility. We are not proposing changes regarding the coverage of short term stays in an IMD as an ILOS, or payments to MCOs and PIHPs for enrollees who are a patient in an IMD in § 438.6(e) (see 81 FR 27555 through 27563 for further details on the existing policy). In acknowledgement of the unique parameters necessary for coverage of services provided in IMDs as an ILOS, given the statutory limitations, we do not believe § 438.16 should apply to a short term IMD stay as an ILOS. For example, a short term stay in an IMD as an ILOS is excluded from the calculation for an ILOS cost percentage, described in further detail in section I.B.4.b. of this proposed rule, as the costs of a short term IMD stay must not be used in rate development given the statutory limitation, and instead States must use the unit costs of providers delivering the same services included in the State plan as required in § 438.6(e). Additionally, as described in § 438.6(e), States may only make a monthly capitation payment to an MCO or PIHP for an enrollee aged 21 to 64 receiving inpatient treatment in an IMD when the length of stay in an IMD is for a short term stay of no more than 15 days during the period of the monthly capitation payment. Therefore, we propose to add § 438.3(e)(2)(v) to explicitly provide an exception from the applicability of § 438.16 for short term stays, as specified in § 438.6(e), for inpatient mental health or substance use disorder treatment in an IMD. This proposal does not replace or alter existing Federal requirements and limitations regarding the use of short term IMD stays as an ILOS, or the availability of FFP for capitation payments to MCOs and PIHPs for enrollees who utilize an IMD.

We do not propose to adopt the IMD exclusion for separate CHIP since there are no similar payment restrictions for stays in an IMD in separate CHIP. As long as a child is not applying for or renewing their separate CHIP coverage while a resident of an IMD, the child remains eligible for separate CHIP and any covered State plan services or ILOSs while in an IMD consistent with the

requirements of § 457.310(c)(2)(ii). For this reason, we propose to amend § 457.1201(e) to exclude references to IMDs in the cross-reference to § 438.3(e).

States and managed care plans will continue to be obligated to comply with other applicable Federal requirements for all ILOS, including short term IMD stays. This includes, but is not limited to, those requirements outlined in §§ 438.3(e)(2), 438.6(e), and 438.66. As required in § 438.66(a) through (c), States must establish a system to monitor performance of their managed care programs. When ILOSs are included in a managed care plan's contract, they too must be part of the State's monitoring activities. As part of such monitoring, States must ensure that all ILOSs, including short term stays in an IMD, are medically appropriate, cost effective, and at the option of the enrollee and managed care plan.

b. ILOS General Parameters (§§ 438.16(a) Through (d), 457.1201(c) and (e))

We believe ILOSs can give States and managed care plans opportunities to strengthen access to care, address unmet needs of Medicaid and CHIP enrollees, and improve the health of Medicaid and CHIP beneficiaries. However, we believe it is necessary to implement appropriate Federal protections to ensure the effective and efficient use of Medicaid and CHIP resources, particularly since these services and settings are not State plan-covered services and settings furnished under managed care plan contracts, and we rely on the authority in sections 1902(a)(4) and 2101(a) of the Act to establish methods for proper and effective operations in Medicaid and CHIP respectively. Therefore, to ensure States and managed care plans utilize ILOSs effectively and in a manner that best meets the needs of the enrollees as well as that related Federal expenditures are reasonable and appropriate, we propose several key requirements in § 438.16.

We believe that a limitation on the types of substitute services or settings that can be offered as an ILOS would be a key protection to ensure an ILOS is an appropriate and efficient use of Medicaid and CHIP resources, and we believe this is a reasonable method to ensure proper and effective operations in Medicaid and CHIP in accordance with authority in sections 1902(a)(4) and 2101(a) of the Act, respectively. We believe that the services and settings that could be provided as an ILOS should be consistent with the services and settings that could be authorized under the Medicaid or CHIP State plan or a program authorized through a waiver under section 1915(c) of the Act. As further described in section I.B.4.a. of this proposed rule, we believe the only Medicaid exception should be a short term stay in an IMD for the provision of inpatient mental health or substance use disorder treatment, which already has appropriate safeguards per requirements outlined in § 438.6(e). Therefore, we propose to require in § 438.16(b) that an ILOS must be approvable as a service or setting through a State plan amendment, including sections 1905(a), 1915(i), or 1915(k) of the Act, or a waiver under section 1915(c) of the Act. For example, personal care homemaker services are approvable as a covered service in a waiver under section 1915(c) of the Act, and would be an approvable ILOS if it is a medically appropriate and cost effective substitute for a service or setting covered under the State plan.

For separate CHIP, we similarly propose that ILOSs must be consistent with services and settings approvable under sections 2103(a) through (c), 2105(a)(1)(D)(ii), and 2110(a) of the Act as well as the services and settings identified in § 438.16(b). For this reason, we propose to adopt the requirements proposed at § 438.16(b) by amending § 457.1201(e) to include a new cross-reference to § 438.16(b). We also remind States that the use of an ILOS does not absolve States and managed care plans of their responsibility to comply with other Federal requirements. States must ensure that contracts with managed care plans comply with all applicable Federal and State laws and regulations in accordance with §§ 438.3(f) and 457.1201(f). For example, with the exception of short term IMD stays as described in section I.B.4.a. of this proposed rule, ILOSs must adhere to general prohibitions on payment for room and board under Title XIX of the Act. Additionally, States and managed care plans must ensure access to emergency services in accordance with the Emergency Medical Treatment and Labor Act and compliance with the Americans with Disabilities Act and Section 504 of the Rehabilitation Act. Moreover, consistent with § 438.208(c)(3), States must comply with person-center planning requirements as applicable.

Because ILOSs are provided as substitutes for State plan-covered services and settings, we believe that we have an obligation to ensure appropriate fiscal protections for Medicaid and CHIP investments in ILOSs, and that there should be a limit on the amount of expenditures for ILOSs to increase accountability, reduce inequities in the services and settings available to beneficiaries across managed care and fee-for-service delivery systems, and ensure enrollees receive State plan-covered services and settings. We rely on the authority in section 1902(a)(4) of the Act to establish methods for proper and efficient operations in Medicaid and section 2101(a) of the Act for establishing efficient and effective health assistance in CHIP. To determine a reasonable limit on expenditures for ILOSs, we propose to limit allowable ILOS costs to a portion of the total costs for each managed care program that includes ILOS(s), hereinafter referred to as an ILOS cost percentage. States claim FFP for the capitation payments they make to managed care plans. Capitation payments are based on the actuarially sound capitation rates as defined in § 438.2, for Medicaid, and rates are developed with ''actuarially sound principles'' as required for separate CHIP at § 457.1203(a). The utilization and cost associated with ILOSs are accounted for in the development of Medicaid and separate CHIP capitation rates in accordance with §§ 438.3(e)(2)(iv) and 457.1201(e) respectively. Therefore, we propose in § 438.16(c), that the ILOS cost percentage must be calculated based on capitation rates and capitation payments as outlined in further detail in this section. In section I.B.2.l. of this proposed rule, CMS proposes requirements for State directed payments as a separate payment term, and we also believe these costs should be accounted for in the denominator of the ILOS cost percentage as these are payments made by the State to the managed care plans. The reporting requirements in this proposal are authorized by sections 1902(a)(6) and 2107(b)(1) of the Act which require that States provide reports, in such form and containing such information, as the Secretary may from time to time require.

Given that actuarially sound capitation rates are developed prospectively based on historical utilization and cost experience, as further defined in § 438.5, we believe that an ILOS cost percentage and associated expenditure limit should be measured both on a projected basis when capitation rates are developed and on a final basis after capitation payments are made by States to the managed care plans. Therefore, we propose to define both a ''projected ILOS cost percentage'' and ''final ILOS cost percentage'' in § 438.16(a) as the amounts for each managed care program that includes ILOS(s) using the calculations proposed in § 438.16(c)(2)

and (3), respectively. Additional details on these percentages are provided later in this section. We also believe the projected ILOS cost percentage and final ILOS cost percentage should be measured distinctly for each managed care program as capitation rates are typically developed by program, ILOSs available may vary by program, and each managed care program may include differing populations, benefits, geographic areas, delivery models, or managed care plan types. For example, one State may have a behavioral health program that covers care to most Medicaid beneficiaries through PIHPs, a physical health program that covers physical health care to children and pregnant women through MCOs, and a program that covers physical health and MLTSS to adults with a disability through MCOs. Another State may have several different managed care programs that serve similar populations and provide similar benefits through MCOs, but the delivery model and geographic areas served by the managed care programs vary. We addressed managed care program variability within the 2016 final rule when we noted that ''This clarification in the regulatory text to reference ''managed care program'' in the regulatory text is to recognize that States may have more than one Medicaid managed care program—for example physical health and behavioral health . . .'' (81 FR 27571). Therefore, we do not believe it would be consistent with our intent to develop an ILOS cost percentage by aggregating data from more than one managed care program since that would be inconsistent with rate development, the unique elements of separate managed care programs, and the ILOSs elements (target populations, allowable provider types, etc.) that vary by managed care program. Developing the ILOS cost percentage by managed care program would further ensure appropriate fiscal safeguards for each managed care program that includes ILOS(s). We believe 5 percent is a reasonable limit on ILOS expenditures because it is high enough to ensure that ILOSs would be used effectively to achieve their intended purpose, but still low enough to ensure appropriate fiscal safeguards. This proposed 5 percent limit would be similar to incentive arrangements at § 438.6(b), which limits total payment under contracts with incentive arrangements to 105 percent of the approved capitation payments attributable to the enrollees or services covered by the incentive arrangement. In § 438.6(b)(2), we note that total payments in excess of 105 percent will not be actuarially sound. We believe this existing limitation for incentive arrangements allows States to design and motivate quality and outcome-based initiatives while also maintaining fiscal integrity. We believe a similar threshold would be necessary and appropriate for ILOSs. Therefore, we propose, at § 438.16(c)(1)(i), to require that the projected ILOS cost percentage could not exceed 5 percent and the final ILOS cost percentage could not exceed 5 percent.

For separate CHIP, we require States at § 457.1203(a) to develop capitation rates consistent with actuarially sound principles, but at § 457.1203(b) we allow for States to establish higher capitation rates if necessary to ensure sufficient provider participation or provider access or to enroll providers who demonstrate exceptional efficiency or quality in the provision of services. While we do not impose a similar limit for incentive arrangements in separate CHIP capitation rates as we do for Medicaid capitation rates, we wish to align with Medicaid in limiting projected and final ILOS cost percentages to 5 percent of capitation payments for separate CHIPs. For this reason, we propose to amend § 457.1203(b) to adopt 5 percent ILOS cost percentage limits by amending § 457.1201(c) to include a new cross-reference to § 438.16(c)(1).

We also propose, in § 438.16(c)(1)(ii), that the State's actuary would have to calculate the projected ILOS cost percentage and final ILOS cost percentage on an annual basis and recalculate these projections annually to ensure consistent application across all States and managed care programs. Furthermore, to ensure that the projected ILOS cost percentage and final ILOS cost percentage would be developed in a consistent manner with how the associated ILOS costs would be included in rate development, we propose at § 438.16(c)(1)(iii) to require that the projected ILOS cost percentage and the final ILOS cost percentage would have to be certified by an actuary and developed in a reasonable and appropriate manner consistent with generally accepted actuarial principles and practices. An ''actuary'' is defined in § 438.2 as an individual who meets the qualification standards established by the American Academy of Actuaries for an actuary and follows the practice standards established by the Actuarial Standards Board, and who is acting on behalf of the State to develop and certify capitation rates. Therefore, we believe that the actuary that would certify the projected and final ILOS cost percentages should be the same actuary that developed and certified the capitation rates that included ILOS(s). For separate CHIP, we do not require actuarial certification of capitation rates and are not adopting the requirement at § 438(c)(1)(iii). We propose to amend § 457.1201(c) to exclude requirements for certification by an actuary. However, we remind States that separate CHIP rates must be developed using ''actuarially sound principles'' in accordance with § 457.1203(a).

We propose at § 438.16(c)(2), that the projected ILOS cost percentage would have to be calculated by dividing the portion of the total capitation payments that would be attributable to all ILOSs, excluding short term stays in an IMD as specified in § 438.6(e), for each managed care program (numerator) by the projected total capitation payments for each managed care program, including all State directed payments in effect under § 438.6(c) and pass-through payments in effect under § 438.6(d), and the projected total State directed payments that are paid as a separate payment term as described in § 438.6(c)(6) (denominator). We also propose, at § 438.16(c)(3), that the final ILOS cost percentage would have to be calculated by dividing the portion of the total capitation payments that is attributable to all ILOSs, excluding a short term stay in an IMD as specified in § 438.6(e), for each managed care program (numerator) by the actual total capitation payments for each managed care program, including all State directed payments in effect under § 438.6(c) and pass-through payments in effect under § 438.6(d), and the actual total State directed payments that are paid as a separate payment term as described in § 438.6(c)(6) (denominator). We believe these proposed numerators and denominators for the projected and final ILOS cost percentages would be an accurate measurement of the projected and final expenditures associated with ILOSs and total program costs in each managed care program in a risk-based contract. For separate CHIP, we propose to align with the projected and final ILOS cost percentage calculations by amending § 457.1201(c) to include cross-references to § 438.16(c)(2) through (3). However, since pass-through payments and State directed payments are not applicable to separate CHIP, we propose to exclude all references to pass-through payments and State directed payments at § 457.1201(c).

We considered proposing that the actual expenditures of the managed care plans for ILOSs and total managed care program costs, tied to actual paid amounts in encounter data, be the numerator and denominator for the final

ILOS cost percentage. However, we determined this would be inconsistent with how States claim FFP for capitation payments in a risk contract (based on the actuarially sound capitation rates as defined in § 438.2 for each managed care program, rather than on the actual plan costs for delivering ILOSs based on claims and encounter data submitted). Consistent with all services and settings covered under the terms of the managed care plans' contracts, we acknowledge the actual plan experience will inform prospective rate development in the future, but it is an inconsistent measure for limiting ILOS expenditures associated with FFP retroactively. We believe expenditures for short term stays in an IMD would have to be excluded from the numerator of these calculations as they are excluded from the proposed requirements outlined in § 438.16. We also believe the denominator of these calculations should include all State directed payments and pass-through payments that are included into capitation rates as outlined in § 438.6(c) and (a) respectively. It is necessary to include these State directed payments and pass-through payments to ensure that the projected and final expenditures would accurately reflect total capitation payments.

We believe the projected ILOS cost percentage should be included in the rate certification for each managed care program that includes ILOS(s) and any subsequent revised rate certification (for example, rate amendment) as applicable, such as those that change the ILOSs offered, capitation rates, pass-through payments and/or State directed payments. As previously described in this section, we propose at § 438.16(c)(1)(iii) that the actuary who certifies the projected ILOS cost percentage would have to be the same actuary who develops and certifies the associated Medicaid capitation rates and the State directed payments paid as a separate payment term (see section I.B.2.l. of this proposed rule for details on this proposal for separate payment terms). We also believe that including this percentage within the rate certification would reduce administrative burden for States and actuaries while also ensuring consistency between how this percentage would be calculated and how ILOS costs would be accounted for in rate development. Therefore, we propose to require, at § 438.16(c)(5)(i), that States annually submit to CMS for review the projected ILOS cost percentage for each managed care program as part of the Medicaid rate certification required in § 438.7(a). For separate CHIP, we do not require actuarial certification of capitation rates or review by CMS, and for this reason we do not adopt the new requirement proposed at § 438.16(c)(5)(i) for separate CHIP.

As the proposed denominator for the final ILOS cost percentage, in § 438.16(c)(3)(i), would be based on the actual total capitation payments and the State directed payments paid as a separate payment term (see section I.B.2.l. of this proposed rule for details on this proposal for separate payment terms) paid by States to managed care plans, we recognize that calculating the final ILOS cost percentage would take States and actuaries some time. For example, changes to the eligibility file and revised rate certifications for rate amendments may impact the final capitation payments that are a component of the calculation. We also believe documentation of the final ILOS cost percentage is a vital component of our monitoring and oversight as it would ensure that the expenditures for ILOSs comply with the proposed 5 percent limit; and therefore, must be submitted timely. Given these factors, we believe that 2 years is an adequate amount of time to accurately perform the calculation. Therefore, we propose, at § 438.16(c)(5)(ii), to require that States must submit the final ILOS cost percentage report to CMS with the rate certification for the rating period beginning 2 years after the completion of each 12-month rating period that included an ILOS(s). Under this proposal, for example, the final ILOS cost percentage report for a managed care program that uses a calendar year 2024 rating period would be submitted to CMS with the calendar year 2027 rate certification. For separate CHIP, we do not require review of capitation rates by CMS and do not propose to adopt the requirements at § 438.16(c)(5)(ii) for separate CHIP.

We considered requiring the final ILOS cost percentage be submitted to CMS within 1 year after the completion of the rating period that included ILOS(s) to receive this data in a more timely fashion. However, we were concerned this may not be adequate time for States and actuaries given the multitude of factors described previously in this section. We request comment on whether our assumption that 1 year is inadequate is correct.

We also believe that it is appropriate for States' actuaries to develop a separate report to document the final ILOS cost percentage, rather than including it in a rate certification, because the final ILOS cost percentage may require alternate data compared to the base data that were used for prospective rate development, given the timing of base data requirements as outlined in § 438.5(c)(2). However, this final ILOS cost percentage could provide details that should inform prospective rate development, such as through an adjustment outlined in § 438.5(b)(4), so we believe it should be submitted along with the rate certification. We note that this proposal is similar to the concurrent submission necessary for the MLR reporting at § 438.74. We considered proposing that States submit this report separately to CMS upon completion. However, we believe there should be consistency across States for when this report is submitted to CMS for review, and we believe receiving this report and the rate certification at the same time would enable CMS to review them concurrently. For these reasons, we propose, at § 438.16(c)(5)(ii), to require that States submit the final ILOS cost percentage annually to CMS for review as a separate report concurrent with the rate certification submission required in § 438.7(a). We intend to issue additional guidance on the standards and documentation requirements for this report. For separate CHIP, we do not require review of capitation rates by CMS and do not propose to adopt the requirements at § 438.16(c)(5)(ii) for separate CHIP.

We believe there must be appropriate transparency on the managed care plan costs associated with delivering ILOSs to aid State oversight and monitoring of ILOSs, and to ensure proper and effective operations in Medicaid in accordance with authority in section 1902(a)(4) of the Act. Therefore, we propose, in § 438.16(c)(4), that States provide to CMS a summary report of the actual managed care plan costs for delivering ILOSs based on claims and encounter data provided by the managed care plans to States. We also believe this summary report should be developed concurrently and consistently with the final ILOS cost percentage to ensure appropriate fiscal safeguards for each managed care program that includes ILOS(s). We believe this summary report should be developed for each managed care program consistent with the rationale described in section I.B.4.b. of this proposed rule for developing the ILOS cost percentage for each managed care program. Therefore, in § 438.16(a), we propose to define a ''summary report for actual MCO, PIHP and PAHP ILOS costs'' and propose that this summary report be calculated for each managed

care program that includes ILOSs. We also propose, in § 438.16(c)(1)(ii), that this summary report be calculated on an annual basis and recalculated annually. We propose, in § 438.16(c)(1)(iii), that this summary report be certified by an actuary and developed in a reasonable and appropriate manner consistent with generally accepted actuarial principles and practices. Finally, we propose, in § 438.16(c)(5)(ii), that this summary report be submitted to CMS for review within the actuarial report that includes the final ILOS cost percentage. For separate CHIP, we do not require similar actuarial reports and do not propose to adopt the annual ILOS cost report requirements by excluding references to them at § 457.1201(c).

To balance States' administrative burden with ensuring fiscal safeguards and enrollee protections related to ILOSs, we believe it would be appropriate to use a risk-based approach for States' documentation and evaluation requirements. This proposed reporting requirement is authorized by sections 1902(a)(6) and 2107(b)(1) of the Act which requires that States provide reports, in such form and containing such information, as the Secretary may from time to time require. Therefore, we propose that the ILOS documentation States would have to submit to CMS, as well as an evaluation States would have to complete, would vary based on a State's projected ILOS cost percentage for each managed care program. We believe the projected ILOS cost percentage would be a reasonable proxy for identifying States that offer a higher amount of ILOSs, in comparison to overall managed care program costs, and likely could have a corresponding higher impact to Federal expenditures. As we considered the types of State activities and documentation that could vary under this proposed risk-based approach, we considered which ones would be critical for all States to undertake for implementation and continual oversight of the use of ILOSs, but would not require our review unless issues arose that warranted additional scrutiny. We propose that documentation requirements for States with a projected ILOS cost percentage that is less than or equal to 1.5 percent would undergo a streamlined review, while States with a higher projected ILOS cost percentage would have more robust documentation requirements. Additionally, we propose States with a higher final ILOS cost percentage would be required to submit an evaluation of ILOSs to CMS. These parameters are explained further in sections I.B.4.d. and g. of this proposed rule.

As we considered a reasonable percentage for this risk-based approach, we evaluated flexibilities currently offered in part 438 to assess if similar thresholds would be reasonable for this purpose. These flexibilities included the opportunity available to States to adjust rates without the requirement for a revised rate certification. Specifically, we are referring to the 1 percent flexibility for States that certify rate ranges in accordance with § 438.4(c)(2)(iii) and the 1.5 percent flexibility for States that certify capitation rates in accordance with § 438.7(c)(3). An additional flexibility currently available to States relates to incentive arrangements. In accordance with § 438.6(b)(2), total payment under States' managed care plan contracts with incentive arrangements are allowed to be no greater than 105 percent of the approved capitation payments attributable to the enrollees or services covered by the incentive arrangement. As we evaluated a reasonable and appropriate threshold to utilize for this risk-based approach, we explored utilizing similar flexibilities of 1 percent, 1.5 percent and 5 percent, and also considered 2.5 percent as a mid-point in this 5 percent range.

We do not believe 5 percent is a reasonable percentage for this risk-based approach as this is the proposed limit for the projected and final ILOS cost percentages described in this section. We believe a greater degree of State documentation, and CMS oversight, is necessary for States that offer ILOSs that represent a higher share of overall managed care program costs, and likely have a corresponding higher impact on Federal expenditures. In the 2020 final rule, we finalized § 438.4(c)(2)(iii) to permit States that certify rate ranges to make rate adjustments up to 1 percent without submitting a revised rate certification. Our rationale was that States using rate ranges were already afforded additional flexibility given the certification of rate ranges so it was not appropriate to utilize the same 1.5 percent flexibility that is offered to States that certify capitation rates (85 FR 72763). We do not believe a similar rationale is appropriate or relevant for this proposal, and thus, we do not believe 1 percent would be the most appropriate threshold. We are also concerned that utilizing 2.5 percent for a risk-based approach would result in inadequate Federal oversight to ensure program integrity, such as fiscal safeguards and enrollee protections related to ILOSs. We believe 1.5 percent, a de minimis amount, is appropriate to propose for utilization of a risk-based approach for States' documentation and evaluation requirements, and associated CMS review, as ILOS expenditures less than or equal to 1.5 percent would likely be a relatively minor portion of overall managed care program expenditures. Therefore, we propose 1.5 percent for this risk-based approach in § 438.16(d)(2); States with a projected ILOS cost percentage that exceeds 1.5 percent would be required to adhere to additional requirements described in sections I.B.4.d. and g. of this proposed rule. For separate CHIP, we propose to adopt the new documentation requirements for States with a cost percentage that exceeds 1.5 percent at § 438.16(d)(2) by amending § 457.1201(e) to include a cross-reference to § 438.16(d)(2).

c. Enrollee Rights and Protections (§§ 438.3(e), 457.1201(e), 457.1207)

Consistent with the ILOS definition proposed in § 438.2, ILOSs are immediate or longer term substitutes for State plan-covered services and settings, or when the ILOSs can be expected to reduce or prevent the future need to utilize the covered services and settings under the State plan. They can be utilized to improve enrollees' health care outcomes, experience, and overall care; however, ILOSs are an option and not a requirement for managed care plans. While ILOSs are offered to Medicaid and CHIP enrollees at the option of the managed care plan, the provision of an ILOS is also dependent on the enrollees' willingness to use the ILOS instead of the State plan-covered service or setting. Medicaid managed care enrollees are entitled to receive covered services and settings under the State plan consistent with section 1902(a)(10) of the Act. As ILOSs can be offered as substitutes for covered State plan services and settings that Medicaid enrollees are otherwise entitled to, we believe that it is of the utmost importance that we identify the enrollee rights and managed care protections for individuals who are offered or opt to use an ILOS instead of receiving State plan-covered service or setting. To ensure clarity for States, managed care plans, and enrollees on the rights and protections afforded to enrollees who are eligible for, offered, or receive an ILOS, we propose to add new § 438.3(e)(2)(ii)(A) and (B) under § 438.3(e)(2)(ii) to specify our meaning of enrollee rights and protections that are not explicitly stated elsewhere in part 438. We believe it would be appropriate to add this clarity to § 438.3(e)(2)(ii) as these are not new rights or protections, but rather, existing rights and protections that we believe

should be more explicitly stated for all ILOSs, including short-term IMD stays.

We propose to specify, in § 438.3(e)(2)(ii)(A), that an enrollee who is offered or utilizes an ILOS would retain all rights and protections afforded under part 438, and if an enrollee chooses not to receive an ILOS, they would retain their right to receive the service or setting covered under the State plan on the same terms as would apply if an ILOS was not an option. We believe this proposed addition would ensure clarity that the rights and protections guaranteed to Medicaid managed care enrollees under Federal regulations remain in full effect when an enrollee is eligible to be offered or elects to receive an ILOS. For example, enrollees retain the right to make informed decisions about their health care and to receive information on available treatment options and alternatives as required in § 438.100(b)(2)(iii). To ensure that enrollee rights and protections would be clearly and consistently provided to enrollees, we propose to revise § 438.10(g)(2)(ix) to explicitly require that the rights and protections in § 438.3(e)(2)(ii) be included in enrollee handbooks if ILOSs are added to a managed care plan's contract. For separate CHIP, enrollee rights and protections are unique from those offered to Medicaid enrollees, and are instead located under subparts K and L of part 457. To acknowledge these differences, we propose to amend § 457.1207, (which includes an existing cross-reference to § 438.10) to reference instead to the separate CHIP enrollee rights and protections under subparts K and L of part 457. Protections to ensure that managed care enrollees have the ability to participate in decisions regarding their health care, and have avenues to raise concerns including their right to appeals related to adverse benefit determinations and grievances are critical to ensure that ILOSs are utilized in a reasonable, appropriate, and effective manner.

We believe safeguards and protections for enrollees that elect to use an ILOS should be specified, particularly since ILOS costs can vary compared to costs for the State plan service or setting for which it is a substitute. Specifically, we want to make clear that the provision or offer of an ILOS may not be used coercively or with the intent to interfere with the provision or availability of State plan-covered service and setting that an enrollee would otherwise be eligible to receive. Therefore, we propose to add § 438.3(e)(2)(ii)(B) to ensure that an ILOS would not be used to reduce, discourage, or jeopardize an enrollee's access to services and settings covered under the State plan, and a managed care plan may not deny an enrollee access to a service or setting covered under the State plan on the basis that an enrollee has been offered an ILOS as a substitute for a service or setting covered under the State plan, is currently receiving an ILOS as a substitute for a service or setting covered under the State plan, or has utilized an ILOS in the past. While ILOSs can be effective substitutes for services and settings covered under the State plan, we want to ensure consistent and clear understanding for enrollees, States, and managed care plans on how ILOSs can be appropriately utilized to meet an enrollee's needs.

For separate CHIP, we propose to adopt the enrollee rights and protections at § 438.3(e)(2)(ii)(A) and (B) through an existing cross-reference at § 457.1201(e). However, separate CHIP enrollee rights and protections are unique from those offered to Medicaid enrollees and are instead located under subparts K and L of part 457. To acknowledge these differences, we propose to amend § 457.1201(e), which already includes a cross-reference to § 438.3(e) to State, ''An MCO, PIHP, or PAHP may cover, for enrollees, services that are not covered under the State plan in accordance with § 438.3(e) of this chapter . . . except . . . that references to enrollee rights and protections under part 438 should be read to refer to the rights and protections under subparts K and L of this part.''

We believe that a strong foundation built on these enrollee rights and protections would also ensure that ILOSs may have a positive impact on enrollees' access to care, health outcomes, experience, and overall care. As such, we believe these enrollee rights and protections must be clearly documented in States' managed care plan contracts. Therefore, we propose this documentation requirement in § 438.16(d)(1)(v). For separate CHIP, we propose to adopt the requirement for enrollee rights and protections for ILOSs to be documented in managed care plan contracts by amending § 457.1201(e) to include a cross-reference to § 438.16(d)(1)(v).

d. Medically Appropriate and Cost Effective (§§ 438.16(d), 457.1201(e))

In § 438.3(e)(2)(i), managed care plans may cover an ILOS if the State determines the ILOS is medically appropriate and cost effective substitute for a covered State plan service or setting. This policy is consistent with authority in section 1902(a)(4) of the Act to establish methods for proper and efficient operations in Medicaid as well as the nature of capitation payments based on risk-based capitation rates recognized in section 1903(m)(2)(A) of the Act. We interpret medically appropriate and cost effective substitute to mean that an ILOS may serve as an immediate or longer term substitute for a covered service or setting under the State plan, or when the ILOS can be expected to reduce or prevent the future need to utilize a covered service or setting under the State plan. We believe this is a reasonable interpretation in acknowledgement that health outcomes from any health care services and settings may also not be immediate. We offer the following examples to illustrate the difference between an ILOS that is an immediate versus longer term substitute for a State plan service or setting, or when the ILOS can be expected to reduce or prevent the future need to utilize a covered service or setting under the State plan.

For example, transportation to and services provided at a sobering center could be offered as a medically appropriate and cost effective immediate substitute for target populations for specific State plan services or settings, such as an emergency room visit or hospital inpatient stay. Alternatively, we can envision target populations for which an ILOS, such as housing transition navigation services, might serve as a longer term substitute for a covered State plan service or setting, or when the ILOS can be expected to reduce or prevent the need to utilize the covered service or setting under the State plan, such as populations with chronic health conditions and who are determined to be at risk of experiencing homelessness. The managed care plan might choose to offer medically tailored meals to individuals with a diabetes diagnosis and poorly managed A1C levels. While not an immediate substitute for a State plan-covered service such as emergency room visits or inpatient hospital stays, medically tailored meals consistently provided to the individual over a period of time could contribute to improved management of the diabetes. In the long term, improved management might lead to fewer complications related to diabetes and consequentially, fewer emergency room visits and inpatient stays thereby demonstrating the ILOS was both medically appropriate and cost effective for the individual.

We believe it is important to ensure appropriate documentation to support a State's determination that an ILOS is a medically appropriate and cost effective substitute, either long or short term, for a State plan-covered service or setting.

ILOS documentation requirements for States would permit CMS and the State to better monitor the use of ILOSs, safeguard enrollee rights, facilitate fiscal accountability, and promote transparency to ensure the efficient and appropriate use of Medicaid and CHIP resources. Therefore, we propose to expand the documentation requirements for ILOSs through the addition of requirements in § 438.16. Specifically, we propose at § 438.16(d)(1), elements that must be included in any managed care plan contract that includes ILOS(s) in order to obtain CMS approval consistent with § 438.3(a). In accordance with § 438.3(e)(2)(iii), States are already required to authorize and identify ILOSs in each managed care plan contract and such ILOSs are offered at the option of the managed care plan. Therefore, we believe it is consistent with a risk contract to require States to provide sufficient detail regarding any ILOSs covered under the contract and accounted for in the capitation rates per § 438.3(e)(2)(iv).

In our experience reviewing managed care plan contracts, States have not always provided sufficient detail in their managed care plan contracts for Federal review. For example, some contracts have included only general language that ILOSs are provided at the option of the managed care plan and have not clearly identified each ILOS that the State has authorized in sufficient detail. We believe clarity is needed to ensure accountability and transparency in managed care plan contracts. Therefore, we propose § 438.16(d)(1)(i) and (ii) to require that States would include within each managed care plan contract that includes ILOS(s), the name and definition for each ILOS and clearly identify the State plan-covered service or setting for which each ILOS has been determined to be a medically appropriate and cost effective substitute by the State. For separate CHIP, we propose to adopt the new documentation requirements at § 438.16(d)(1)(i) and (ii) by amending § 457.1201(e) to include the cross-reference. By requiring that this information be clearly identified in the contract, we believe that managed care plans would have sufficient detail on the ILOSs to be able to utilize ILOSs appropriately while enabling States and CMS to more effectively monitor each ILOS over time. We also believe including this level of detail in the contract would be an appropriate fiscal protection to ensure that capitation rates are developed in an actuarially sound manner in accordance with § 438.4 for Medicaid, and developed with actuarially sound principles in accordance with § 457.1203(a) for separate CHIP. Actuarially sound capitation rates, as defined in § 438.4(a) for Medicaid, and actuarially sound principles as defined at § 457.10 for CHIP, are projected to provide for all reasonable, appropriate, and attainable costs that are required under the terms of the contract and for the operation of the managed care plan for the time period and the population covered under the terms of the contract. Additionally, for Medicaid, such capitation rates must be developed in accordance with the requirements in § 438.4(b), including the requirements that the actuarially sound capitation rates must be appropriate for the populations to be covered and the services to be furnished under the contract as required in § 438.4(b)(2).

The existing regulation § 438.3(e)(2)(i) indicates that a managed care plan may offer an ILOS if the State determines that the ILOS is a medically appropriate and cost-effective substitute for a covered service or setting under the State plan. As noted in section I.B.4.a of this proposed rule, we are proposing a definition of ILOS in § 438.2 to specify that ILOSs may be determined to be cost effective and medically appropriate as immediate or longer-term substitutes for State plan-covered services and settings, or when the ILOSs can be expected to reduce or prevent the future need to utilize State plan-covered services and settings. Current regulations do not require States or managed care plans to document any details related to the determination of medical appropriateness and cost effectiveness, either broadly or for a specific enrollee who is offered an ILOS. For managed care plans to appropriately offer ILOSs to enrollees consistent with the State's determination of medical appropriateness and cost effectiveness, States would have to identify the target populations for each ILOS using clear clinical criteria. Prospective identification of the target population for an ILOS would also be necessary to ensure capitation rates are developed in an actuarially sound manner in accordance with § 438.4, including the requirements that the actuarially sound capitation rates must be appropriate for the populations to be covered and the services to be furnished under the contract as required in § 438.4(b)(2) and meet the applicable requirements of part 438, including ILOS requirements as required in § 438.4(b)(6). For these reasons, we propose a new requirement at § 438.16(d)(1)(iii) to require States to document within each managed care plan contract the clinically defined target population(s) for which each ILOS has been determined to be a medically appropriate and cost effective substitute. For separate CHIP, we propose to adopt the new documentation requirements at § 438.16(d)(1)(iii) by amending § 457.1201(e) to include the cross-reference. We propose the phrase ''clinically defined target populations'' as we believe that States would have to identify a target population for each ILOS that would have to be based on clinical criteria. This would not preclude States from using additional criteria to further target certain clinically defined populations for ILOSs.

While States may establish target population(s) for which an ILOS is medically appropriate, we believe that the actual determination of medical appropriateness should be completed by a provider, for each enrollee, using their professional judgement, and assessing the enrollee's presenting medical condition, preferred course of treatment, and current or past medical treatment to determine if an ILOS is medically appropriate for that specific enrollee. Therefore, we propose, at § 438.16(d)(1)(iv), to require that the managed care plan contract document a process by which a licensed network or managed care plan staff provider would have to determine that an ILOS is medically appropriate for a specific enrollee. Under this proposal, this determination and documentation could be done by either a licensed network provider or a managed care plan staff provider to ensure States and managed care plans have capacity to implement this requirement, consistent with State standards. For separate CHIP, we propose to adopt the new documentation requirements at § 438.16(d)(1)(iv) by amending § 457.1201(e) to include the cross-reference. The provider would have to document the determination of medical appropriateness within the enrollee's records, which could include the enrollee's plan of care, medical record (paper or electronic), or another record that details the enrollee's care needs. This documentation would have to include how each ILOS would be expected to address those needs.

As discussed in section I.B.4.b. of this proposed rule, we propose a risk-based approach based on a State's projected ILOS cost percentage, for State documentation and evaluation requirements of ILOSs that would require standard streamlined documentation to CMS for States with a

projected ILOS cost percentage less than or equal to 1.5 percent while States with a projected ILOS cost percentage that exceeds 1.5 percent would be required to submit additional documentation. To specify the proposed additional documentation requirements for a State with a projected ILOS cost percentage that exceeds 1.5 percent, we propose, at § 438.16(d)(2), the documentation requirements in paragraphs § 438.16(d)(2)(i) and (ii), and that this documentation would be submitted to CMS concurrent with the managed care plan contract that includes the ILOS(s), for review and approval by CMS under § 438.3(a). We believe concurrent submission is the most efficient, since each ILOS must be authorized and identified in States' contracts with a managed care plan as required in § 438.3(e)(2)(ii). In § 438.16(d)(2)(i), we propose that the State submit a description of the process and supporting evidence the State used to determine that each ILOS would be a medically appropriate service or setting for the clinically defined target population(s), consistent with proposed § 438.16(d)(1)(iii). As ILOSs are often substitutes for State plan-covered services and settings that have already been determined medically appropriate, we expect that States would have to use evidence-based guidelines, peer reviewed research, randomized control trials, preliminary evaluation results from pilots or demonstrations, or other forms of sound evidence to support the State's determination of an ILOS' medical appropriateness. Lastly, in § 438.16(d)(2)(ii), we propose that the State provide a description of the process and supporting data that the State used to determine that each ILOS is a cost effective substitute for a State plan-covered service or setting for the defined target population(s), consistent with the proposed § 438.16(d)(1)(iii). CMS has the authority to deny approval of any ILOS that does not meet standards in regulatory requirements, and thereby does not advance the objectives of the Medicaid program, as part of our review of the associated Medicaid managed care plan contracts and capitation rates. For separate CHIP, we propose to adopt the new documentation requirements at § 438.16(d)(2) by amending § 457.1201(e) to include the cross-reference.

While we believe that a risk-based approach for States' ILOS documentation and evaluation requirements is a reasonable and appropriate balance of administrative burden and fiscal safeguards, we always reserve the right to ask for additional documentation from a State as part of our review and approval of the managed care plan contracts and rate certifications as required respectively in §§ 438.3(a) and 438.7(a), and we are not precluded from doing so by our proposal to add § 438.16(d)(2)(i) through (ii). Therefore, we propose to require at § 438.16(d)(3) that any State must provide additional documentation, whether part of the managed care plan contract, rate certification, or supplemental materials, if we determine that the requested information would be pertinent to the review and approval of a contract that includes ILOS(s). For separate CHIP, we propose to adopt the new documentation requirements at § 438.16(d)(3) by amending § 457.1201(e) to include the cross-reference, except that references to rate certifications do not apply.

e. Payment and Rate Development (§§ 438.3(c), 438.7(b), 457.1201(c))

In accordance with existing regulations at § 438.3(e)(2)(iv), States are required to ensure the utilization and actual cost of ILOSs are taken into account in developing the benefit component of the capitation rates that represents covered State plan services, unless a statute or regulation explicitly requires otherwise. Additionally, through existing regulations at § 438.4(b)(6), States' actuaries are required to certify that Medicaid capitation rates have been developed in accordance with the ILOS requirements outlined in § 438.3(e). We relied on authority in section 1903(m)(2)(A)(iii) of the Act and regulations based on our authority under section 1902(a)(4) of the Act, to establish actuarially sound capitation rates. While ILOS utilization and actual costs, when allowed, are included in rate development, the existing regulations at § 438.3(c)(1)(ii) do not clearly acknowledge the inclusion of ILOSs in the final capitation rates and related capitation payments. Existing regulations at § 438.3(c)(1)(ii) require that the final capitation rates must be based only upon services covered under the State plan and additional services deemed by the State to be necessary to comply with the requirements of part 438 subpart K (Parity in Mental Health and Substance Use Disorder Benefits), and represent a payment amount that is adequate to allow the managed care plan to efficiently deliver covered services to Medicaid-eligible individuals in a manner compliant with contractual requirements. As an ILOS is not a managed care plan requirement, but rather offered at the option of the managed care plan, it would not be included within the requirement in § 438.3(c)(2)(ii) related to contractual requirements. We propose to revise § 438.3(c)(1)(ii) to include ''ILOS'' to ensure clarity on this matter. This technical change would be included in separate CHIP regulations through an existing cross-reference at § 457.1201(c). We consider this a technical correction to § 438.3(c)(1)(ii) as §§ 438.3(e)(2)(iv) and 438.4(b)(6) clearly denote the inclusion of ILOSs in rate development and we believe this was inadvertently excluded from the final regulatory text in the 2016 final rule.

Additionally, we propose to revise § 438.7(b)(6) and the proposed § 438.7(c)(4) (see section I.B.2.l. of this proposed rule) to add ''ILOS in § 438.3(e)(2)'' to ensure any contract provision related to ILOSs must be documented in all rate certifications submitted to CMS for review and approval. We believe this is necessary to ensure compliance with proposed new regulatory requirements in § 438.16(c)(1)(i) and (c)(4)(i), described in section I.B.4.b. of this proposed rule, to ensure that the projected ILOS cost percentage documented in the rate certification would not exceed the proposed 5 percent limit. This is a similar approach to the current requirements in § 438.7(b)(6) which require a revised rate certification for any change to a contract provisions related to payment in § 438.6, including incentive arrangements that have a similar 5 percent limit in accordance with § 438.6(b)(2). We intend to issue additional guidance in the Medicaid Managed Care Rate Development Guide, in accordance with § 438.7(e), on the Federal standards and documentation requirements for adequately addressing ILOSs in all rate certifications. For separate CHIP, we do not plan to adopt the proposed change at § 438.7(b)(6) since rate certifications are not applicable to separate CHIP.

As risk-based capitation rates are developed prospectively, States' actuaries will make initial assumptions regarding managed care plan and enrollee utilization of ILOSs and associated costs. Since ILOS are offered at the option of the managed care plan and Medicaid enrollee, States and their actuaries should closely monitor whether managed care plans elect to offer these ILOs and enrollees utilize these ILOSs. States' actuaries should assess if adjustments to the actuarially sound capitation rates are necessary in accordance with §§ 438.4, 438.7(a) and 438.7(c)(2). For example, a rate adjustment may be necessary if managed care plan actual uptake of

ILOSs varies from what is intially assumed for rate development and results in an impact to actuarial soundness.

f. State Monitoring (§§ 438.16(d) and (e), 438.66(e), 457.1201(c))

In the 2016 final rule, we clarified the term ''monitoring'' to include oversight responsibilities, and we required standard data elements that a State's monitoring system must collect to inform performance improvement efforts for its managed care program(s). We wish to continue to strengthen State and CMS oversight of each Medicaid managed care program with the addition of proposed text to explicitly address States' monitoring of ILOSs. We rely on the authority in section 1902(a)(4) of the Act to establish methods for proper and effective operations in Medicaid.

Currently, § 438.66 requires that States establish a system to monitor performance of managed care programs broadly, § 438.66(b) outlines the data elements that a State's system must collect, § 438.66(c) establishes expectations for State use of such data for performance improvement, and § 438.66(e) requires States to provide a report on and assessment of each managed care program. When ILOSs are included in a managed care plan's contract, they too must be included in the State's monitoring activities required in § 438.66(b) and (c). We believe States must ensure appropriate monitoring, evaluation, and oversight of ILOSs. We believe additional protections are necessary to ensure the delivery of ILOSs. In the 2015 notice of proposed rulemaking, we proposed expanded State monitoring requirements in § 438.66 and noted that our experience since the 2002 final rule has shown that strong State management and oversight of managed care is important throughout a program's evolution, but is particularly critical when States transition large numbers of beneficiaries from FFS to managed care or when new managed care plans are contracted (see 80 FR 31158). We subsequently finalized these requirements in the 2016 final rule. We believe that this logic is also applicable when a State expands the use of ILOSs as we have seen in recent years. Therefore, our proposals in this section further strengthen these existing Federal requirements related to States' monitoring activities for each managed care program.

As with all covered services and settings, States and their managed care plans must comply with all enrollee encounter data requirements in §§ 438.242 and 438.818. We rely on authority in section 1903(m)(2) of the Act to require sufficient encounter data and a level of detail specified by the Secretary. Complete, accurate, and validated encounter data would also support the evaluation and oversight of ILOS proposals described in sections I.B.4.g. and h. of this proposed rule, and ensure appropriate rate development, as described in section I.B.4.e. of this proposed rule. In § 438.242(c)(2), we require that contracts between a State and its managed care plans provide for the submission of enrollee encounter data to the State at a frequency and level of detail to be specified by CMS and the State, based on program administration, oversight, and program integrity needs. Further, at § 438.242(d), States must review and validate that encounter data collected, maintained, and submitted to the State by the managed care plan is a complete and accurate representation of the services and settings provided to enrollees. Because ILOSs may not be easily identifiable in CPT® and Healthcare Common Procedure Coding System (HCPCS), we believe it is imperative that States identify specific codes and modifiers, if needed, for each ILOS and provide that information to its managed care plans to ensure consistent use. For example, the use of a modifier is useful when a State needs to separately identify an ILOS from a State plan-covered service or setting that may utilize the same HCPCS code. We propose in § 438.16(d)(1)(vi), to require that States include a contractual requirement that managed care plans utilize the specific codes established by the State to identify each ILOS in enrollee encounter data. States could require the use of specific HCPCS or CPT codes and modifiers, if needed, that identify each ILOS. To the extent possible, we encourage States to work towards the development of standard CPT® and HCPCS codes for ILOSs, and States may wish to collaborate with appropriate interested groups. For separate CHIP, while the provisions at § 438.66 are not applicable, we propose to adopt the new coding requirements at § 438.16(d)(1)(vi) by amending § 457.1201(c) to include the cross-reference.

We considered allowing States to include this level of data outside of the managed care plan contract, such as in a provider manual or similar documents; however, those documents are frequently not readily available to interested parties and some are not made publicly available. We believe requiring specific codes to be in the managed care plan contracts would ensure that we can easily identify ILOSs in T–MSIS data, support program integrity activities, and ensure that the information is publicly available as required at § 438.602(g)(1). For these reasons, we believe requiring the codes in the managed care plan contract would be the most appropriate and efficient option. We also believe this proposal would ensure that ILOSs are easily identifiable in the base data utilized for development of capitation rates in accordance with rate development standards described in § 438.5(c), and the associated development of the projected and final ILOS cost percentage which are built off of capitation rates and capitation payments as proposed in section I.B.4.b. of this proposed rule.

States are required to submit an annual performance report to CMS for each Medicaid managed care program administered by the State in accordance with § 438.66(e)(1), known as the MCPAR. In § 438.66(e)(2), we specify the content of the MCPAR, including § 438.66(b)(11) that specifies accessibility and availability of covered services in the managed care plan contract. As ILOSs are substitutes for State plan-covered services and settings, we believe States should already be reporting on ILOSs in MCPAR, but to improve clarity for States, we propose to add an explicit reference. Therefore, we propose a minor revision to § 438.66(e)(2)(vi) to add the phrase ''including any ILOS.'' To facilitate States' reporting of their monitoring activities and findings for ILOSs in MCPAR, we intend to update the MCPAR report template to enable States to easily and clearly include ILOS data throughout the report. We believe that it is important for States to monitor trends related to the availability and accessibility of ILOSs given the unique and innovative nature of some ILOSs, and we believe using MCPAR would be an efficient way for States to report their activities.

g. Retrospective Evaluation (§§ 438.16(e) and 457.1201(e))

As part of Federal monitoring and oversight of Medicaid and CHIP programs, we regularly require States to submit evaluations to CMS that analyze cost or cost savings, enrollee health outcomes or enrollee experiences for a specific Medicaid or CHIP benefit, demonstration, or managed care program. For example, as set forth in an SMDL [140] published on December 22, 1998, States with a program authorized by a waiver of section 1915(b) of the Act

[140] *https://www.medicaid.gov/federal-policy-guidance/downloads/smd122298.pdf.*

must conduct two independent assessments of the quality of care, cost effectiveness and impact on the State's Medicaid program, and access to care to ensure compliance with § 431.55(b)(2)(i) through (iii). There are also quality requirements at §§ 438.340 and 457.1240(e) for States contracting with a managed care plan to develop and implement a written quality strategy for assessing and improving the quality of health care and services furnished by the plan. We also believe that States should evaluate and demonstrate that ILOSs are cost effective, medically appropriate, and an appropriate and efficient use of Medicaid and CHIP resources and that such a requirement would be consistent with those existing requirements and the proposals outlined in sections I.B.4. of this proposed rule. We rely on the authority in sections 1902(a)(4) and 2101(a) of the Act to establish methods for proper and effective operations in Medicaid and CHIP respectively, and sections 1902(a)(6) and 2107(b)(1) of the Act which requires that States provide reports, in such form and containing such information, as the Secretary may from time to time require. To reduce State and Federal administrative burden, where possible, we again propose a risk-based approach to the State documentation requirement that would be proportional to a State's ILOS cost percentage. We propose, in § 438.16(e)(1) for Medicaid, and through a proposed cross-reference at § 457.1201(e) for separate CHIP, to require States to submit a retrospective evaluation to CMS of ILOSs, if the final ILOS cost percentage exceeds 1.5 percent, though we do strongly encourage all States that include ILOSs in their managed care plan contracts to conduct a retrospective evaluation of all ILOSs. As a State could authorize multiple ILOSs in one managed care program, we believe that this evaluation should evaluate each ILOS in order to clearly assess the impact and effectiveness of each ILOS.

With § 438.16(e)(1)(i) for Medicaid, and through a proposed cross-reference at § 457.1201(e) for separate CHIP, we propose that an evaluation be completed separately for each managed care program that includes an ILOS. We considered allowing States to evaluate ILOSs across multiple managed care programs to reduce State administrative burden and alleviate potential concerns regarding sample size for the evaluation. We further considered permitting States to self-select the appropriate level at which to evaluate ILOSs including for each managed care program, across managed care programs, or by managed care plan contract. However, in our experience, a State with multiple managed care programs (for example, behavioral health, physical health, etc.) could have differing enrollee eligibility criteria, populations, covered benefits, managed care plan types, delivery models, geographic regions, or rating periods among the separate managed care programs. Including more than one managed care program in an evaluation would likely impact evaluation rigor and could dilute or even alter evaluation results due to the variability among managed care programs. As States would be required to provide the ILOS cost percentage for each managed care program, we believe that it is necessary for the evaluation to also be conducted at the individual program level as it is one measure to aid in evaluating the overall impact of the ILOSs. For these reasons, we believe it would be critical for States to provide separate evaluations for each managed care program that includes ILOSs. We seek public comment on whether the evaluation should be completed for each managed care program, across multiple managed care programs, each managed care plan contract, or at a level selected by the State.

Since these proposed retrospective evaluations would utilize complete encounter data, we considered several options for the length of the evaluation period. Often, evaluation reports are required on an annual basis, such as MCPAR in § 438.66(e) or the Network Adequacy and Access Assurances report in § 438.207(d). We considered requiring an annual submission for the report required in § 438.16(e)(1), but believed that encounter data would be insufficient to result in meaningful analysis. We also considered a 3-year evaluation period, which may be sufficient for ILOSs that are immediate substitutes, but enrollees may need to receive longer term substitutes for a period of several years in order for a State to have robust data. We also considered a 10-year period, but we concluded that seemed to be an unreasonably long time to obtain information on the efficient and effective use of these unique services and settings. We concluded that a 5-year period would provide sufficient time to collect complete data. Therefore, we propose in § 438.16(e)(1)(ii) for Medicaid, and through a proposed cross-reference at § 457.1201(e) for separate CHIP, that a State's retrospective evaluation would have to use the 5 most recent years of accurate and validated data for the ILOSs. We believe the 5-year period would allow managed care plans and enrollees to become comfortable with the available ILOSs and opt to provide or receive them, thus generating the necessary data for the evaluation. Even for ILOSs that are longer term substitutes, we believe a 5-year period would be sufficient to permit robust data collection for cost effectiveness and medical appropriateness. We request comment on the appropriate length of the evaluation period.

By proposing that retrospective evaluations be completed using the five most recent years of accurate and validated data for the ILOS(s), we recognize that we need to also propose the scope of the evaluation. We considered permitting States to identify an appropriate 5-year evaluation period, but ultimately decided against this as it could create a perverse incentive to identify a favorable evaluation period for each ILOS in order to circumvent the termination process proposed in § 438.16(e)(2)(iii) and described in section I.B.4.h. of this proposed rule. We also considered if the evaluation period should begin with the first year that a State exceeds the 1.5 percent final ILOS cost percentage threshold, but decided against this option as we believe it is necessary for evaluation rigor to establish an early or, ideally pre-intervention, baseline from which to evaluate the impact of a new ILOS over time. We concluded that States' evaluations should be retroactive to the first complete rating period following the effective date of this provision in which the ILOS was included in the managed care plan contracts and capitation rates; we propose this in § 438.16(e)(1)(iv) for Medicaid, and through a proposed cross-reference at § 457.1201(e) for separate CHIP. We believe that our proposed approach is aligned with identified best practices for evaluation. We would encourage States to consider developing a preliminary evaluation plan for each ILOS as part of the implementation process for a new ILOS and any time States significantly modify an existing ILOS. We request comment on the appropriate timing of an ILOS evaluation period.

To ensure some consistency and completeness in the retrospective evaluations, we believe there should be a minimum set of required topics to be included. First, in § 438.16(e)(1)(ii) for Medicaid, and through a proposed cross-reference at § 457.1201(e) for separate CHIP, we propose to require that States must utilize data to at least evaluate cost, utilization, access, grievances and appeals, and quality of care for each ILOS. Similar elements are

required in evaluations for programs authorized by waivers approved under sections 1915(b) and 1915(c) of the Act and demonstrations under section 1115(a) of the Act. We believe these five proposed elements would permit CMS and States to accurately measure the impact and programmatic integrity of the use of ILOSs. We expand upon these elements in § 438.16(e)(1)(iii) wherein we propose the minimum elements that a State, if required to conduct an evaluation, would have to evaluate and include in an ILOS retrospective evaluation. We propose, in § 438.16(e)(1)(iii)(A) for Medicaid, and through a proposed cross-reference at § 457.1201(e) for separate CHIP, to require States to evaluate the impact each ILOS had on utilization of State plan-covered services and settings, including any associated savings. As an intended substitute for a State plan-covered service or setting, that is cost effective and medically appropriate as required in § 438.3(e)(2)(i), we believe that it is important to understand the impact of each ILOS on these State plan-covered services and settings and any cost savings that result from reduced utilization of such specific services and settings. We believe that this evaluation element would also require the State to evaluate potentially adverse trends in State plan services and settings utilization, such as underutilization of adult preventive health care. Per § 438.3(e)(2)(i), the State must determine that an ILOS is a cost effective substitute; therefore, we believe that it would be appropriate for a State to evaluate any cost savings related to utilization of ILOSs in place of State plan-covered services and settings.

Similarly, we propose in § 438.16(e)(1)(iii)(B) for Medicaid, and through a proposed cross-reference at § 457.1201(e) for separate CHIP, to require that States evaluate trends in managed care plan and enrollee use of each ILOS. We believe that it is necessary to understand actual utilization of each ILOS in order to evaluate enrollee access to ILOSs and related trends that occur over time. Trends in enrollee utilization of ILOSs could also be compared to data related to State plan services and settings utilization to determine if there is a correlation between utilization of certain ILOSs and decreased or increased utilization of certain State plan services and settings. Trends in utilization of ILOSs may also help identify when enrollees choose not to utilize an ILOS to help States and managed care plans assess future changes in authorized ILOSs. We believe this is a key evaluation element necessary to determine if the ILOS was cost effective.

Critical to the authority for the allowable provision of ILOSs, is a State determination that an ILOS is a cost effective and medically appropriate substitute for a covered service or setting under the State plan as required in § 438.3(e)(2)(i). Therefore, we believe States should evaluate whether, after 5 years, its determinations are still accurate given actual enrollee utilization and experience. To achieve this, we propose § 438.16(e)(1)(iii)(C) for Medicaid, and through a proposed cross-reference at § 457.1201(e) for separate CHIP, which would require that States use encounter data to evaluate if each ILOS is a cost effective and medically appropriate substitute for the identified covered service or setting under the State plan or a cost effective measure to reduce or prevent the future need to utilize the identified covered service or setting under the State plan. We have included the following example to identify how a State could use encounter data to evaluate the medical appropriateness of an ILOS. A State may initially determine that the provision of air filters as an ILOS is a medically appropriate substitute service for individuals with an asthma diagnosis for emergency department visits, inpatient and outpatient services, and HCBS for activities of daily living (ADLs). After analyzing the actual encounter data, the State may discover that the provision of air filters to the target population did not result in decreased utilization of a State plan service such as emergency department, inpatient and outpatient services, nor HCBS for ADLs. In this instance, the evaluation results would demonstrate that the ILOS as currently defined was not cost effective for the target population of individuals as currently defined.

As ILOSs are services and settings provided to Medicaid and CHIP managed care enrollees in lieu of State plan-covered services and settings, we believe that it is important for States to evaluate the quality of care provided to enrollees who utilized ILOSs to ensure that the ILOS(s) are held to the same quality standards as the State plan services and settings enrollees would otherwise receive. Quality of care is also a standard domain within evaluations of Medicaid and CHIP services, Medicaid and CHIP managed care plans, and Medicaid and CHIP programs as demonstrated by the ubiquitous use of the National Committee for Quality Assurance (NCQA) Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey and Healthcare Effectiveness Data and Information Set (HEDIS) measure set which includes standardized and validated quality of care measures for use by States and managed care plans operating within Medicaid and CHIP managed care environments. Accordingly, in § 438.16(e)(1)(iii)(D) for Medicaid, and through a proposed cross-reference at § 457.1201(e) for separate CHIP, we propose that States evaluate the impact of each ILOS on quality of care. We believe that States should use validated measure sets, when possible, to evaluate the quality of care of ILOSs, though we do not want to stifle State innovation in this area so we are not proposing to require it. We considered proposing to require that States procure an independent evaluator for ILOS evaluations. In consideration of the myriad of new proposed requirements within this proposed rule, we weighed the value of independent evaluation with increased State burden. We are concerned that it would be overly burdensome for States to procure independent evaluators for ILOS(s) due, in part, to the timing of the final ILOS cost percentage submission. In section I.B.4.b. of this proposed rule, we are proposing that the final ILOS cost percentage be submitted 2 years following completion of the applicable rating period, and we propose here that if the final ILOS cost percentage exceeds the 1.5 percent, States would be required to submit an evaluation. While States should conduct some evaluation planning efforts, it could be difficult and time consuming to procure an independent evaluator in a timely manner solely for the purpose of the ILOS evaluation since States would not know definitely whether an evaluation is required until 2 years following the rating period. We solicit comment on whether we should consider a requirement that States use an independent evaluator for ILOS evaluations.

We believe that States should, to the extent possible, leverage existing quality improvement and evaluation processes for the retrospective ILOS evaluation. Through §§ 438.364(a) and 457.1250(a), we require States to partner with an EQRO to produce an annual technical report that summarizes findings related to each MCO's, PIHP's, PAHP's, or PCCM entity's performance relative to quality, timeliness, and access to health care services furnished to Medicaid and CHIP enrollees. Through these existing EQR activities at § 438.364(b), and, if finalized, the newly proposed optional activity at § 438.64(c)(7), discussed in

more detail in section I.B.5.c.3. of this proposed rule, we believe States could leverage the CMS-developed protocol or their EQRO to assist with evaluating the impact of ILOSs on quality of care. We believe this new optional activity could reduce burden associated with these new evaluation requirements for ILOSs.

The elements we have proposed in the evaluation should communicate a complete narrative about the State, managed care plans, and enrollees' experience with ILOSs. As key thresholds and limits on ILOSs, the projected and final ILOS cost percentages would be another element that CMS would consider as part of the overall mosaic to understand the impact that an ILOS might have on each managed care program. Although the final ILOS cost percentage is proposed to be submitted with the rate certification submission required in § 438.7(a) for the rating period beginning 2 years after each rating period that includes ILOS(s), we believe it is important to the completeness of the retrospective evaluation, that all final ILOS cost percentages available be included. Therefore, we propose in § 438.16(e)(1)(iii)(E) for Medicaid, and through a proposed cross-reference at § 457.1201(e) for separate CHIP, that States provide the final ILOS cost percentage for each year in their retrospective evaluation, consistent with the report proposed in § 438.16(c)(5)(ii), (described in section I.B.4.b. of this proposed rule) with a declaration of compliance with the allowable 5 percent threshold proposed in § 438.16(c)(1)(i). We believe this necessary documentation of State compliance would be appropriate to be documented in the evaluation alongside the other data we have proposed to ensure a fulsome evaluation that accurately demonstrates whether the ILOS(s) are an appropriate and efficient use of Medicaid and CHIP resources.

In section I.B.4.c. of this rule, we proposed to identify enrollee rights and protections for individuals who are offered or who receive an ILOS, and in section I.B.4.f. of this proposed rule we outlined requirements for States' monitoring of enrollee rights and protections. To determine if States have appropriately safeguarded and adequately monitored enrollee rights and protections, we propose in § 438.16(e)(1)(iii)(F) for Medicaid, and through a proposed cross-reference at § 457.1201(e) for separate CHIP, to require States to evaluate appeals, grievances, and State fair hearings data, reported separately for each ILOS, including volume, reason, resolution status, and trends. As ILOSs are substitutes for covered State plan services and settings, and are offered at the option of the managed care plan, we believe it would be important to evaluate appeals, grievances, and State fair hearing trends to ensure that enrollees' experience with ILOSs is not inconsistent or inequitable compared to the provision of State plan services and settings. We acknowledge that we already require for Medicaid, through § 438.66(e)(2)(v), that States include an assessment of the grievances, appeals, and State fair hearings annually in MCPAR. But the information we propose that States submit with the ILOS retrospective evaluation is different as it would be specific to each ILOS compared to the summary level information required by MCPAR. We believe collecting these data by ILOS will help evaluate the quality of care and enrollee experience related to the provision of each ILOS.

Finally, we believe an evaluation of the impact ILOSs have on health equity efforts is a critical component to measure enrollee experience, health outcomes, and whether ILOSs are an appropriate and efficient use of Medicaid and CHIP resources. As ILOSs can be an innovative option States may consider employing in Medicaid and CHIP managed care programs to address SDOHs and HRSNs, we also believe it is critical to measure their impact on improving population health and reducing health disparities. We propose in § 438.16(e)(1)(iii)(G) for Medicaid, and through a proposed cross-reference at § 457.1201(e) for separate CHIP, to require States to evaluate the impact of each ILOS on health equity efforts undertaken by the State to mitigate health disparities. To do this, managed care plans should submit enrollee encounter data, to the extent possible, that includes comprehensive data on sex (including sexual orientation and gender identity), race, ethnicity, disability status, rurality and language spoken. We remind managed care plans of their obligations in §§ 438.242(c)(3) and 457.1233(d) to submit all enrollee encounter data that States are required to report to CMS under § 438.818; currently, T–MSIS provides fields for sex, race, ethnicity, disability status, and language spoken.

To allow adequate time for claims run-out and the evaluation to be conducted, we propose in § 438.16(e)(1)(iv) for Medicaid, and through a proposed cross-reference at § 457.1201(e) for separate CHIP, to require that States submit a retrospective evaluation to CMS no later than 2 years after the completion of the first 5 rating periods that included the ILOS following the effective date of this provision, if finalized. This 2-year timeframe is similar to the timeframe utilized for independent assessments to evaluate programs authorized by waivers approved under section 1915(b) of the Act.

While we believe many ILOSs can be sufficiently validated as medically appropriate and cost effective substitutes within 5 years, we know that some may not. To fulfill our program monitoring obligations, we believe we must be able to require additional evaluations if the initial evaluation demonstrates deficiencies. We propose in § 438.16(e)(1)(v) for Medicaid, and through a proposed cross-reference at § 457.1201(e) for separate CHIP, to explicitly assert our right to require States to provide additional 5-year retrospective evaluations. We believe that this could be a necessary flexibility when additional evaluation time might be needed, such as to demonstrate that an ILOS acting as a longer term substitute for a covered State plan service or setting is cost effective and medically appropriate. We also believe we may need to utilize this flexibility when a State substantially revises the ILOSs that are options within a managed care program.

For CHIP, our typical mechanism for retrospective managed care cost evaluation is through the CHIP Annual Report Template System (CARTS). We recognize that CARTS is completed annually by States and that our proposed timeframe for the retrospective evaluation is for a period of 5 years, but we considered whether it would be less burdensome to States to incorporate the CHIP ILOS retrospective evaluation into CARTS rather than as a stand-alone report. We seek public comment on whether or not the proposed retrospective evaluation should be incorporated into CARTS for CHIP ILOSs.

h. State and CMS Oversight (§§ 438.16(e) and 457.1201(e))

If a State determines that an ILOS is no longer a medically appropriate or cost effective substitute or the State identifies another area of noncompliance in the provision of ILOSs, we believe CMS must be promptly notified. We rely on the authority in sections 1902(a)(4) and 2101(a) of the Act to establish methods for proper and effective operations in Medicaid and CHIP, and sections 1902(a)(6) and 2107(b)(1) of the Act which require that States provide reports, in such form and containing such information, as the Secretary may from time to time require. We propose,

in § 438.16(e)(3) for Medicaid, and through a proposed cross-reference at § 457.1201(e) for separate CHIP, to establish processes and timelines for State and CMS oversight of ILOSs. In § 438.16(e)(2)(i)(A) and (B) for Medicaid, and through a proposed cross-reference at § 457.1201(e) for separate CHIP, we propose to require that States notify CMS within 30 calendar days if the State determines that an ILOS is no longer a medically appropriate or cost effective substitute for a State plan-covered service or setting, or the State identifies another area of noncompliance in this proposed section. Issues of noncompliance that would require State notification to CMS include, but are not limited to, contravening statutory requirements (for example, the provision of room and board), failure to safeguard the enrollee rights and protections enumerated under part 438, or the absence of the proposed provider documentation necessary to establish that an ILOS is medically appropriate for a specific enrollee. We believe that 30 days is a reasonable period of time for a State to identify and confirm an area of noncompliance. We considered a 60-day notification period, but believe that States should notify CMS in a more expeditious manner so that CMS may assess and swiftly remediate issues of noncompliance that might cause harm to enrollees. We seek comment on the time period for State notification to CMS to ensure it is reasonable and appropriate.

We believe a termination process for ILOSs is critical to properly safeguard the health and safety of Medicaid and CHIP enrollees. Therefore, we propose a Federal oversight process at § 438.16(e)(2)(ii) for Medicaid, and through a proposed cross-reference at § 457.1201(e) for separate CHIP, which would permit CMS to terminate the use of an ILOS, if we determine noncompliance or receive State notification of noncompliance as proposed in § 438.16(e)(2)(i). In § 438.16(e)(2)(iii) for Medicaid, and through a proposed cross-reference at § 457.1201(e) for separate CHIP, we propose a process for termination of an ILOS that would apply when a State terminates an ILOS, a managed care plan elects to no longer offer an ILOS to its enrollees, or CMS notifies the State that it must terminate an ILOS. In any of these events, we propose that the State would be required to submit an ILOS transition plan to CMS for review and approval within 15 calendar days of the decision by the State to terminate an ILOS, a managed care plan notifying the State it will no longer offer an ILOS, or receipt of notice from CMS to terminate. In addition to 15 calendar days, we also considered 30, 60, and 90 calendar days, but ultimately decided on the former option. We recognize that 15 calendar days is a rapid submission timeline, but we firmly believe that such a transition plan would need to be implemented immediately following an ILOS termination to safeguard enrollee health and safety, and to maintain the integrity and efficient operation of the Medicaid program in accordance with sections 1902(a)(4) and 2101(a) of the Act. Given the submission timeline and that ILOSs are provided at the option of the managed care plan, we believe States should prepare an ILOS transition plan as part of the implementation process for any new ILOSs. The process for termination proposed at § 438.16(e)(2)(iii) is the same, regardless of whether the State, managed care plan or CMS terminates the ILOS as the potential risks to enrollees are the same irrespective of which entity directs termination of the ILOS.

In § 438.16(e)(2)(iii)(A) through (D) for Medicaid, and through a proposed cross-reference at § 457.1201(e) for separate CHIP, we propose the elements States should include in the transition plan for the ILOS. We believe that a transition plan is necessary to protect the health and well-being of Medicaid and CHIP enrollees for whom the sudden termination of an ILOS, without an adequate transition plan, could have a significant negative impact. We rely on the authority in sections 1902(a)(4) and 2101(a) of the Act to establish methods for proper and effective operations in Medicaid and CHIP, and sections 1902(a)(6) and 2107(b)(1) of the Act which require that States provide reports, in such form and containing such information, as the Secretary may from time to time require. In § 438.16(e)(2)(iii)(A) for Medicaid, and through a proposed cross-reference at § 457.1201(e) for separate CHIP, we propose to require that States establish a process to notify enrollees that the ILOS they are currently receiving will be terminated as expeditously as the enrollee's health condition requires. We also propose, in § 438.16(e)(2)(iii)(B) for Medicaid, and through a proposed cross-reference at § 457.1201(e) for separate CHIP, to require that States create and make publicly available a transition of care policy, not to exceed 12 months, to arrange for State plan services and settings to be provided timely and with minimal disruption to the care for any enrollees receiving an ILOS at the time of termination. From the period of notification onward, we would expect that a State and its managed care plans cease provision of the ILOS to any new enrollees. Together, we believe that these two actions would ensure adequate beneficiary protections, including adequate beneficiary notice and access to medically appropriate State plan-covered services and settings in a timely fashion.

In addition to enrollee focused activities, we propose that the transition plan also include administrative actions that States would take to remove a terminated ILOS from the applicable managed care plan contract(s) and capitation rates. ILOSs must be authorized and identified in the managed care plan contract consistent with § 438.3(e)(2)(iii) and § 457.1201(e), and we believe it is equally important to ensure any terminated ILOS is removed from the managed care plan contract (and rate certification if necessary) to ensure clarity on contractual obligations and appropriate program integrity. We propose, in § 438.16(e)(2)(iii)(C) for Medicaid, and through a proposed cross-reference at § 457.1201(e) for separate CHIP, to direct States to remove the ILOS from the applicable managed care plan contracts and submit a modified contract to CMS for review and approval as required for Medicaid in § 438.3(a). Similarly, we permit States, through §§ 438.3(e)(2)(iv) and § 457.1201(e), to account for the utilization and actual cost of ILOSs in developing the component of the capitation rates that represents the covered State plan services, unless a statute or regulation explicitly requires otherwise. As part of the transition plan, States would be required to provide an assurance that it would submit the necessary contract amendment, and outline a reasonable timeline for submitting the contract amendment to CMS for review and approval. In the event that an ILOS is terminated from the managed care plan contract, the State and its actuary, should evaluate if an adjustment(s) to the capitation rates is necessary to ensure Medicaid capitation rates continue to be actuarially sound, such as if the programmatic change would have a material impact to the rate development. As outlined in § 438.4 for Medicaid, actuarially sound capitation rates must be appropriate for the populations to be covered and the services to be furnished under the managed care plan contract, and the State's actuary must ensure that the capitation rates continue to be actuarially sound given any change to

the contract. Therefore, we propose in § 438.16(e)(2)(iii)(D) to direct States to adjust the actuarially sound capitation rate(s), as needed, to remove utilization and cost of the ILOS from Medicaid capitation rates as required in §§ 438.4, 438.7(a) and 438.7(c)(2). As part of the transition plan, States would be required to provide an assurance that it would submit an adjustment to the capitation rates, as needed, and outline a reasonable timeline for submitting the revised rate certification to CMS for review and approval.

For separate CHIPs, States must develop capitation rates consistent with actuarially sound principles as required at § 457.1203(a). We also believe that in the event a CHIP ILOS is terminated, a State should evaluate if an adjustment to the capitation rate is needed to account for the removal of ILOS utilization and cost from the managed care plan contract. For this reason, we propose to adopt § 438.16(e)(2)(iii)(D) for separate CHIP through a new cross-reference at § 457.1201(e). However, we note that the requirements at § 438.7 are not applicable for 42 CFR part 457.

i. Applicability Dates (§§ 438.3(e), 438.7(g), 438.16(f), 457.1200(d))

We propose that States and managed care plans would be required to comply with the provisions outlined in §§ 438.2, 438.3(c)(1)(ii) and (e)(2)(i) through (iv), 438.10(g)(2)(ix), 438.66(e)(2)(vi) and applicable cross-references for separate CHIP at §§ 457.10, 457.1201(c) and (e), and 457.1207 no later than the effective date of the final rule. We believe this is appropriate as these proposals are technical corrections or clarifications of existing requirements. Additionally, we propose that States and managed care plans would have to comply with §§ 438.3(e)(2)(v), 438.16, 438.7(b)(6) no later than the rating period for contracts with MCOs, PIHPs, and PAHPs beginning on or after 60 days following the effective date of the final rule as we believe this is a reasonable timeframe for compliance. We propose to revise § 438.3(v) to add this proposed date, remove ''July 1, 2017,'' and update ''2015'' and referenced citations; and add 438.7(g)(1) and 438.16(f). We propose to adopt the applicability date at § 438.16(f) for separate CHIP by adding § 457.1200(d).

5. Quality Assessment and Performance Improvement Program, State Quality Strategies and External Quality Review (§§ 438.330, 438.340, 438.350, 438.354, 438.358, 438.360, 438.364, 457.1201, 457.1240, 457.1250)

a. Quality Assessment and Performance Improvement Program (§ 438.330)

Regulations at § 438.330 establish the Quality Assessment and Performance Improvement (QAPI) programs that States must require of Medicaid managed care plans (that is, MCOs, PIHPs, and PAHPs). Section 438.330(d) describes the performance improvement projects (PIPs) that States must require of Medicaid managed care plans as part of the QAPI program. Medicare Advantage (MA) plans are subject to similar (but not identical) requirements at § 422.152. Section 422.152 outlines the quality improvement program requirements for MA organizations, including the development and implementation of a Chronic Care Improvement Program (CCIP). Previously, CMS required MA organizations to develop and implement Quality Improvement Project (QIPs), which were an organization's initiatives focusing on specified clinical and nonclinical areas and were expected to have a favorable effect on health outcomes and enrollee satisfaction. However, CMS found the implementation of the QIP and CCIP requirements had become burdensome and complex, and removed the requirements for the QIP. With the removal of the QIP requirement with the 2019 Final Rule (83 FR 16440), we are proposing to update our regulations at § 438.330(d)(4) which still reference a QIP as a substitute for a PIP in managed care plans exclusively serving dually eligible individuals.

Through previous rulemaking, in the 2016 final rule (81 FR 27682), we implemented a policy, at § 438.330(d)(4), to allow States to permit Medicaid managed care plans exclusively serving dually eligible individuals to substitute an MA plan's quality improvement project (QIP) conducted under § 422.152(d) in the place of a Medicaid PIP, to prevent unnecessary duplication and increase flexibility for plans and States. Subsequently, in the final rule ''Medicare Programs; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs and the PACE Program,'' we removed the QIP from the requirements for MA organizations at § 422.152, because we determined that they did not add significant value and many were duplicative of existing activities, such as the Chronic Care Improvement Program (CCIP) (83 FR 16669). Due to an oversight at that time, we neglected to remove a reference to the QIP from § 438.330(d)(4) to conform with the changes at § 422.152. We are now proposing to replace the outdated reference at § 438.330(d)(4) to § 422.152(d) (which previously described the now-removed QIP), with a reference to the CCIP requirements for MA organizations in § 422.152(c). This change would allow States to permit a Medicaid managed care plan exclusively serving dually eligible individuals to substitute an MA organization CCIP, conducted in accordance with the requirements at § 422.152(c), for one or more of the PIPs required under § 438.330(d). We believe the CCIP meets the same intent of the current regulation as an appropriate substitute for a PIP based on the quality improvement standards in a CCIP, including the identification of intervention goals and objectives, the collection and analysis of valid and reliable data, the assessment of performance and outcomes using quality indicators and measures, systematic and ongoing follow-up for increasing or sustaining improvement, and the reporting of results to CMS. We believe that permitting such a substitution would also maintain the intent of the current regulation to prevent unnecessary duplication and increase flexibility for plans and States, while allowing Medicaid managed care plans to maintain robust health improvement initiatives for dually enrolled individuals. Since the change to remove QIPs has been in place since 2019, we expect some States to already have CCIPs in place in lieu of QIPs, and therefore, are proposing that States must comply with this update in § 438.330(d)(4) no later than the rating period for contracts beginning after the effective date of the final rule in the applicability date provision at § 438.310(d)(1). We note this proposed change does not apply to separate CHIP because we did not apply § 438.330(d)(4) to separate CHIP in the 2016 final rule, and because § 457.310(b)(2) does not allow for concurrent health coverage in separate CHIP.

b. Managed Care State Quality Strategies (§§ 438.340, 457.1240)

Current regulations at § 438.340, which are included in separate CHIP regulations through an existing cross-reference at § 457.1240(e), set forth requirements for States to draft and

implement a written quality strategy for assessing and improving the quality of health care and services furnished by the MCO, PIHP, or PAHP. The requirement also applies to a PCCM entity whose contract with the State provides financial incentives for improved quality outcomes, as described in § 438.310(c)(2). The quality strategy is intended to serve as a foundational tool for States to set goals and objectives related to quality of care and access for their managed care programs. Current regulations at § 438.340(c) require States to make their quality strategy available for public comment when drafting or revising it, and require States to submit their initial quality strategy to CMS for feedback prior to adopting in final. These regulations also stipulate that States must review and update their quality strategy as needed, but no less than once every three years and submit the strategy to CMS whenever significant changes are made to the document or whenever significant changes occur within the State's Medicaid program. Building upon these requirements, we are proposing several changes to increase transparency and opportunity for meaningful ongoing public engagement around States' managed care quality strategies. We are proposing that States must comply with these updates in § 438.340 no later than 1 year from the effective date of the final rule, and are proposing to codify this applicability date at § 438.310(d)(2) for Medicaid, and through a proposed amendment at § 457.1200(d) to include a cross-reference to § 438.310(d) for separate CHIP.

First, we are proposing to increase the opportunity that interested parties have to provide input into States' managed care quality strategy. Current regulations at § 438.340(c)(1) require that States make their quality strategy available for public comment when it is first adopted and when revisions are made. However, the current regulations do not require that the quality strategy be posted for public comment at the three-year renewal mark if significant changes have not been made. We are proposing to revise § 438.340(c)(1) to require that States make their quality strategy available for public comment at the 3-year renewal, regardless of whether or not the State intends to make significant changes, as well as whenever significant changes are made. The proposed change would promote transparency and give interested parties an opportunity to provide input on changes they think should be made to the quality strategy, even if the State itself is not proposing significant changes. Consistent with current policy, States will retain discretion under the proposed rule to define the public comment process. This proposed change would apply equally to separate CHIP through the existing cross-reference at § 457.1240(e).

Second, we are proposing to revise § 438.340(c)(2)(ii) to clarify that the State Medicaid agency must post on its website the results of its 3-year review. The current regulations make clear at § 438.340(c)(2) that the review must include an evaluation, conducted within the previous 3 years, of the effectiveness of the quality strategy and that the results of the review must be made available on the State's website, but do not specifically state that the full evaluation must be posted on the website. Proposed revisions at § 438.340(c)(2)(ii) make clear that the evaluation, as part of the review, must be posted. We note that current § 438.340(c) allows for States to post the evaluation on the website as a standalone document or to include the evaluation in the State's updated and finalized quality strategy, which is required to be posted under § 438.340(d). The proposed change at § 438.340(c)(2)(ii) would apply equally to separate CHIP through the existing cross-reference at § 457.1240(e). For additional information on the components and purpose of the managed care quality strategy, see the Quality Strategy Toolkit, available at *https://www.medicaid.gov/medicaid/downloads/managed-care-quality-strategy-toolkit.pdf.*

Third, we are proposing to clarify when States must submit a copy of their quality strategy to CMS. Current regulations at § 438.340(c)(3) require that States submit to CMS a copy of their initial quality strategy for feedback and a copy of the revised quality strategy whenever significant changes are made. The current regulations do not require States to submit to CMS subsequent versions of their quality strategy unless the State has made significant changes to the document or to their Medicaid program. We are proposing to modify § 438.340(c)(3)(ii) to require that States, prior to finalizing a revised or renewed quality strategy as final, submit a copy of the revised strategy to CMS at minimum every 3 years, following the review and evaluation of the strategy described at § 438.340(c)(2), in addition to when significant changes are made. These proposed changes would allow CMS the opportunity to provide feedback periodically to help States strengthen their managed care quality strategies before they are finalized, whether or not significant changes are made to a State's strategy or to their Medicaid program. We propose to include this requirement into the provision at § 438.340(c)(3)(ii) for Medicaid by adding § 438.340(c)(3)(ii)(A) through (C), which would apply to separate CHIP through an existing cross-reference at § 457.1240(e). We are proposing at § 438.310(d)(2) for Medicaid, and through a proposed amendment at § 457.1200(d) to include a cross-reference to § 438.310(d) for separate CHIP, that States must comply with updates to § 438.340 no later than 1 year from the effective date of the final rule, which we believe would give States time to update internal processes accordingly.

Finally, we are proposing a technical correction to § 438.340(c)(3)(ii) to correct an internal citation related to State-defined significant changes. Currently, § 438.340(c)(3)(ii) references significant changes ''as defined in the State's quality strategy per paragraph (b)(11) of this section[.]'' However, § 438.340(b)(10) contains the information on a State's definition of a significant change. Therefore, we are proposing to replace ''paragraph (b)(11)'' with ''paragraph (b)(10)'' in § 438.340(c)(3)(ii). This proposed change would apply equally to separate CHIP through the existing cross-reference at § 457.1240(e).

c. External Quality Review (§§ 438.350, 438.354, 438.358, 438.360, 438.364, 457.1201, 457.1240, 457.1250)

Current regulations at §§ 438.350, 438.354, 438.358, 438.360, 438.364, and 457.1250 provide requirements for the annual External Quality Review (EQR) on quality, timeliness, and access to the health care services furnished to Medicaid and CHIP beneficiaries enrolled in managed care. The regulations set forth the EQR-related activities that States or a qualified EQR organization (EQRO) must perform, and the information that must be produced from an EQR and included in an annual detailed EQR technical report. States must submit to CMS an annual EQR technical report, which must include, among other things, a description of data, including validated performance measurement data for certain mandatory EQR-related activities. The regulations also delineate the circumstances in which States may use the results from a Medicare or private accreditation review in lieu of conducting an EQR for a given managed care entity. The EQR requirements in 438 Subpart E apply to each MCO, PIHP, and PAHP that has a contract with a State Medicaid or CHIP agency as well as certain PCCM entities

whose contract with the State provides financial incentives for improved quality outcomes, as described in § 438.310(c)(2). We are proposing several changes to the EQR regulations that seek to accomplish two overarching goals: (1) eliminate unnecessary burdensome requirements; and (2) make EQR more meaningful for driving quality improvement.

(1) Removal of PCCM Entities From Scope of Mandatory External Quality Review

In the final 2016 final rule, we added a definition of ''primary care case management entity'' in §§ 438.2 and 457.10 to recognize a new type of primary care case management system in Medicaid and CHIP. Previously, the regulations recognized, and continue to recognize, a primary care case manager (PCCM) as a physician or a physician group practice or, at State option, a physician assistant, nurse practitioner, or certified nurse-midwife that contracts with the State to furnish case management services to Medicaid beneficiaries. The 2016 final rule added the term ''PCCM entity,'' which is defined in §§ 438.2 and 457.10 as an organization that provides one or more additional specified functions in addition to primary care case management services, for example, intensive case management, development of care plans, execution of contracts with and/or oversight responsibilities for other FFS providers, and review of provider claims, utilization and practice patterns, among others. We further recognized in the 2016 final rule that some PCCM entities have contracts with the State that provide financial incentives for improved quality outcomes. Per current § 438.310(c)(2), such PCCM entities are subject to a number of the requirements in 42 CFR part 438, subpart E (relating to Quality Measurement and Improvement and External Quality Review) to which PCCMs are not similarly subject.

Of particular relevance to this proposed rule, the regulations have long provided that States are not required to perform an annual EQR of the State's PCCMs. However, in the 2016 final rule, we provided at §§ 438.350 and 457.1250(a) that States are required to conduct an annual EQR of PCCM entities operating under a risk-bearing contract described in § 438.310(c)(2). We reasoned at the time that, while PCCMs traditionally are paid a per capita fee to provide case management services for Medicaid beneficiaries and otherwise are reimbursed for services rendered on a fee-for-service (FFS) basis, such PCCM entities function more like a managed care entity because their contracts include shared financial risk, and thus should be subject to the EQR requirements.

The 2016 final rule also provided for CMS review of States' contracts with their PCCM entities under § 438.3(r). Our reviews of these contracts have led us to reevaluate the policy to require an annual EQR of PCCM entities described in § 438.310(c)(2), as these contracts exhibit wide variability in the size, structure, and scope of case management and other services provided by risk-bearing PCCM entities. This variation calls into question the appropriateness of EQR as an oversight tool for many of the PCCM entities. For example, the scope of services for some of these PCCM entities may yield little to no data for EQR. In addition, some PCCM entities are a single provider or a small provider group, and we believe the cost and burden imposed by the EQR process may disincentivize them from entering into risk-bearing contracts with States aimed at improving quality and outcomes in the fee-for-service delivery system. We do not believe the EQR requirement should be a barrier for these types of PCCM entities to establish arrangements aimed at quality improvement when States have additional quality monitoring and oversight tools that may be sufficient (for example, QAPI program reviews described at § 438.330(e)).

Therefore, we propose to remove PCCM entities described in § 438.310(c)(2) from the managed care entities subject to EQR under § 438.350. Other requirements in 42 CFR part 438, subpart E that currently apply to risk-bearing PCCM entities described at § 438.310(c)(2) are not impacted by this proposed rule.[141] We note that States may perform additional oversight and monitoring activities that are similar to external quality reviews for PCCM providers (and other providers not subject to EQR such as non-emergency medical transportation providers) at their discretion, and may choose to use an entity that is also an EQRO for these activities, however these activities would not be subject to 438 Subpart E regulations for EQR. Further, we believe that the removal of all PCCM entities from the mandatory scope of EQR will alleviate burden on States and PCCM entities while retaining appropriate tools for quality monitoring and oversight.

We propose conforming amendments to remove reference to PCCM entities described in § 438.310(c)(2) in §§ 438.310(b)(5), 438.358(a)(1), 438.364(a)(3) through (6), and 438.364(c)(2)(ii), and to remove the reference to § 438.350 from § 438.310(c)(2). We also propose removing the current provision at § 438.358(b)(2) that applies risk-bearing PCCM entities to the mandatory EQR activities, to conform with the proposed changes at § 438.350, and reserve this provision for future use. We maintain that EQROs must be independent from any PCCM entities they review at the State's discretion, as currently required under § 438.354(c), and propose a modification at § 438.354(c)(2)(iii) to clarify this. We note that these changes, if finalized, would be effective as of the effective date of the final rule. For separate CHIP, we likewise propose to exclude all PCCM entities from EQR requirements by removing the cross-reference to § 438.350 at § 457.1201(n)(2), by removing the reference to PCCM entities entirely from § 457.1250(a), and removing the cross-reference to § 457.1250(a) for quality requirements applicable to PCCM entities at § 457.1240(f).

(2) EQR Review Period

The current regulations provide that most EQR activities are performed using information derived from the preceding 12 months, but do not clearly indicate to which 12-month period the activity should pertain. Specifically, the current regulations at § 438.358(b)(1) (which apply to separate CHIP through § 457.1250(a)) require validation of information collected or calculated during ''the preceding 12 months'' for three of the mandatory EQR activities (validation of performance improvement projects, validation of performance measurement data, and validation of network adequacy activities). The optional EQR activities described in § 438.358(c) also must be performed using information derived ''during the preceding 12 months''. In addition, we do not currently specify in the regulations when the EQR activity must take place relative to the finalization and posting of the annual report. The result is a lack of uniformity in the review periods included in States' annual EQR technical reports each year. In some cases, for example, States have

[141] States are currently required to include their PCCM entities in CMS contract review under § 438.3(r), and for PCCM entities described at § 438.310(c)(2), States must include them in aspects of their quality assessment and performance improvement programs (QAPI) including an annual utilization and program reviews (§ 438.330(b)(2), (b)(3), (c), and (e)), and their quality strategy (§ 438.340), which includes a quality strategy effectiveness evaluation. States have the discretion under § 438.358(d) to use their EQRO to provide technical assistance to PCCM entities described at § 438.310(c)(2).

reported on the results of EQR activities conducted three or more years ago, while other States have reported on the results of EQR activities conducted relatively close to the completion of the report. To support States' and CMS' ability to use the reports for quality improvement and oversight, we are proposing modifications to ensure consistency and align the data in the annual reports with the most recently available information used to conduct the EQR activities.

We propose to add a new paragraph (a)(3) in § 438.358 to define the 12-month review period for all but one the EQR-related activities described in § 438.358(b)(1) and the optional activities described in § 438.358(c). The one exception is the activity described in § 438.350(b)(1)(iii), which requires a review within the previous 3 years. Under proposed § 438.358(a)(3), the 12-month review period for the applicable EQR activities begins on the first day of the most recently concluded contract year or calendar year, whichever is nearest to the date of the EQR-related activity.

We understand that most performance measures run on a calendar year, while performance improvement projects and network adequacy assessments typically align with the contract year. Under the proposed rule, the 12-month review period for EQR activities does not have to be the same. For example, if an EQRO begins the performance measurement validation activity in July of 2022, and the State calculates performance measures on the calendar year, the review period for the performance measurement validation activity would be January 1 through December 31, 2021. Similarly, if the EQRO validates PIPs in November 2021 and the most recent contract year ended in March 2021, the review period for the EQRO would be March 2020–March 2021.

We are also proposing to require at § 438.358(b)(1) and (c) that the EQR-related activities must be performed in the 12 months preceding the finalization and publication of the annual report. We believe these two proposed changes would result in more recent data being publicly posted in the annual EQR technical reports, and also would create more consistency among States regarding the time period represented by the data. Consistency in what data is reported could help make the EQR technical reports a more meaningful tool for monitoring quality between plans within and between States.

As noted, the proposed clarification of the 12-month review period for the applicable EQR-related activities described in § 438.350(b)(1) and (c) would be effectuated at proposed § 438.358(a)(3). We propose conforming changes to § 438.358(b)(1)(i), (ii) and (iv), and (c) to reference the EQR review period proposed at § 438.358(a)(3). We propose to modify the language at § 438.350(b)(1) and (c) to indicate that the EQR-related activities must be performed in the 12 months preceding the finalization of the annual reports. These proposed changes would apply equally to separate CHIP EQR requirements for MCOs, PIHPs, and PAHPS through an existing cross-reference to Medicaid's EQR-related activities in § 438.358 at § 457.1250(a). We are proposing that States must comply with these updates to § 438.358 no later than December 31, 2025, and are proposing to codify this applicability date at § 438.310(d)(3) for Medicaid, and through a proposed amendment at § 457.1200(d) to include a cross-reference to § 438.310(d) for separate CHIP. This applicability date aligns with the new annual due date for EQR technical reports as proposed at § 438.364(c)(2)(i), which we believe provides States sufficient time to make any contractual or operational updates following the final rule.

(3) Using an Optional EQR Activity To Support Current and Proposed Managed Care Evaluation Requirements

We are proposing to add a new optional EQR activity to support States in their evaluations to learn more about quality outcomes and timeliness of and access to care in managed care plans and programs. Specifically, we believe the existing or proposed evaluation requirements included in this proposed rule for quality strategies at § 438.340(c)(2)(i), State Directed Payments (SDPs) at § 438.6(c)(2)(iv) and (v), and In Lieu of Services or Settings (ILOSs) at § 438.16(e)(1) may be implemented using this new EQR activity. We currently require at § 438.340(c)(2)(i) that States review their quality strategy at a minimum every 3 years, and that this review include an evaluation of the effectiveness of the quality strategy conducted within the previous 3 years. In this proposed rule, we are proposing new requirements related to the evaluation of SDPs at § 438.6(c)(2)(iv) and (v) and ILOSs at § 438.16(e)(1), described in more detail in sections I.B.2.j. and I.B.4.g. We discuss at length the challenges States have demonstrated regarding the SDP evaluation plans and results in section I.B.2.j. of this proposed rule, which indicates to us that States would likely benefit from additional technical assistance and support in conducting evaluations under the newly proposed SDP and ILOS requirements. Additionally, CMS' reviews of State quality strategy evaluations have revealed many challenges for States and a similar need for greater technical assistance. For this reason, we propose to add a new optional EQR activity at § 438.358(c)(7) to assist in evaluations of quality strategies, SDPs, and ILOSs, that pertain to outcomes, quality, or access to health care services. We are focusing the scope of the EQR optional activity to activities permissible under the statutory authority at Section 1932(c)(2) of the Act, which requires external review of the quality outcomes and timeliness of, and access to, the items and services for which the organization is responsible under the contract. We believe by adding this optional activity, States, their agent, or an EQRO could use the accompanying protocol that CMS would develop (in coordination with the National Governors Association in accordance with § 438.352) to assist with evaluation activities related to quality strategies, SDPs, and ILOS, that are within the scope of EQR. We also believe EQROs may be well positioned to help with evaluations since their qualifications, as required under § 438.354(b), include research design and methodology, including statistical analysis, and quality assessment and improvement methods. We believe this optional activity would provide States critical technical assistance via a CMS-developed protocol that would enable more robust evaluations, which could lead to greater transparency and quality improvement in States' implementation of their quality strategy, SDPs and ILOSs. It could also reduce burden by allowing States to receive an enhanced match for activities carried out by an EQRO under this optional activity in accordance with section 1903(a)(3)(C)(ii) of the Act.

For separate CHIP, we did not adopt the proposed evaluation of SDPs at § 438.6(c)(2)(iv) and (v) (see sections I.B.2.a. and I.B.2.j. of this proposed rule). For this reason, we propose to amend separate CHIP EQR requirements at § 457.1250(a) to exclude references to § 438.6. However, we proposed to adopt the new ILOS retrospective evaluation requirements at § 438.16(e)(1) through our proposed cross-reference at § 457.1201(e) (see section I.B.4.g. of this proposed rule). Since section 2103(f)(3) of the Act requires external review of CHIP managed care plans, we also believe that CHIP EQROs are well positioned to assist with the proposed ILOSs evaluations and agree it would be beneficial to States to have this optional

EQR activity. We propose to adopt the new EQR optional activity for separate CHIP through an existing cross-reference to § 438.358 at § 457.1250(a). If finalized, this optional activity would be available to States as of the effective date of the final rule.

(4) Non-Duplication of Mandatory EQR Activities With Medicare or Accreditation Review

Current § 438.360 provides an option for States to exempt MCOs, PIHPs, or PAHPs from EQR-related activities that would duplicate activities conducted as a part of either a Medicare review of a Medicare Advantage (MA) plan or a private accreditation review. Section 438.360(a)(1) requires that, in order for a State to exercise this option with respect to private accreditation, the plan accreditation must be from a private accrediting organization recognized by CMS ''as applying standards at least as stringent as Medicare under the procedures in § 422.158 of this chapter[.]'' Section 422.158 describes the procedures for private, national accreditation organizations (PAOs) to apply for approval of accreditation as a basis for deeming compliance with Medicare requirements, also referred to as ''deeming authority.'' Sections 422.156 and 422.157 discuss conditions and applications of the deeming authority, under which a PAO may accredit MA plans for the purposes of deeming compliance with one or more specific areas of the MA program. The implementation of this current requirement at § 438.360(a)(1) has meant that PAOs must obtain deeming authority from CMS as a prerequisite for the States to use the PAO's plan accreditation review for the purposes of nonduplication of mandatory EQR activities. This means the PAO must obtain and periodically renew their MA deeming authority from CMS even if it is solely for the purpose of providing States the opportunity to use their reviews of a Medicaid managed care plans in lieu of conducting a similar EQR-related activity.

We believe the current regulation creates an unnecessary administrative burden on both CMS and PAOs and may restrict the availability of the EQR nonduplication option for States. We also do not believe that the current requirement is compelled under the statute. The statutory basis for the nonduplication provision, found at section 1932(c)(2)(B) of the Act, states, a State may provide that, in the case of a Medicaid managed care organization that is accredited by a private independent entity (*such as those described in section 1852(e)(4)*) or that has an external review conducted under section 1852(e)(3) of the Act, the external review activities conducted under subparagraph (A) with respect to the organization shall not be duplicative of review activities conducted as part of the accreditation process or the external review conducted under such section (*emphasis added*). Section 1852(e)(4) of the Act is the statutory basis for PAOs to obtain MA deeming authority from CMS. We do not read this provision as requiring every private independent entity to be described under section 1852(e)(4) of the Act in order for a State to exercise the nonduplication provision. Rather, we read section 1932(c)(2)(B) of the Act as describing in general terms the types of organizations that would be eligible to participate in nonduplication, and providing organizations described in section 1852(e)(4) of the Act as an example.

Therefore, we propose at § 438.360(a)(1) to remove the requirement that PAOs must apply for MA deeming authority from CMS in order for States to rely on PAO accreditation reviews in lieu of EQR activities. We are proposing conforming changes to the title of § 438.362(b)(2) to remove language specific to Medicare Advantage deeming. Additionally, we are proposing to remove the requirements for PAOs related to MA deeming authority at § 438.362(b)(2)(i). This proposal would remove paragraph (b)(2)(i)(B) and modify paragraph (b)(2)(i) to include current § 438.362(b)(2)(i)(A). We believe this proposed change will reduce administrative burden among the private accreditation industry, as well as create more flexibility for States to leverage PAO reviews for nonduplication. We note that under § 438.360(a)(2) States will still be required to ensure the review standards used by any PAO are comparable to standards established through the EQR protocols under § 438.352, and pursuant to § 438.360(c), will need to explain the rationale for the State's determination that the activity is comparable in their quality strategy at § 438.340. If finalized, these changes would be effective as of the effective date of the final rule.

(5) External Quality Review Results (§ 438.364)

(a) Data Included in EQR Technical Reports

The current regulations at § 438.364, included in separate CHIP programs through an existing cross-reference at § 457.1250(a), describe what information must be included in the annual EQR technical reports as well as the public availability of the reports. While the information currently provided in the EQR technical reports is useful to CMS in our work with States to improve beneficiary access to and quality of care provided through a managed care delivery system, we believe these reports could and should provide additional information useful to both CMS and the public.

Current regulations at § 438.364(a)(2) describe the information the State must include in the annual EQR technical report for each EQR-related activity. Under § 438.364(a)(2)(iii), the EQR technical reports must include a description of data obtained, including validated performance measurement data for each PIP validation and performance measurement validation activity at § 438.358(b)(1)(i) and (ii), respectively. The current regulations, however, limit the data included in the reports to performance measurement data; the regulations do not require that other types of data that may be used to measure the outcomes associated with a PIP, such as percentages of enrollees that participated in the PIP or data on patient satisfaction based on services received from the plan, be included in the annual reports. The result is that reports often focus on whether the methods used to implement or evaluate the PIP were validated, but do not include the measurable data reflecting the outcomes of the PIP. Additionally, the regulations do not currently require the reports to include any data obtained from the mandatory network adequacy validation activity.

We believe validation alone is insufficient to provide CMS and interested parties with insight into plan performance on PIPs or States' effectiveness in driving quality improvement through PIPs. We also believe data on network adequacy validation is critical to understanding plan performance regarding timeliness and access to care. Therefore, we are proposing to revise § 438.364(a)(2)(iii) in two ways: (1) to require that the EQR technical reports include ''any outcomes data and results from quantitative assessments'' for the applicable EQR activities in addition to whether or not the data has been validated, and (2) to require this type of data from the mandatory network adequacy validation activity to also be included the EQR technical report. We believe this change will result in more meaningful EQR technical reports because they will include, in addition to validation information, the data demonstrating the outcome of PIPs and the results of quantitative assessments that determined plan compliance with

network adequacy standards. This, in turn, will make the EQR technical reports a more effective tool to drive quality improvement and oversight in managed care. The proposed revisions to § 438.364(a)(2)(iii) for Medicaid would apply to separate CHIP through an existing cross-reference at § 457.1250(a). We propose at § 438.310(d)(4) for Medicaid, and through a proposed amendment at § 457.1200(d) to include a cross-reference to § 438.310(d) for separate CHIP, that States must comply with these updates to the type of data in the EQR technical report no later 1 year from the issuance of the associated protocol, which we believe will provide the guidance and time for States and EQROs need to update their processes.

In addition to the proposed regulations in this section, we are considering adding guidance in the EQR protocols, described under § 483.352, for States to stratify performance measures collected and reported in the EQR technical reports under the performance measure validation activity. We believe stratification of performance measure data in EQR technical reports would support States' efforts to monitor disparities and address equity gaps. Stratifying performance measure data also aligns with proposed requirements for the mandatory reporting of Medicaid and CHIP Core Sets and proposed requirements in the MAC QRS proposed under new 42 CFR part 438 subpart G. We seek comment on how CMS could best support States in these efforts using future guidance we develop in the EQR protocols.

(b) Revising the Date Annual EQR Technical Reports Must Be Finalized and Posted

We currently require at § 438.364(c) that EQR technical reports be completed and available on the State's website required under § 438.10(c)(3) no later than April 30th of each year. However, we understand that most States with managed care programs use Healthcare Effectiveness Data and Information Set (HEDIS) measures. HEDIS measures represent the majority of measures included in the performance measure validation EQR activity. Data on these measures from the previous calendar year are audited and finalized in June annually. We therefore are proposing to revise § 438.364(c)(1) and (c)(2)(i) to change the April 30th date to December 31st. We believe this proposed change would align better with the HEDIS timeframes because the EQR performance measurement activity could then follow the HEDIS audit. We considered aligning the EQR technical report posting date with the end of the Federal fiscal year on September 30th. However, we believe States and EQROs need more time to complete the EQR activities after receiving audited HEDIS data. We also believe December 31st is most appropriate because performance measurement data is most often calculated on a calendar year, so the December 31st date would result in data being at most 1 year old at the time the reports are posted on the State's website. We believe this change, coupled with those discussed in section I.B.5.c.2. of this proposed rule regarding changes to the EQR review period, would improve the utility of the technical reports for States, CMS and interested parties by making the data reported in them more current. The proposed changes at § 438.364(c)(1) and (c)(2)(i) for Medicaid would apply to separate CHIP through an existing cross-reference at § 457.1250(a).

We seek comment on changing the posting date to December 31st annually. We also seek comment on whether additional time beyond December 31st is needed by States, and if so, how much time and why, or whether the posting date should remain at April 30th of each year, or a date between April 30th and December 31st and why. We are proposing at § 438.310(d)(3) for Medicaid, and through a proposed amendment at § 457.1200(d) to include a cross-reference to § 438.310(d) for separate CHIP, that States come into compliance with this new due date by December 31, 2025, which we believe would provide enough time for contractual and operational updates.

(c) Notifying CMS When Annual EQR Technical Reports Are Posted

Current regulations do not require States to notify CMS that their EQR technical report has been completed and posted on the State's website. We propose to revise § 438.364(c)(2)(i) to require that States notify CMS within 14 calendar days of posting their EQR technical reports on their website, for example, by providing CMS with a link to the report. Section 401 of the Children's Health Insurance Reauthorization Act (CHIPRA) of 2009 (Pub. L. 111–3, enacted February 4, 2009) and section 2701 of the ACA require that CMS review and aggregate data from these reports in an annual report to the Secretary by September 30th. This proposed change would facilitate our review and aggregation of the required data and ensure that all States' data are included in the annual report. We are proposing that the notice to CMS be provided ''in a form and manner determined by CMS.'' However, we seek comment on whether we should require that this notice be provided via email or some other mode of communication. The proposed revisions at § 438.364(c)(2)(i) would apply to separate CHIP through an existing cross-reference at § 457.1250(a). We note that this requirement be effective as of the effective date of the final rule, which we do not believe will impose a great burden on States since most States already notify CMS when their EQR technical reports are posted by email.

(d) Revising Website Requirements for Historical EQR Technical Reports

Currently, States are encouraged, but not required, to retain EQR technical reports from previous years on their websites. We are proposing to require States maintain at least the previous 5 years of EQR technical reports on their website. Retaining at least 5 years of past EQR technical reports would provide administrative efficiencies and additional transparency by allowing CMS to use historical data and information within the annual EQR technical reports for the purposes of reviewing States' managed care program and plan performance during contract renewals and waiver renewals. In addition, having archived reports would provide other interested parties insight into historical plan performance. In addition, section 1915(b) waivers can be approved for up to 5 years, and section 1115 demonstrations are often approved for 5 years, providing additional support for 5 years being an appropriate timeframe for this requirement.

We understand that almost half of States already retain at least 2 years' worth of EQR technical reports based on a review of State websites in 2022, and we seek comment on whether archiving 5 years of reports would pose a significant burden on States. We propose to add this provision to the requirements at § 438.364(c)(2) for Medicaid, which would apply to separate CHIP through an existing cross-reference at § 457.1250(a).

We are proposing that States must comply with this update to § 438.364(c)(2)(iii) no later than December 31, 2025, and are proposing to codify this applicability date at § 438.310(d)(3) for Medicaid, and through a proposed amendment at § 457.1200(d) to include a cross-reference to § 438.310(d) for separate CHIP. This applicability date aligns with the new proposed due date for the EQR technical reports, which we believe would provide the time needed to update websites accordingly.

(6) Technical Changes

We are proposing a technical change at § 438.352 to eliminate the apostrophe from National Governors Association to align with the correct name of the organization.

6. Medicaid Managed Care Quality Rating System (§§ 438.334 and 457.1240)

a. Background

In the 2016 final rule we established the authority to require States to operate a Medicaid managed care quality rating system (QRS) at § 438.334 and adopted the requirement for this provision, excluding provisions regarding consultation with the Medical Care Advisory Committee, to apply to separate CHIP at § 457.1240(d). We use the term ''Medicaid and CHIP Managed Care Quality Rating System'' (''MAC QRS'') for this proposed rule in line with the terminology used in the 2020 final managed care rule (85 FR 72754). The MAC QRS requirements currently include public posting of quality ratings on the State's website, which is intended to provide beneficiaries and their caregivers with a web-based interface to compare Medicaid and CHIP managed care plans based on assigned performance indicators and ratings. As described in previous rulemaking, the policy objectives of the MAC QRS are threefold: (1) to hold States and plans accountable for the care provided to Medicaid and CHIP beneficiaries; (2) to empower beneficiaries with useful information about the plans available to them; and (3) to provide a tool for States to drive improvements in plan performance and the quality of care provided by their programs. Managed care is the dominant delivery system in the Medicaid program; of the 80.8 million individuals covered by Medicaid as of July 1, 2020, 67.8 million (84 percent) were enrolled in a type of managed care.[142] Numerous States have implemented rating systems for Medicaid and CHIP managed care plans, but the MAC QRS represents the first time that States would be held to a minimum Federal standard for their rating systems and that Medicaid and CHIP beneficiaries in every State contracting with a managed care plan could access quality and other performance data at the plan level, supporting the ability of Medicaid and CHIP beneficiaries to select plans that meet their needs. The policies we are now proposing would establish the MAC QRS as a one-stop-shop where beneficiaries could access information about Medicaid and CHIP eligibility and managed care; compare plans based on quality and other factors key to beneficiary decision making, such as the plan's drug formulary and provider network; and ultimately select a plan that meets their needs. Many of the policies proposed for States' MAC QRS websites build upon existing data and information that States are already required to report publicly and to us. Thus, we believe that under the proposals in this rulemaking, States would be able to leverage many existing reporting systems and their current quality infrastructure to build their MAC QRS websites and provide a user-friendly experience for beneficiaries that informs their understanding of managed care plan performance and choice of plan.

Current requirements at § 438.334(b)(1) for Medicaid, which is adopted by cross-reference at § 457.1240(d) for separate CHIP, provide that CMS, in consultation with States and other interested parties, including beneficiaries, managed care plans, external quality review organizations (EQROs), tribal organizations, and beneficiary advocates (hereafter referred to as ''interested parties''), will develop a MAC QRS framework that includes quality measures and a methodology for calculating quality ratings. The current regulations also provide States the option to either use the CMS-developed framework or establish an alternative QRS that produces substantially comparable information about plan performance, subject to our approval. Furthermore, the current regulations require that we develop a minimum set of mandatory quality measures that must be used, regardless of whether a State chooses to implement the CMS-developed QRS or an alternative QRS; this supports the goal of State-to-State comparisons of plan performance while reducing plan burden through standardization. The current regulations also require the MAC QRS framework to align, where appropriate, with other CMS managed care rating approaches (such as the Medicaid Scorecard initiative, the Medicare Advantage (MA) and Part D 5-star and the Qualified Health Plan (QHP) quality rating systems) as a way to reduce State and plan burden across quality reporting systems.

Since these regulations were issued, we have used a variety of forums to engage in robust consultation with interested parties to develop the framework of the MAC QRS to fulfill our obligation under § 438.334(b)(1) for Medicaid and under § 457.1240(d) for separate CHIP. These forums included beneficiary interviews, workgroup meetings, listening sessions, user testing of a MAC QRS prototype, and in-depth interviews with participants from State Medicaid programs, managed care plans, and EQROs. Through these extensive consultations, which took place between 2018 and 2022 and are summarized below, we learned about current State quality measure collection and reporting efforts and beneficiary needs and preferences related to the selection of a health plan. What we learned informed the MAC QRS framework proposed in this rulemaking. We summarize our consultation activities here:

- *2018 to 2022 Beneficiary and Caregiver Interviews:* Between 2018 and 2022, we conducted two rounds of individual interviews with a diverse selection of potential users of the MAC QRS. We conducted 96 interviews with people of differing age, race, ethnicity, geographic location, and Medicaid experience. The first round of 48 individual interviews focused on discovering beneficiary values and understanding the measures of health plan quality that matter to beneficiaries. Using a Human Centered Design approach, a MAC QRS website prototype was developed following an initial round of engagement with States and other interested parties as well as beneficiary and caregiver interviews, and then tested by the second group of 48 potential users. This second group of individuals provided feedback on: website navigation and usability; the features that aided users' ability to identify health plans that align with their needs and preferences, such as being able to search for plans that cover specific providers and/or prescriptions; the ability to filter quality measures to show ratings stratified based on user-identified specifications such as age, race, and ethnicity; and information on health plan quality, including quality measures identified as desirable by participants. The two rounds of engagement culminated in a revised MAC QRS website prototype, linked to in section I.B.6.g. of this proposed rule, that incorporate content and features found most desirable by potential MAC QRS users.
- *2019 Measure Workgroup:* A workgroup consisting of 27 members from key groups, including State Medicaid and CHIP agencies, Medicaid and CHIP managed care plans, EQROs, and national organizations representing health care providers and beneficiaries, met between July and December 2019 to identify potential measures for the

[142] *https://www.medicaid.gov/medicaid/managed-care/downloads/2020-medicaid-managed-care-enrollment-report.pdf.*

mandatory measure set and the feasibility of reporting certain measures.

- *2019 Interested Parties Listening Sessions:* Between August and November 2019, we held 15 listening sessions with 380 interested parties including Medicaid and CHIP Directors, Medicaid medical directors, managed care plan officials, and managed long-term services and supports (MLTSS) officials. Participants were requested to consider the presented measures and the feasibility of data collection and reporting. Website prototypes were presented to elicit feedback on feasibility, the comparison of measures by program and plan type, population stratification, and concerns related to measure presentation.
- *2019 and 2020 State, Health Plan and EQRO Interviews:* In 2019 and 2020, we conducted 20 interviews with 39 representatives from State Medicaid programs, managed care plans, and EQROs to obtain feedback regarding appropriate measures for inclusion in the MAC QRS, implementation of an alternative QRS, concerns about implementation of a MAC QRS, and technical assistance needs. In addition, we obtained information on current approaches and methodologies used by States and plans to calculate quality measures.
- *2021 and 2022 Listening Sessions:* In 2021 and 2022, we held 11 listening sessions with over 280 participants, during which we shared a sample mandatory measure set containing over 25 measures. We requested feedback on feasibility of data collection and reporting; reliability of the measures; actionability for use in quality improvement by the managed care plan; gaps in representation of specific populations or conditions; and a feasible timeline for collecting, calculating, and displaying the sample mandatory measures.

Based on this consultation, we are now proposing a MAC QRS framework that includes mandatory measures, a rating methodology (either the CMS-developed methodology or an alternate methodology approved by CMS), and a mandatory website display format; the website display would be an additional third component of the MAC QRS framework. We are proposing that States must include the mandatory measures under the MAC QRS framework but that States may also include additional measures without implementing an alternative QRS. This would change the current regulations that include both mandatory and non-mandatory measures in the CMS-developed framework. We are also proposing the initial mandatory measure set that States must use regardless of whether they use the MAC QRS framework or a CMS-approved alternative QRS, as well as a subregulatory process under which CMS would engage regularly with interested parties in order to update the mandatory measure set over time.

Additionally, after consulting with prospective MAC QRS users, we now believe displaying quality ratings alone would not be useful in selecting a health plan without additional context about Medicaid and CHIP as well as other information about health plans. We are therefore proposing website display requirements as a new component of the overall framework, and propose that the MAC QRS website include information that draws from existing State data and information to ensure a State's MAC QRS is a meaningful and usable tool for beneficiaries. Finally, in light of the diverse starting points from which States will begin to implement their MAC QRS, we are proposing to delay the deadline by which States must come into compliance with several of the requirements of the proposed MAC QRS framework to provide States with more time to implement the more complex requirements, including certain interactive display features. Importantly, States can use the optional EQR activity at § 438.358(c)(6) to assist with the quality rating of MCOs, PIHPs, and PAHPs. This could reduce burden by allowing States to receive an enhanced match for certain, limited activities carried out by an EQRO under this optional activity in accordance with section 1903(a)(3)(C)(ii) of the Act.

This proposal is made under our authority to implement and interpret in sections 1932(c)(1), 1932(a)(5)(C) and 2103(f)(3) of the Act, which provide that States that contract with MCOs for Medicaid managed care and CHIP, respectively, must develop and implement a quality assessment and improvement strategy that examines standards for access to care as well as other aspects of care and services directly related to the improvement of quality of care (including grievance procedures and information standards) and must provide comparative information on available plans related to health plan benefits and cost-sharing, service area, and available quality and performance indicators. As with most other requirements for managed care plans, we rely on section 1902(a)(4) of the Act to extend the same requirements to PIHPs and PAHPs that apply to MCOs in a Medicaid managed care program and on section 2103(f)(3) of the Act to extend the same requirements that apply to MCOs in CHIP to PIHPs and PAHPs. Throughout this section of the proposed rule, we note how the proposed Medicaid managed care regulations in part 438, subpart G (related to the MAC QRS) would apply equally to separate CHIP by a proposed cross-referenced added to § 457.1240(d).

The proposed set of minimum quality measures are intended to evaluate performance on quality of care, access to services, and outcomes. By measuring performance annually on specific quality measures (that is, mandatory measures adopted by us and any additional measures elected by the State), States will have information and data to monitor and evaluate performance of their managed care plans.

In exercising our authority under sections 1932(c)(1) and 2103(f)(3) of the Act, CMS may not implement standards for the implementation of a quality assessment or improvement strategies unless the Secretary implements such standards in consultation with the States. To fulfill this requirement, we have engaged in robust consultation with States, as described in section I.B.6.a. of this proposed rule, on the design of the MAC QRS, including the mandatory measure set, methodology, and display requirements. Going forward, we are proposing to continue to engage in consultation prior to making updates to the three components of the MAC QRS framework. In section I.B.6.e.3. of this proposed rule, we discuss our proposal for a subregulatory process through which we will continue to consult with States and interested parties to update the mandatory measure set; in section I.B.6.f. of this proposed rule, we discuss our proposal to continue to consult with States and interested parties to update the MAC QRS methodology, and in section I.B.6.g. of this proposed rule, we discuss our proposal to consult with States and interested parties to update our proposed website display requirements.

b. Provisions of the Proposed Rule (§§ 438.334, 438 Subpart G, and 457.1240(d))

We are proposing to create a new subpart G in 42 CFR part 438 to implement the MAC QRS framework required under § 438.334 of the current regulations and establish the standards which States must meet for CMS to approve adoption of an alternative QRS and related requirements. Existing regulations at § 438.334 are redesignated to newly-created proposed sections in Subpart G with proposed revisions, discussed in detail below in this proposed rule. For separate CHIP, we propose to adopt the new provisions of

subpart G in part 438 by cross-reference through an amendment at § 457.1240(d).

c. Definitions (§§ 438.334, 438.500, and 457.1240(d))

There are some technical and other terms relevant to our proposed regulations. Therefore, we propose the following definitions at § 438.500(a) for Medicaid, and for separate CHIP by cross-reference through a proposed amendment at § 457.1240(d). Some proposed definitions are discussed in more detail later in this proposed rule in connection with other proposed regulation text related to the definition.

- *Measurement period* means the period for which data are collected for a measure or the performance period that a measure covers.
- *Measurement year* means the first calendar year and each calendar year thereafter for which a full calendar year of claims and encounter data necessary to calculate a measure are available.
- *Medicaid managed care quality rating system framework* (*QRS framework*) means the mandatory measure set identified by CMS in the Medicaid and CHIP managed care quality rating system technical resource manual described in § 438.530, the methodology for calculating quality ratings described in § 438.515, and the website display described in § 438.520 of this subpart.
- *Medicare Advantage and Part D 5-Star Rating System (MA and Part D quality rating system)* means the rating system described in subpart D of parts 422 and 423 of this chapter.
- *Qualified health plan rating system (QHP quality rating system)* means the health plan quality rating system developed in accordance with 45 CFR 156.1120.
- *Quality rating* means the numeric or other value of a quality measure or an assigned indicator that data for the measure is not available.
- *Technical resource manual* means the guidance described in § 438.530.
- *Validation* means the review of information, data, and procedures to determine the extent to which they are accurate, reliable, free from bias, and in accord with standards for data collection and analysis.

d. General Rule and Applicability (§§ 438.334(a), 438.505(a) and 457.1240(d))

Currently, § 438.334(a) lays out the general rule for the MAC QRS, including general requirements for States contracting with MCOs, PIHPs and/or PAHPs to furnish services to Medicaid beneficiaries. These requirements also apply to separate CHIP through a cross-reference to § 438.334 at § 457.1240(d). Specifically, § 438.334(a) requires States to adopt a quality rating system using the CMS framework or an alternative quality rating system and to implement such quality rating system within 3 years of the date of the final rule published in the **Federal Register**. We are proposing at § 438.505(a)(2) for Medicaid, and for separate CHIP by cross-reference to Part 438, Subpart G at § 457.1240(d), to require States to implement their MAC QRS (or alternative QRS) by the end of the fourth calendar year following the effective date of the final rule (meaning the fourth calendar year following issuance of the final rule). This proposed change from the current 3-year implementation date under § 438.344(a) would provide States more time to make the operational and contractual changes needed to meet the requirements in this proposed rule and also give States flexibility to determine what time of year to publish their quality ratings. To illustrate the proposed timeline change, we provide the following example: if the final rule is effective on April 1, 2024, States would be required to implement their MAC QRS no later than December 31, 2028, and the data displayed in 2028 would be from the measurement year between January 1, 2026 and December 31, 2026. The timeline for future measurement and display years is discussed in detail in section I.B.6.e.7. of this proposed rule. The proposal at § 438.520(a)(6) for Medicaid, and for separate CHIP by cross-reference through a proposed amendment at § 457.1240(d), would require implementation of some website display requirements, discussed in section I.B.6.g. of this proposed rule, after the proposed implementation date. We also discuss in section I.B.6.g. of this proposed rule, how several of the proposed display requirements build upon existing information and data States either already have or are currently required to report publicly or to CMS. We seek comment on whether these proposed policies, all together, would give States sufficient time to implement their MAC QRS or alternative QRS on a timeline that meets their operational needs.

We are also proposing for Medicaid, as a general rule, that States provide a support system for beneficiaries or users of a State's MAC QRS, leveraging existing State resources. In our user testing, described in greater detail in I.B.6.g. of this proposed rule, users responded positively to the availability of live consumer assistance through telephone or online chat, which 83 percent of participants found useful as it helped them navigate the MAC QRS website and get the information they were looking for right away. Per § 438.71, States are currently required to develop and implement a beneficiary support system. The elements of the beneficiary support system are identified at § 438.71(b)(1) as including choice counseling for all beneficiaries in § 438.71(b)(1)(i), assistance for enrollees in understanding managed care in § 438.71(b)(1)(ii), and assistance related to the receipt of long-term services and supports at § 438.71(b)(1)(iii). Currently, § 438.2 provides that choice counseling means the provision of information and services designed to assist beneficiaries in making enrollment decisions and includes answering questions and identifying factors to consider when choosing among managed care plans and primary care providers. Choice counseling does not include making recommendations for or against enrollment into a specific MCO, PIHP, or PAHP. We believe that this existing support is an appropriate system for States to build upon to assist beneficiaries in using and understanding the information in the MAC QRS to select a managed care plan. In a new § 438.505(a)(3), we are therefore proposing for Medicaid that States would be required to use the beneficiary support system implemented under current § 438.71 to provide choice counseling to all beneficiaries, and assistance for enrollees on understanding how to use the managed care quality rating system to select a managed care plan, including the receipt of long-term services and supports. With the support system already in place, we believe States could leverage existing resources by developing new scripts and training existing staff. We discuss the importance of providing this assistance in section I.B.6.g. of this proposed rule where we provide an overview of the input we received from beneficiaries. However, since a beneficiary support system is not required for separate CHIP, we do not propose to adopt this provision for subpart L of part 457.

The current regulations at § 438.334(b)(1) for Medicaid, and applied by cross-reference at § 457.1240(d) for separate CHIP, require the MAC QRS framework to align, where appropriate, with the QHP quality rating system, the MA and Part D quality rating system and other related CMS quality rating approaches as a way to reduce State burden across Federal quality reporting systems. We believe this requirement should

continue to apply broadly to the MAC QRS framework and are therefore proposing to require this alignment, to the extent appropriate, as part of CMS' maintenance the MAC QRS framework. We propose to redesignate this requirement for alignment in § 438.334(b)(1) to its own provision at § 438.505(c) for Medicaid, and for separate CHIP by cross-reference through a proposed amendment at § 457.1240(d). The importance of alignment of the MAC QRS with the MA and Part D and QHP quality rating systems was shared by States, managed care plans and other interested parties, affirming the requirement in our current regulations that, to the extent possible, the MAC QRS be aligned with the MA and Part D and QHP quality ratings systems, the Medicaid and CHIP Child Core Set, the Medicaid Adult Core Set, and other similar CMS initiatives such as the Medicaid and CHIP Scorecard and the CMS Universal Foundation.[143] We are also proposing, at § 438.505(c), that in maintaining the MAC QRS mandatory measure set and rating methodology, CMS will align with these other similar CMS programs and approaches when appropriate.

Finally, current regulations at § 438.334(a) for Medicaid managed care programs (applied to separate CHIP through a cross-reference in § 457.1240(d)) apply the requirements for the MAC QRS to each State contracting with an MCO, PIHP or PAHP to furnish services to Medicaid or CHIP beneficiaries. We are proposing to revise this to refer to ''an applicable managed care plan as described in paragraph (b) of this section'' in proposed § 438.505(a), and add an applicability provision at new § 438.505(b) stating that the provisions of newly-proposed subpart G apply to States contracting with MCOs, PIHPs, and PAHPs for the delivery of services covered under Medicaid. The proposed provisions at § 438.505(a) and (b) are also proposed to apply to separate CHIP through a cross-reference at § 457.1240(d), but excluding all references to beneficiary support systems. We note that the current and proposed regulations in Subpart G do not apply to PCCM entities, consistent with current regulations at §§ 438.10(c)(2) and 457.1207; non-emergency medical transport PAHPs are also not included in the MAC QRS, in accordance with §§ 438.9 and 457.1206(b). In addition, our proposal for the MAC QRS framework excludes contracts between States and MA Dual Eligible Special Needs Plans (D–SNP) where the contract is only for the D–SNP to provide Medicaid coverage of Medicare cost sharing for the D–SNP enrollees; this is reflected in proposed § 438.505(b).

e. Establishing and Modifying a Mandatory Measure Set for MAC QRS (§§ 438.334(b), 438.510 and 457.1240(d))

The current regulations at § 438.334(b)(1) direct CMS, after consulting with States and other interested parties, to identify a mandatory set of QRS quality measures that align, where appropriate, with the MA and Part D and QHP quality rating systems and other related CMS quality rating approaches, and to provide an opportunity for public notice and comment on such mandatory measures. In this section we discuss the standards that guided CMS in identifying the initial mandatory measures and propose an initial mandatory measure set. We seek comment on our proposed initial mandatory measure set, which we will finalize in the preamble of the final rule. Under this proposal, we would not duplicate the list of the mandatory measures and specifications in regulation text in light of the regular updates and revisions contemplated by the rules we are proposing for ongoing maintenance of the MAC QRS. We also propose a subregulatory process to modify the mandatory measure set over time, including proposing to codify the standards that guided development of the proposed initial mandatory measure set.

(1) Standards for Including Measures in Mandatory Measure Set (§§ 438.510(c), 457.1240(d))

Three distinct considerations guided the process of selecting individual measures to establish a concise proposed initial mandatory measure set. We are proposing at § 438.510(c)(1)–(3) to codify these three considerations as standards that we would apply in the future to determine when to add measures to the mandatory measure set, when to make substantive updates to an existing mandatory measure, and in some circumstances, when to remove a measure from the mandatory measure set. Specifically, a measure is only included in our proposed initial mandatory measure set and would only be added in the future if (1) it meets five of the six measure inclusion criteria proposed in this section; (2) it would contribute to balanced representation of beneficiary subpopulations, age groups, health conditions, services, and performance areas (for example, preventive health, long term services and supports, etc.) within a concise set of mandatory measures; and (3) the burdens associated with including the measure do not outweigh the benefits to the overall quality rating system framework of including the new measure based on the measure inclusion criteria we are proposing. Under our proposal, and as discussed in section I.B.6.e.4. of this proposed rule, a measure would be added to the mandatory set if it meets each of these three standards. To determine whether a measure meets these standards, CMS would rely on the input received throughout the subregulatory process proposed in § 438.510(b) and discussed in section I.B.6.e.3. of this proposed rule and other relevant research and information. Similarly, a measure would be removed from the mandatory measure set if it no longer met these standards. This approach would ensure that each of the three proposed standards are met.

Using the MAC QRS goals described in section I.B.6.a. of this proposed rule as a guidepost during our discussion with States and other interested parties, we identified and refined six measure inclusion criteria: (1) is the measure meaningful and useful for beneficiaries and their caregivers when choosing a managed care plan; (2) does the measure align with other CMS rating programs described in § 438.505(c) of this chapter; (3) does the measure assess health plan performance in at least one of the following areas: customer experience, access to services, health outcomes, quality of care, health plan administration, and health equity; (4) does the measure provide an opportunity for managed care plans to influence their performance on the measure; (5) is the measure based on data that are readily available, or available without undue burden on States and plans, such that it is feasible to report by most States and managed care plans; and (6) does the measure demonstrate scientific acceptability, meaning that the measure, as specified, produces consistent and credible results.

We used these six criteria to assess hundreds of measures suggested throughout our engagement with interested parties. We explain each proposed criterion here and describe how we assessed measures suggested during our engagement with interested parties against the criteria to select the proposed initial mandatory measure set of 18 measures, displayed in Table 1. In doing so, we also show how we would make future updates to the mandatory measure list using these criteria.

[143] *https://www.nejm.org/doi/full/10.1056/NEJMp2215539.*

• *Usefulness to beneficiaries:* Whether the measure is meaningful and useful for beneficiaries or their caregivers when choosing a managed care plan. For the proposed mandatory set, we assessed whether a measure meets this criterion by seeking beneficiaries' feedback on which measures of health plan performance are most relevant to them. We then gave preference to measures that assess the quality of care or services most commonly identified by beneficiaries as relevant to selection of a health plan or their assessment of a health plan's quality. When adding, updating or removing measures, we intend to rely on the continued engagement with beneficiaries proposed in § 438.520(c) (discussed in section I.B.6.g.4. of this proposed rule) to apply a similar preference for changes that are either most meaningful and useful or most commonly described as meaningful and useful. Input from beneficiaries or beneficiary advocates with experience assisting beneficiaries will be particularly important in evaluating this criterion, but input from other interested parties will also be considered.

• *Alignment:* Whether the measure or measure concept is consistent with the principles of, or is represented in, one or more existing Federal, State, and/or Medicaid and CHIP quality reporting programs. For the measures listed in Table 1, we assessed whether a measure meets this criterion by identifying the extent to which States and other Federal programs (such as the Medicaid and CHIP Scorecard, the MA and Part D quality rating system, and the QHP quality rating system) currently collect or report the measure. We considered feedback on measures commonly used to assess health plan performance as well as the challenges and concerns with these measures. We gave preference to measures commonly collected or reported with few reporting challenges. However, we also considered emerging measures that are not yet commonly collected or reported but align with a performance area or health outcomes measured by commonly used measures. As an example, an emerging measure such as the Person-Centered Contraception Counseling measure, which is not currently adopted at the plan level, could meet the alignment criterion if our workgroup identified that it overlaps with an existing, widely used measure in the area of contraception. We believe this approach more accurately reflects the continuing evolution of quality measurement and would allow the consideration of new, better measures, as they are developed. We note, however, that emerging measures would still be assessed based on the other criteria and standards described here and proposed at § 438.510(c)(1), (2), and (3), and it may take time for emerging measures to meet the final regulatory standards. Within the proposed measure set, 15 of the 18 measures are commonly reported by States,[144] 16 of the 18 measures overlap with the 2023 and 2024 Core Set measures, 11 with the QHP quality ratings system, 13 with the 2021 Medicaid and CHIP Scorecard, and 5 with the MA and Part D quality rating system.

• *Relevance:* Whether the measure evaluates or measures the managed care plan's performance in at least one of the following areas: customer experience, access to services, health outcomes, quality of care, health plan administration, and health equity. For the proposed measure set, we determined which of the areas each measure evaluates or measures. Preference was given to measures that evaluate or measure more than one area.

• *Actionability:* Whether there are opportunities for managed care plans to influence their performance on the measure. For the proposed measure set, we assessed whether a measure met this criterion by considering input on what actions managed care plans may take to improve or maintain measure performance and the extent to which the plans control, or are capable of influencing, what is being measured. We also considered whether the measure is currently specified at the plan level, meaning that measure specifications are available to calculate the measure at the plan (as opposed to provider or State) level. We gave preference to measures that are currently specified at the plan level and are more easily controlled or influenced by health plans.

• *Feasibility:* Whether the data needed to calculate the measure are readily available or could be captured without undue burden and could be implemented by most States and health plans. For the proposed measure set, we assessed whether a measure meets this criterion by considering the accessibility of the data required to calculate the measures and the proportion of plans or States that currently collect data for the measure. We gave preference to measures that require data that are easily accessible to plans (such as claims data) or are commonly collected.

• *Scientific Acceptability:* Whether the measure produces consistent (reliable) and credible (valid) results. We assessed whether a measure meets this criterion by reviewing evidence that use of the measure can draw reasonable conclusions about care in a given domain.[145]

Using feedback throughout our consultations related to the mandatory measure list, we assessed our list of suggested measures to identify the extent to which each measure met these inclusion criteria. During the same consultations, we received feedback (and our own evaluation showed) that while each of the six criteria were important to consider, it would be difficult for a measure to meet all six criteria. For instance, we found that requiring all six criteria could prevent the inclusion of either measures that are meaningful to beneficiaries but not commonly used by States, or measures aligned with State priorities for managed care quality and plan performance, but less useful to beneficiaries. We are therefore proposing in § 438.510(c)(1) that a measure must meet at least five of the six measure inclusion criteria to be considered against our other standards and included in the mandatory measure set in the future. We seek comment on the six criteria we are proposing to evaluate prospective measures for the mandatory measure set, and whether there are additional objective measure inclusion criteria that we should use to evaluate quality measures for inclusion as mandatory measures. Additionally, we seek comment on our proposal to require measures to meet five out of the six proposed criteria, and whether that threshold produces a sufficient number of measures to consider for the MAC QRS. Finally, we seek comment on the extent to which the measures in our proposed measure set meet the proposed measure inclusion criteria, including the reasons and/or supporting data for why the measure meets or does not meet the criteria. In our review of measures and development of the list of mandatory measures, we believe that each meets at least 5 if not all 6 of the criteria proposed at § 438.510(c)(1).

Through our work to develop the proposed mandatory measure set, we found that many measures meet at least five of the six measure inclusion criteria, and without additional guardrails in place we believe the set would quickly expand and become burdensome to States and plans. States

[144] As reported by States for the 2020–2021 EQR reporting cycle.

[145] CMS Measures Blueprint: *https://mmshub.cms.gov/measure-lifecycle/measure-testing/evaluation-criteria/overview.*

and managed care plans generally recommended limiting the mandatory set to between 10 and 30 measures to ensure plans' ability to improve on selected measures and States' capacity to succeed in reporting, and to limit the impact of implementing a QRS on State and plan resources. Furthermore, our MAC QRS website prototype user testing showed that beneficiaries were evenly split between those with high informational needs who preferred detailed information from a lot of measures and those who valued clear, concise information on the big picture using fewer measures.

To maintain a concise measure set, we are proposing to codify two additional measure inclusion standards in § 438.510(c)(2) and (3). These two additional standards reflect the feedback we received on maintaining a ''concise'' mandatory measure list and provide a process by which to identify further distinctions among measures that meet our inclusion criteria and to consider the measure set as a whole as part of the selection process. First, in § 438.510(c)(2), we propose that a measure must contribute to balanced representation of beneficiary subpopulations, age groups, health conditions, services, and performance areas that are assessed within a concise mandatory measure set. We have included as part of our standard proposed in § 438.510(c)(2) that the overall measure set should be ''concise,'' given the feedback we received on limiting the number of measures in the mandatory measure set. we established and intend to maintain a goal of no more than 20 measures for the initial mandatory measure set. However, the proposed rule would retain flexibility for the number of measures to increase as the mandatory set is updated over time. we would consider each suggested measure in relation to other suggested measures and the overall mandatory measure set to identify those that are very similar or duplicative, keeping in mind the need for a mandatory measure set that is both representative and concise.

Second, we propose in § 438.510(c)(3) that a measure would be added to the mandatory measure set when the burdens of adding the measure do not outweigh the benefits based on the 6 criteria proposed at § 438.510(c)(1)(i) through (vi). we would compare similar measures, that is, those suggested for inclusion that measure performance within similar subpopulations of beneficiaries, health conditions, services, and performance areas as well as the extent to which a contemplated new measure meets the criteria listed in proposed paragraph (c)(1), to assess the benefits and burdens of including each measure in the mandatory measure set. Under our proposal, we would include a measure when all three of the standards proposed in § 438.510(c) are met. CMS would use the subregulatory process proposed in § 438.510(b) and discussed in section 1.B.6.e.3. of this proposed rule to determine which measures meet the proposed standards.

We seek comment on the standards proposed at § 438.510(c)(2) and (3) and how measures should be assessed using these standards. In particular, we seek comment on the appropriate balance of representation (of populations and performance areas) in the mandatory measure set and any additional considerations that may be missing from our proposed paragraph (c)(2). Further, we seek comment on whether there are additional considerations for the weighing of burdens and benefits of a measure under proposed § 438.510(c)(3).

(2) Mandatory Measure Set (§§ 438.510(a), (b), and 457.1240(d))

We propose in § 438.510(a) for Medicaid, and for separate CHIP by cross-reference through a proposed amendment at § 457.1240(d), that the quality rating system for managed care plans implemented by the State for Medicaid (and CHIP) managed care programs must include the measures in a mandatory measure set, which will be identified by CMS in the technical resource manual as proposed in § 438.530(a)(1). We note that in proposed § 438.520(b), discussed in section I.B.6.g.5. of this proposed rule, States can include other, additional measures outside the mandatory measure set. We received input through our consultations with interested parties, detailed in section I.B.6.a. of this proposed rule, on how to construct a mandatory measure set for the MAC QRS, including the number of measures, measure inclusion criteria, and performance areas and populations represented by the measures. After considering the priorities and other information gleaned through the several years of consultations described in section I.B.6.a. of this proposed rule, and applying the standards discussed in section I.B.6.e.1. of this proposed rule, we are proposing for public comment an initial set of 18 mandatory measures that represents the collective input we received during those consultations. This proposed initial set of mandatory measures can be found in Table 1. These proposed mandatory measures reflect a wide range of preventive and chronic care measures representative of Medicaid and CHIP beneficiaries.

TABLE 1: Proposed MAC QRS Mandatory Measure Set

NQF #*	Measure Steward	Measure Name	Measure Description	Data Collection Method
2801	NCQA	Use of First-Line Psychosocial Care for Children and Adolescents on Antipsychotics (APP-CH)	The percentage of members who had a new prescription for an antipsychotic medication and had documentation of psychosocial care as first-line treatment. Ages: 1 to 17	Administrative**
0004	NCQA	Initiation and Engagement of Substance Use Disorder (SUD) Treatment	The percentage of new SUD episodes for members that result in the following: • Initiation of SUD Treatment. Percentage of new SUD episodes for members that result in treatment initiation through an inpatient SUD admission, outpatient visit, intensive outpatient encounter or partial hospitalization, telehealth, or medication treatment within 14 days of the diagnosis • Engagement of SUD Treatment. The percentage of new SUD episodes for members that have evidence of treatment engagement within 34 days of the initiation visit. Ages: 13 – 17 | 18 to 64 | 65 and older	Administrative or EHR
0418* **	CMS	Preventive Care and Screening: Screening for Depression and Follow-Up Plan (CDF)	The percentage of members screened for depression on the date of the encounter or 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool, and if positive, a follow-up plan is documented on the date of the eligible encounter. Ages: 12 to 17 | 18 to 64 | 65 and older	Administrative or EHR
3489	NCQA	Follow-Up After Hospitalization for Mental Illness (FUH)	The percentage of emergency department (ED) visits for members with a principal diagnosis of mental illness or intentional self-harm and who had a follow-up visit for mental illness. The following rates are reported: • The percentage of ED visits for mental illness for which the member received follow-up within 30 days of the ED visit (31 total days) • The percentage of ED visits for mental illness for which the beneficiary received follow-up within 7 days of the ED visit (8 total days). Ages: 6 to 17 | 18 to 64	Administrative
1392	NCQA	Well-Child Visits in the First 30 Months of Life (W30)	The percentage of members who had the following number of well-child visits with a primary care practitioner (PCP) during the last 15 months. The following rates are reported:	Administrative

NQF #*	Measure Steward	Measure Name	Measure Description	Data Collection Method
			• Well-Child Visits in the First 15 Months. Children who turned age 15 months during the measurement year: Six or more well-child visits. • Well-Child Visits for Age 15 Months to 30 Months. Children who turned age 30 months during the measurement year: Two or more well-child visits. Ages: 0 to 15 months | 15 to 30 months	
1516	NCQA	Child and Adolescent Well-Care Visits (WCV)	The percentage of members who had at least one comprehensive well-care visit with a primary care practitioner (PCP) or an obstetrician/gynecologist (OB/GYN) during the measurement year. Ages: 3 to 21	Administrative
2372	NCQA	Breast Cancer Screening (BCS)	The percentage of women who had a mammogram to screen for breast cancer. Ages: 50 to 74	Administrative, EHR, or Electronic Clinical Data System (ECDS)♦
0032	NCQA	Cervical Cancer Screening (CCS)	The percentage of women who were screened for cervical cancer using either of the following criteria: • Women ages 21 to 64 who had cervical cytology performed within the last 3 years • Women ages 30 to 64 who had cervical high-risk human papillomavirus (hrHPV) testing performed within the last 5 years • Women ages 30 to 64 who had cervical cytology/high-risk human papillomavirus (hrHPV) co-testing within the last 5 years Ages: 21 to 64	Administrative, hybrid, or EHR
0034	NCQA	Colorectal Cancer Screening (COL)	The percentage of members who had appropriate screening for colorectal cancer. Ages: 50 to 75	Administrative, hybrid, or ECDS
2517	DQA	Oral Evaluation, Dental Services (OEV)	The percentage of members who received a comprehensive or periodic oral evaluation within the reporting year. Ages: 0 to 20	Administrative
2902	OPA	Contraceptive Care - Postpartum Women (CCP)	Among women who had a live birth, the percentage that: 1. Were provided a most effective or moderately effective method of contraception within 3 and 60 days of delivery. 2. Were provided a long-acting reversible method of contraception (LARC) within 3 and 60 days of delivery. Ages: 15 to 20 | 21 to 44	Administrative
1517**	NCQA	Prenatal and Postpartum Care (PPC)	Percentage of deliveries of live births on or between October 8 of the year prior to the measurement year and October 7 of the measurement year that: 1. Received a prenatal care visit in the first trimester, on or before the enrollment start date or within 42 days of enrollment in Medicaid/CHIP (Timeliness of Prenatal Care Rate).	Administrative or hybrid

NQF #*	Measure Steward	Measure Name	Measure Description	Data Collection Method
			2. That had a postpartum visit on or between 7 and 84 days after delivery (Postpartum Care Rate). Ages: All Ages	
0575/0059	NCQA	Hemoglobin A1c Control for Patients with Diabetes (HBD)	The percentage of members with diabetes (types 1 and 2) whose hemoglobin A1c (HbA1c) was at the following levels during the measurement year: • HbA1c control (<8.0%). • HbA1c poor control (>9.0%). Ages: 18 to 75	Administrative or hybrid
1800	NCQA	Asthma Medication Ratio (AMR)	The percentage of members who were identified as having persistent asthma and had a ratio of controller medications to total asthma medications of 0.50 or greater during the measurement year. Ages: 5 to 18 | 19 to 64	Administrative
0018	NCQA	Controlling High Blood Pressure (CBP)	The percentage of members who had a diagnosis of hypertension and whose blood pressure (BP) was adequately controlled (< 140/90 mm Hg) during the measurement year. Ages: 18 to 85	Administrative, hybrid, or EHR
0006	AHRQ❖	CAHPS – How people rated their health plan	The percentage of members who rated their health plan a 9 or 10, where 0 is the worst health plan possible and 10 is the best health plan possible. Ages: 0 to 17 | 18 and older	Consumer Survey
0006	AHRQ❖	CAHPS – Getting care quickly	Composite of the following items: • The percentage of members who indicated that they always got care for illness, injury, or condition as soon as they needed, in the last six months. • The percentage of members who indicated they always got check-up or routine care as soon as they needed, in the last six months. Ages: 0 to 17 | 18 and older	Consumer Survey
0006	AHRQ❖	CAHPS – Getting needed care	Composite of the following items: • The percentage of members who indicated that it was always easy to get necessary care, tests, or treatment, in the last six months. • The percentage of members who indicated that they always got an appointment with a specialist as soon as needed, in the last six months. Ages: 0 to 17 | 18 and older	Consumer Survey
0006	AHRQ❖	CAHPS – How well doctors communicate	Composite of the following items: • The percentage of members who indicated that their doctor always explained things in a way that was easy to understand. • The percentage of members who indicated that their doctor always listened carefully to enrollee.	Consumer Survey

NQF #*	Measure Steward	Measure Name	Measure Description	Data Collection Method
			• The percentage of members who indicated that their doctor always showed respect for what enrollee had to say. • The percentage of members who indicated that their doctor always spent enough time with enrollee. Ages: 0 to 17 | 18 and older	
0006	AHRQ❖	CAHPS – Health plan customer service	Composite of the following items: • The percentage of members who indicated that customer service always gave necessary information or help, in the last six months. • The percentage of members who indicated that customer service always was courteous and respectful, in the last six months. Ages: 1 to 17 | 18 and older	Consumer Survey
Not endorsed	CMS	MLTSS-1 LTSS Comprehensive Assessment and Update	The percentage of Medicaid MLTSS plan participants who have documentation of a comprehensive assessment in a specified timeframe that includes documentation of core elements. Two performance rates and two exclusions rates are reported for this measure: • Assessment of Core Elements. Medicaid MLTSS plan participants who had a long-term services and supports comprehensive assessment with nine core elements documented within 90 days of enrollment (for new participants) or during the measurement year (for established participants) • Assessment of Supplemental Elements. Medicaid MLTSS plan participants who had a long-term services and supports comprehensive assessment with nine core elements and at least 12 supplemental elements documented within 90 days of enrollment (for new participants) or during the measurement year (for established participants) Ages: 18 and older	Case Management Record Review
3547	CMS	MLTSS-7: LTSS Minimizing Institutional Length of Stay	The proportion of admissions to an institutional facility (for example, nursing facility, intermediate care facility for individuals with intellectual disabilities (ICF/IID)) for managed long-term services and support (MLTSS) plan enrollees that result in successful discharge to the community (community residence for 60 or more days) within 100 days of admission. This measure is reported as an observed rate and a risk-adjusted rate. Ages: 18 and older	Claims, Enrollment Data

* Refers to National Qualify Forum number. Measure endorsed by NQF can be found at NQF: Quality Positioning System ™ (qualityforum.org)

** Examples of administrative data collection methods are claims, encounters, vital records, and registries.

*** This measure is no longer endorsed by NQF.

♦ The HEDIS® Electronic Clinical Data System (ECDS) reporting standard defines data sources and types of structured data acceptable for use for a measure. The measures are provided as digital quality measures.

❖ AHRQ is the measure steward for the survey instrument (NQF #0006) and NCQA is the developer of the survey administration protocol.

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We considered including several other measures that are not included in the proposed initial mandatory set. These other measures were not included because they did not meet one or more of the standards described in section I.B.6.e.1. of this proposed rule. These other measures and the reason we did not include them in Table 1, are described here:

- *Contraceptive measure:* States and other interested parties stated a desire for the MAC QRS to include a quality measure involving contraceptive services that would be relevant for all women, but many noted that there is not yet a measure they would recommend that meets this description. Beneficiaries did not specifically speak to the importance of a contraceptive measure, but consistently noted the desire to be involved in their care decisions and for providers to respect their health goals and needs when providing counseling on health care options. We considered various contraceptive measures in addition to CCP, the measure currently included in the proposed mandatory set. They include Contraceptive Care—All Women Ages 15 to 44 (CCW) and a new survey-based measure, Person-Centered Contraceptive Counseling (PCCC), that uses patient provided responses to assess the person-centeredness of contraceptive counseling. While we believe the PCCC measure aligns well with beneficiary preferences stated during beneficiary consultations, it failed to meet two of the six measure inclusion criteria. First, PCCC does not currently meet our requirement of feasibility as we did not find evidence that plans are currently collecting the data necessary to produce this measure and some interested parties stated concern about the perceived burden of reporting PCCC. Second, we believe the measure does not meet the scientific acceptability criterion as it is currently specified only at the provider level so it is unknown whether it produces consistent and credible results at the plan level. With respect to CCW and CCP, both measures meet at least five of the six inclusion criteria. Furthermore, both measures measure access to contraception that reduces unintended pregnancy in their respective populations and therefore each would contribute to balanced representation of beneficiaries by providing insight into the accessibility of contraceptive care among beneficiaries who may become pregnant. However, while both CCP and CCW would contribute to balanced representation within a concise mandatory measure set, we believe the benefits of including CCP are greater than those of CCW because CCP focuses on measuring access to effective contraceptive care during the postpartum period, which can improve birth spacing and timing and improve the health outcomes of women and children.
- *Follow-up after Emergency Department Visit for Mental Illness (FUM) versus Follow-up After Hospitalization for Mental Illness (FUH):* There was support from States and other interested parties to include both of these measures, and including both would give a fuller picture of the percentage of emergency department and inpatient hospital discharges for which beneficiaries received follow-up services. These measures met all of our measure inclusion criteria and had similar benefits and burdens, but the two measures assessed important, but very similar services. We concluded that including both would not contribute to balanced representation within an overall mandatory set. Upon balancing benefits and burdens associated with each measure, we selected FUH because it was more commonly collected or reported at both the State and Federal level and more frequently used by States to assess plan performance. We provide a detailed analysis of our review of the FUH and FUM measures in section I.B.6.e.4. of this proposed rule.
- *Childhood Immunization Status (CIS):* We considered including the childhood immunization status measure, however, we included the well-child visit measure instead. Both measures met at least five of the six inclusion criteria and each could contribute to balanced representation within the overall mandatory set. However, when reviewing the burdens and benefits to the overall MAC QRS, we concluded the CIS measure would have little added benefit because our beneficiary testing showed that parents cared a lot about whether their children can get appointments (reflected in the well-child visit measure), but no beneficiary commented specifically on childhood immunizations.
- *Postpartum Depression Screening:* We considered this measure based on recommendations from the 2019 Measure Workgroup. However, we did not include this measure because it did not meet two of our six inclusion criteria. First, the measure is not aligned with any other CMS programs. Second, the measure did not meet our feasibility criterion because the measure relies solely on a proprietary electronic clinical data systems (ECDS) reporting method. While this measure has been recommended for addition to the Core Set, CMS has deferred decisions related to the measure to assess how the proprietary nature of this information impacts the feasibility of reporting.

(3) Subregulatory Process To Update Mandatory Measure Set (§§ 438.510(b) and 457.1240(d))

The current regulations at § 438.334(b)(2) establish that we may, after consulting with States and other interested parties and providing public notice and opportunity to comment, periodically update the Medicaid managed care QRS framework developed under current § 438.334(b)(1). We remain dedicated to the policy currently reflected in § 438.334(b)(1) and (b)(2) that requires engagement with interested parties for continuous improvement of the MAC QRS. In addition, continued engagement with States is consistent with our obligations under sections 1932(c)(1)(D) and 2103(f)(3) of the Act to consult with States in setting standards for measuring and monitoring managed care plan performance. However, we believe that requiring rulemaking to add new measures that may better meet beneficiaries' and States' needs or to remove measures whose utility has been surpassed by other measures would be overly restrictive and would undermine our ability to adapt the mandatory set to keep pace with changes in the quality field and user preferences. We also believe that a robust subregulatory process in which we interpret and apply substantive regulatory standards governing the measures to be included in the mandatory measure set can ensure that any changes reflect the extensive input from interested parties that is needed. We are therefore

proposing to revise § 438.334(b)(2), redesignated at new proposed § 438.510(b) for Medicaid, and for separate CHIP by cross-reference through a proposed amendment at § 457.1240(d), that we undergo a subregulatory process to engage with States and other interested parties, to obtain expert and public input and recommendations prior to modifying the mandatory measure set. Once the mandatory measure set is finalized through this rulemaking, we believe periodic, subregulatory updates and maintenance to add, remove, or update measures would ensure that the mandatory measure set continues over time to adhere to our three proposed standards at § 438.510(c). To achieve these goals, we are proposing these modifications occur at least every other year (biennially).

With exceptions for removing measures for specific reasons proposed at § 438.510(d) and non-substantive updates to existing measures as proposed at § 438.510I(1), we are proposing in new § 438.510(b) that we will engage in a two-step subregulatory process to obtain input and recommendations from States and other interested parties prior to finalizing certain types of changes to the mandatory measure set in the future. This proposed engagement with States is similar to the public notice and comment process currently required by § 438.334(b) and consistent with our obligations under sections 1932(c)(1)(D) and 2103(f)(3) of the Act to consult with States in setting standards for measuring and monitoring managed care plan performance. Proposed § 438.510(b) would apply to separate CHIP by cross-reference through a proposed revision to § 457.1240(d).

As the first step in the process, we propose at § 438.510(b)(1) that CMS would engage with States and interested parties (such as State officials, measure experts, health plans, beneficiaries and beneficiary advocates or organizations, tribal organizations, health plan associations, health care providers, external quality review organizations and other organizations that assist States with MAC QRS ratings) to evaluate the current mandatory measure set and make recommendations to add, remove, or update existing measures. The purpose of this evaluation would be to ensure the mandatory measures continue to meet the standards proposed in § 438.510(c). We envision that this engagement could take several forms. For example, a workgroup could be convened to hold public meetings where the workgroup attendees would make recommendations to CMS to add and remove measures. Alternatively, a smaller series of meetings with interested parties could be held, or a request for information could be published to solicit recommendations from experts. In either case, we intend that recommendations would be based on the standards proposed in § 438.510(c) and discussed in section I.B.6.e.1. of this proposed rule.

At § 438.510(b)(2) we propose that the second step in the process would be for CMS to provide public notice and opportunity to comment through a call letter (or similar subregulatory process using written guidance) that includes the mandatory measures identified for addition, removal or updating through the public engagement step. Following the public notice and opportunity for public comments, we propose at § 438.510(f) that we will publish the modifications to the mandatory measure set in the technical resource manual proposed at § 438.530 (this proposal is discussed in more detail in section I.B.6.e.7. of this proposed rule).

This subregulatory process shares similarities with the QHP quality rating system, which uses a call letter process to gather feedback on measure updates. It also aligns with how the Core Sets are updated annually. As part of the Core Set annual review and selection process, a workgroup made up of Medicaid and CHIP interested parties and measurement experts convenes annually, in a public meeting, and develops a set of recommendations for changes to the Core Sets. These recommendations are posted in a draft report for public comment, and the final report that is submitted to CMS includes both the workgroup recommendations and public comments. The annual updates to the Core Sets are based on the workgroup recommendations and comments, and using input from States and Federal partners, CMS decides whether to accept them prior to the updated Core Sets being finalized. Details on this process are available at *https://www.medicaid.gov/medicaid/quality-of-care/downloads/annual-core-set-review.pdf.* While we generally are aligning the MAC QRS workgroup processes, as noted above, with the QHP quality rating and Core Set processes as appropriate, the MAC QRS is independent and will have its own processes.

If the proposed rule is finalized in 2024, the implementation deadline for each State's MAC QRS per proposed § 438.505(b) (which provides for such implementation to be no later than the fourth calendar year following publication of the final rule) would be December 31, 2028, and the first measurement year would be 2026. Since we are proposing to finalize our initial measure set in this rulemaking, any updates to the initial mandatory measure list made pursuant to the subregulatory process proposed at § 438.510(b) would be effective no earlier than the year after the implementation of each State's MAC QRS. We believe it would be appropriate to initiate the proposed subregulatory process for the second display year (for example, 2029 if the rule is finalized in 2024) because the mandatory measure list would be 5 years old by then, and at least biennially thereafter (in line with proposed § 438.510(b)(2)). However, we seek comment on whether we should instead initiate the subregulatory process to update the mandatory measure list for the third display year (for example, 2030 if the rule is finalized in 2024). We also seek comment on the types of engagement that would be important under this proposed subregulatory process (for example, workgroups, smaller meetings, requests for information), the types of experts that CMS should include in the engagement, and the use of a call letter or similar guidance to obtain public input.

(4) Adding Mandatory Measures (§§ 438.510(b)(2), (d) and (e) and 457.1240(d))

Our proposal at § 438.510(c) states that CMS would add a measure to the mandatory measure set when all three standards proposed at § 438.510(c)(1)–(3) are met, based on available information, including input from the subregulatory process. Under our proposal, at least biennially, we would use the subregulatory process proposed in § 438.510(b) to gather input that would be used to determine if a measure meets the proposed standards to be added to the mandatory measure set. For example, CMS could request the workgroup's assessment of the list of measures suggested for addition (from the workgroup, CMS, or both), using our three proposed standards: the proposed criteria (per proposed § 438.510(c)(1)), input on how best to curate a balanced representation of measures from the suggested measures (per proposed § 438.510(c)(2)), and the benefits and burdens of adopting the measures (per proposed § 438.510(c)(3)). Using this input, CMS could identify a subset of measures from that list that best represents these standards. This subset of measures would then be considered eligible to add to the mandatory measure set and described in a call letter or similar written guidance, which would explain how standards in

§ 438.510(c) were applied using input from prior engagement activities and CMS's research and preliminary evaluation. Through the call letter process, CMS would gather public comment including any additional evidence, explanations, and perspectives to determine whether the subset of measures meet the standards in proposed § 438.510(c). The measures that meet the proposed standards based on the totality of input and information compiled by CMS would be added to future iterations of the mandatory measure set. To further illustrate how we intend for the standards proposed in § 438.510(c) to be applied using the subregulatory process, we provide more specific detail in this section of our assessment of two measures considered for inclusion in the proposed mandatory measure set. We intend for the subregulatory process for adding measures to follow this same approach.

In previous discussions, States and other interested parties recommended both the Follow-Up After ED Visit for Mental Illness (FUM) and the Follow-Up After Hospitalization for Mental Illness (FUH) as potential measures to include in our preliminary measure set. As a first step, we used our own research and input from our consultations to assess the measures against the measure inclusion criteria, that we are now proposing as our first standard, and found that both measures meet each of our six proposed criteria (see Table 2).

TABLE 2—EXAMPLE INCLUSION CRITERIA ASSESSMENT

Criteria	FUM	FUH
Alignment	• Identified by 16 States as a measure collected from managed care plans in the '20–'21 EQR reporting cycle. • Reported publicly as a measure of plan performance in 2 States. • Core Set measure	• Identified by 19 States as a measure collected from managed care plans in the '20–'21 EQR reporting cycle. • Reported publicly as a measure of plan performance in 4 States. • Core Set and QHP QRS measure.
Usefulness to Beneficiaries	• The importance of timely access to mental health services were consistently identified in our conversations with Medicaid beneficiaries.	
Relevance	• Both measures address access to services.	
Actionability	• States and plans identified various ways in which plans can address follow-up. The 30-day measure was generally thought to be more actionable than 7-day due to supply of mental health providers and the need for plan coordination in States that carve out behavioral health.	• States and plans identified various ways in which plans can address follow-up. The 30-day measure was generally thought to be more actionable than 7-day due to supply of mental health providers and the need for plan coordination in States that carve out behavioral health. • Used by 3 States to assess plan performance as part of the State's quality strategy.
Feasibility	• Relies on administrative data from claims that are owned or available to plans, but would require coordination between plans in States that offer behavioral through a separate managed care program.	
Scientific Acceptability	• Generally regarded as reliable and valid measure in our listening sessions. • Endorsed by the National Quality Forum.	

Second, we considered the two measures in light of our goals for balanced representation within a concise measure set. Given our goal to limit the initial mandatory measure set to fewer than 20 measures and the fact that both measures focus on assessing follow-up care for mental illness, we determined that including one of the two measures would best maintain balanced representation within the overall measure set and within the behavioral health performance area. We then weighed the benefits and burdens of including each measure using our assessment of the extent to which each measure met our inclusion criteria. As represented in Table 2, we found that both measures had similar benefits and burdens, but the FUH measure had more benefits as it was more commonly collected or reported at both the State and Federal level and more frequently used by States to assess plan performance. We therefore chose to include the FUH measure in the proposed mandatory set.

(5) Removing Existing Mandatory Measures (§§ 438.510(b)(2), (d) and (e) and 457.1240(d))

We are proposing at § 438.510(d)(1) that we may remove existing mandatory measures from the mandatory measure set if, after following the subregulatory process proposed at § 438.510(b), we determine that the measure no longer meets the standards for the mandatory measure set proposed at 438.510(c). We would use the same approach we described in section I.B.6.e.2. of this proposed rule and illustrated with our FUH/FUM example in section I.B.6.e.4. of this proposed rule to assess whether a measure continues to meet our measure inclusion criteria to remain in the mandatory measure set. We are also proposing at § 438.510(d)(2) through (4) to provide CMS the authority to remove mandatory measures outside of the subregulatory process proposed in § 438.510(b) in three circumstances: when the measure steward (other than CMS) retires or stops maintaining a measure (proposed at § 438.510(d)(2)), if CMS determines that the clinical guidelines associated with the specifications of the measure change such that the specifications no longer align with positive health outcomes (proposed at § 438.510(d)(3)), or if CMS determines that a measure shows low statistical reliability under the standard identified in § 422.164(e) of this chapter (proposed at § 438.510(d)(4)).

These proposed criteria for removing measures outside the subregulatory process align with the current regulations governing the MA and Part D quality rating system.[146] When a

[146] "Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and

Continued

measure steward such as NCQA or PQA retires a measure, they go through a process that includes extensive review by experts and solicit public comments from a variety of interested parties, including health plans, purchasers, consumers and other interested parties. The proposal to allow CMS to remove a measure if an external measure steward retires or stops maintaining a mandatory measure would allow us flexibility to ensure that measures included in the QRS mandatory measure set are maintained by the measure steward and consistent with the measure steward's underlying standards of clinical meaningfulness, reliability, and appropriateness for measures. Additionally, when there is a change in clinical guidelines such that measure specifications no longer align with or promote positive health outcomes, we believe it would be appropriate to remove the measure. Finally, we are proposing that CMS would have the authority to remove measures that show low statistical reliability (that is, how much variation between measure values that is due to real differences in quality versus random variation). We are using the same standard for statistical reliability as applied for the MA and Part D quality rating system under §§ 422.164(e) and 423.184(e). Any measures removed under these three circumstances proposed at § 438.510(d)(2) through (4) would be announced in the annual technical resource manual, proposed at § 438.530. We believe these criteria will allow us to swiftly remove measures that are no longer appropriate quality indicators of health plan performance. We seek comments on whether there are additional circumstances in which we should be able to remove a mandatory measure without engaging in the subregulatory process proposed at § 438.510(b).

(6) Updating Mandatory Measure Technical Specifications (§§ 438.510 and 457.1240(d))

In addition to adding and removing measures, we are also proposing rules at § 438.510(e) for Medicaid, and for separate CHIP by cross-reference through a proposed amendment at § 457.1240(d), governing how we would handle updates to mandatory measures in the MAC QRS that are a result of changes made by a measure steward other than CMS to an existing mandatory measure's technical specifications. These are updates that measure stewards routinely make to quality measures, and can be non-substantive (such as changes that clarify instructions to identify services or procedures) or substantive in nature (for example, major changes to how the measures are calculated). We are proposing different subregulatory processes by which these non-substantive and substantive updates to existing mandatory measures would be made. First, in proposed paragraph § 438.510(e)(1) for Medicaid, and for separate CHIP by cross-reference through a proposed amendment at § 457.1240(d), we propose that we would update the technical resource manual to revise descriptions of the existing mandatory measures that undergo non-substantive measure technical specification changes. In alignment with current practices in the MA and Part D quality rating system and the Core Sets, we are not proposing to use the subregulatory process proposed in § 438.510(b) for non-substantive changes because we believe they reflect routine measure maintenance by measures stewards that do not significantly affect the measure and would not need additional review by the workgroup and CMS. We are proposing in new paragraph § 438.510(e)(1)(i)–(iv) for Medicaid, and for separate CHIP by cross-reference through a proposed amendment at § 457.1240(d), to codify examples of the types of updates that are non-substantive under this proposal. This proposal is consistent with current practice and regulations for the MA and Part D quality rating system at §§ 422.164(d)(1) and 423.184(d)(1). We identify and describe the proposed non-substantive updates in detail below and seek comment on whether this list is exhaustive, whether it is an adequate list of examples of non-substantive changes, or whether we should consider adding other examples of non-substantive changes to the list. Examples of the types of changes we believe would be non-substantive for purposes of proposed § 438.510(e)(1) include, but are not limited to the following:

- If the change narrows the denominator or population covered by the measure with no other changes, the change would be non-substantive. For example, if an additional exclusion—such as excluding nursing home residents from the denominator—is added, the change would be considered non-substantive and would be incorporated through announcement in the annual technical resource manual.
- If the change does not meaningfully impact the numerator or denominator of the measure, the change would be non-substantive. For example, if additional codes are added that increase the numerator for a measure during or before the measurement period, such a change would not be considered substantive. This type of change has no impact on the current clinical practices of the plan or its providers.
- If revisions are made to the clinical codes without change in the target population or the intent of the measure and the target population, the change would be non-substantive. The clinical codes for quality measures (such as HEDIS measures) are routinely revised as the code sets are updated. Examples of clinical codes, include, but are not limited to:

+ ICD–10–CM code sets, which are updated annually,

+ Current Procedural Terminology (CPT) codes, which are published and maintained by the American Medical Association (AMA) to describe tests, surgeries, evaluations, and any other medical procedure performed by a healthcare provider on a patient, and

+ National Drug Code (NDC) which is updated bi-annually.

- If the measure specification change provides additional clarifications for reporting, without changing the intent of the measure, the change would be non-substantive. Examples include:

+ Adding additional tests that would meet the numerator requirements.

+ Clarifying documentation requirements (for example, medical record documentation).

+ Adding additional instructions to identify services or procedures that meet (or do not meet) the specifications of the measure.

+ Adding alternative data sources or expanding of modes of data collection to calculate a measure.

Second, we propose at § 438.510(e)(2) for Medicaid, and for separate CHIP by cross-reference through a proposed amendment at § 457.1240(d), that we may update an existing mandatory measure that has undergone a substantive measure specification update (that is, an update not within the scope of non-substantive updates, which are illustrated in § 438.510(e)(1)(i) through (iv), only after completing the subregulatory process proposed in § 438.510(b). We believe that most substantive measure specification updates to existing measures could result in new or different measures, thereby necessitating consideration and

Programs of All-Inclusive Care for the Elderly'' (CMS–4201–F). Published in the **Federal Register** on April 12, 2023 (88 FR 22120). Available online at *https://www.federalregister.gov/documents/2022/12/27/2022-26956/medicare-program-contract-year-2024-policy-and-technical-changes-to-the-medicare-advantage-program.*

evaluation against the criteria and standards in proposed paragraph (c) using the process in proposed § 438.510(b). We seek comment on our proposal to incorporate substantive measure specification updates to existing mandatory measures only after consultation with States, other interested parties, and the public, or whether we should consider a separate process for these types of updates.

(7) Finalization and Display of Mandatory Measures and Updates (§§ 438.510(f) and 457.1240(d))

In new paragraph § 438.510(f) for Medicaid, and for separate CHIP by cross-reference through a proposed amendment at § 457.1240(d), we propose that CMS would communicate modifications to the mandatory measure set and the timeline States would be given to implement modifications to the mandatory measure set in the annual technical resource manual. We propose to use the technical resource manual described in proposed § 438.530 to communicate the final updates. We are proposing that States would be given at least 2 calendar years from the start of the measurement year immediately following the technical resource manual in which the mandatory measure addition or substantive update was finalized to display the measurement results and ratings using the new or updated measure(s). We believe giving States at least 2 years would allow for contract and systems updates when new measures are added or substantive updates are made to the mandatory measure set. For example, if the technical resource manual finalized updates in August 2026, and the next measurement year after August started in January 2027, States would have, at a minimum, until January 2029 before they would be required to display the ratings for the mandatory measure updates in their MAC QRS. A State may elect to display the ratings for a new mandatory measure sooner. As two years from the start of the measurement year would always be in January, we seek comment on whether there is a need for States to have the flexibility to update their quality ratings by the end of the second calendar year, which, based on the example above, would give States the flexibility to update the rating between January and December of 2029.

We are proposing the same implementation timeline for substantive updates to existing mandatory measures, since we believe these should be treated in the same manner as new measures. We are proposing this timeline based on discussions with States and other interested parties about operational considerations for implementation of new and substantively updated measures and the posting of the associated ratings. We are not proposing a specific deadline for States to stop display of a measure that has been removed from the mandatory measure set because States have the option to continue to display measures removed from the mandatory set as additional measures as described in section I.B.6.g.5. of this proposed rule. We seek comment on this flexibility considering the criteria under which measures can be removed at proposed § 438.510(d). We seek comment on whether our timeframes are appropriate for updates to the mandatory measure set or whether we should consider allowing for more or less time, and why.

In conclusion, we seek comment on the proposed subregulatory process to add and remove measures, as described in sections I.B.6.e.3. of this proposed rule, specifically the types of engagement (workgroup, smaller meetings, requests for information) and the types of experts that would be included in the engagement, and the use of a call letter or similar guidance to obtain public input on the MAC QRS mandatory measure set before it is substantively updated. We note that we are proposing the subregulatory process to update the mandatory measure set take place *at least* biennially. However, CMS could engage in this process more frequently in certain circumstances, such as in the case of rapidly evolving public health concerns. We seek comment on whether we should consider implementing the process on an annual basis, or another frequency, and why. We note that we are proposing to release the technical resource manual annually regardless of whether we are making any modifications to the mandatory measure set, to address any non-substantive changes to measure specifications or any removals that occur outside of the subregulatory process, as described in section I.B.6.i. of this proposed rule.

f. MAC QRS Methodology (§§ 438.334(d), 438.515, 457.1240(d))

Fundamental to any QRS is the methodology used to calculate the quality ratings for States' managed care plans. Under current regulations at § 438.334(b)(1) CMS must, after consulting with interested parties and providing public notice and opportunity to comment, develop a methodology that States must use in the MAC QRS adopted by the State to calculate its plans' quality ratings, unless we approve an alternative methodology as part of an alternative MAC QRS in accordance with proposed § 438.525. During the extensive engagement with States and other interested parties described in section I.B.6.a. of this proposed rule, we identified two main themes to consider in the development of a MAC QRS methodology: (1) States are concerned about the burden associated with data collection and quality rating calculation, and (2) beneficiaries desire transparent, representative quality ratings. In developing the MAC QRS methodology that we are proposing here, we sought to balance these two, often competing preferences, while ensuring that quality ratings remained comparable within and among States. We also considered the Interoperability and Patient Access for Medicare Advantage Organization and Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans on the Federally-Facilitated Exchanges, and Health Care Providers,[147] (referred to as ''CMS Interoperability and Patient Access final rule'') published in May 2020. That rule placed several requirements on State Medicaid FFS programs as well as on Medicaid managed care plans for the implementation of application programming interfaces to facilitate sharing information between payers, enrollees, and providers. Based on these considerations, at § 438.515 we propose requirements for collecting and using data to calculate managed care quality ratings for mandatory measures (that is, the MAC QRS methodology which we propose that States must use), unless we have approved an alternative QRS. The same requirements are proposed for separate CHIP managed care plans through a proposed cross-reference at § 457.1240(d).

Under current regulations at § 438.334(d), each year States would be required to collect data from each managed care plan with which they contract and issue an annual quality rating for each managed care plan based on the data collected. We are proposing to replace that policy with more specific requirements in proposed new § 438.515(a) for States to collect and validate data used by the State to calculate and issue quality ratings for

[147] *https://www.govinfo.gov/content/pkg/FR-2020-05-01/pdf/2020-05050.pdf* Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Interoperability and Patient Access for Medicare Advantage Organization and Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans on the Federally-Facilitated Exchanges, and Health Care Providers. CMS–9115–F. Published in the **Federal Register** on May 1, 2020 (85 FR 25510 through 25640).

each mandatory measure on an annual basis. First, we propose, at proposed § 438.515(a)(1) for Medicaid, and for separate CHIP by cross-reference through a proposed amendment at § 457.1240(d)), that States must collect the data necessary to calculate quality ratings for mandatory measures from their contracted managed care plans and, as applicable and available without undue burden, the State's Medicaid fee-for-service program and Medicare. Specifically, we propose that data be collected from managed care plans that meet a minimum enrollment threshold of 500 or more enrollees on July 1 of the measurement year. This enrollment threshold is the same as the enrollment threshold for the QHP quality rating system requirement at section 1311(c)(4) of the Patient Protection and Affordable Care Act.

We believe that requiring States to calculate quality ratings for plans with fewer than 500 enrollees would be overly burdensome, as these plans may have limited resources for collecting and reporting data, and are more likely than plans with higher enrollment to have small denominator sizes that would make it inappropriate to issue and display quality ratings for some measures due to privacy or validity concerns. Further, through an analysis of 2019 Transformed Medicaid Statistical Information System (T–MSIS) Analytic Files (which are research-optimized files of T–MSIS data), we determined that neither the number of managed care plans nor the percentage of beneficiaries reported in the MAC QRS would be significantly reduced by excluding plans with enrollment below 500. Thus, we believe the proposed enrollment threshold maximizes inclusion of plans and enrollees, while also minimizing the burden of data collection and reporting on smaller plans. States would have the flexibility to include plans with fewer than 500 enrollees at their discretion, and we would encourage States to do so when appropriate and feasible.

At § 438.515(a)(1)(ii) for Medicaid, and for separate CHIP by cross-reference through a proposed amendment at § 457.1240(d), we propose that States would also be required to collect available data from the State's Medicaid fee-for-service (FFS) program, Medicare (including Medicare Advantage plans), or both if all necessary data cannot be provided by the managed care plans for the measures and collection of these data does not impose an undue burden on the State. For example, if a State delivers behavioral health services through a managed care program and all other services through its FFS program, the State would need to collect both managed care and FFS data to calculate quality ratings for the managed care plans participating in its behavioral health managed care program for many of our proposed behavioral health mandatory measures. Similarly, if a managed care plan provides services to enrollees who are dually eligible for Medicare and Medicaid services, it would be necessary for the State to collect data about services provided by Medicare to such enrollees to calculate quality ratings for some measures included on the proposed mandatory set. While we are proposing that States must collect data from these other sources as needed to calculate mandatory measures if the data are available for collection without undue burden, we are not proposing that States would calculate or assign quality ratings to Medicaid FFS or Medicare plans.

We considered requiring States to collect data only from their contracted managed care plans and then only when a plan is able to provide all data necessary to calculate and issue a quality rating for a given performance measure, which is a common practice among measure stewards. However, we are concerned that there would be instances where there is no single plan from which a State could collect all data necessary to calculate one or more of the measures on our mandatory measure list. For example, of the 18 measures on our proposed mandatory measure set, four require data from more than one setting, including three of our proposed behavioral health mandatory measures. These four measures include Use of First-Line Psychosocial Care for Children and Adolescents on Antipsychotics (APP), Initiation and Engagement of Alcohol and Other Drug Abuse or Dependence Treatment (IET), Follow-Up After Hospitalization for Mental Illness) (FUH), and Asthma Medication Ratio (AMR). To calculate the three behavioral health measures, it is necessary to collect behavioral health or substance use service data as well as either pharmacy or physical health data. When these services are covered by separate plans or delivery systems, such as where a State has chosen to split Medicaid coverage of these services between separate managed care programs or use a combination of managed care and FFS delivery systems, these mandatory measures would be at risk of going unreported. Similar issues are raised for dually eligible individuals who receive coverage through Medicare and Medicaid. We note that Medicaid is the single largest payer of mental health services in the U.S., and behavioral health and substance use measures would be at particular risk of going unreported, as services provided in these settings are commonly provided through a separate managed care plan. We believe that our proposal for States to collect and use data from multiple sources will mitigate the risk of underreporting of mandatory measures, particularly those measures assessing behavioral health and substance use services.

We believe our proposal is aligned with ongoing efforts to expand access to health plan data at both the State and Federal level. For example, State data collection required for measures in the Child Core Set and behavioral health measures in the Adult Core Set, which will become mandatory effective for calendar year 2024, requires States to report measures using data from both managed care and FFS programs as well as Medicare data for dually eligible beneficiaries. Many of these measures overlap with the mandatory measures proposed for the MAC QRS, which means States will already be obligated to collect Medicaid managed care and FFS data and to obtain Medicare data needed to calculate certain performance measures. Thus, we believe that the benefits of proposed § 438.515(a)(1)(ii) outweigh the costs of any increased burden on States.

Furthermore, there is an ongoing effort at the Federal and State levels to increase data availability and interoperability, including State access to managed care plan data. At the time of this proposed rule, data available for collection include encounter data received from a State's own Medicaid managed care plans under § 438.242 and data from FFS providers through claims and other reporting. Given existing data availability, we believe that the collection of such data would rarely result in an undue State burden. States can also obtain Medicare Part A, B and D data free of charge through the CMS State Data Resource Center (SDRC). Although Part C data are not available publicly through the SDRC, States may use their contracts with MA Dual Eligible Special Needs Plans (D–SNPs), which are required under § 422.107, to obtain Medicare data about the dually eligible individuals enrolled in those plans. As a significant number of States already obtain Part C data in this way, we believe such data would be available without undue burden in many cases, particularly where a State has already opted to obtain some Medicare Part C data in this way.

We understand that making contractual or systems changes to allow a State to collect such data without

causing an undue burden, such as a substantial financial or resource investment, may mean that a State implements these changes over time, and that this timeline may extend past the implementation date proposed in § 438.505(a)(2). We intend the proposed standard ''without undue burden'' to facilitate a gradual implementation of contract or system changes to collect the necessary data. We also would be available to provide technical assistance to help States acquire and use available data to calculate MAC QRS quality ratings. We seek comment on the proposed requirement that States collect available data from multiple sources on the mandatory measures. In addition, we request comment on the type of technical assistance that would be most helpful in assisting States in obtaining and using data from the sources specified in the proposed regulation.

Once the necessary data are collected to calculate quality ratings for each mandatory measure, our proposal at § 438.515(a)(2) would require States to ensure that all collected data are validated. This aligns with similar requirements in 45 CFR 156.1120(a)(2), which requires QHP issuers to validate data for the QHP QRS, and 42 CFR 422.162(c)(2), which requires MA organizations to provide unbiased, accurate and complete quality data to CMS for the MA and Part D quality rating system. Currently, § 438.320 defines validation for purposes of subpart E of part 438 as the review of information, data, and procedures to determine the extent to which they are accurate, reliable, free from bias, and in accord with standards for data collection and analysis. We are proposing the same definition for purposes of new subpart G at § 438.500. States may use the current optional EQR activity at § 438.358(c)(6) and 457.1250(a)—for which enhanced match may be available for Medicaid EQR-related activities performed for MCOs per § 438.370(a)—to assist with the calculation and validation of data used to generate quality ratings for the MAC QRS. Use of this optional activity may help reduce burden on States.

We are proposing in § 438.515(a)(3) that States use the validated data to calculate performance rates for managed care plans. Under this proposal, States would calculate, for each mandatory measure, a measure performance rate for each managed care plan whose contract includes a service or action being assessed by the measure, as determined by the State. Under this proposal, the mandatory measures would be assigned to the plan(s) based on whether the plan's contract covers the service or action being assessed by the measure, as identified by the State. We believe this would be straightforward for measures assessing single services or actions, but, as we noted previously in this section of the proposed rule, some States choose to deliver Medicaid services through different managed care programs. In these States, data necessary to calculate a measure performance rate for a given measure may be collected from two managed care plans. However, a State may determine that only one of these services or actions for which data must be collected is being assessed by the measure. In such a case, the State must identify, among those plans from which the State collected data, the plans whose contract includes the service of action identified by the States as being assessed by the measure, and calculate and assign quality ratings accordingly.

For example, the Follow-Up After Hospitalization (FUH) measure listed in Table 2 requires data on two services: hospitalization and mental health services. In a State that offers behavioral and physical health services through separate managed care programs, the State would need hospitalization data from plans participating in the physical health program and mental health service data from the plans participating in the behavioral health program to calculate FUH performance rates. Because data are collected from more than one plan, our proposal would require States to determine which service or action is being assessed by the measure. If a State determines that the service or action being assessed by the FUH measures is the provision of timely follow-up of mental health services to an enrollee following a hospitalization for mental illness, the State would then be required to identify all plans that are contracted to provide the follow-up mental health services assessed by the FUH measure and assign each of those plans a quality rating for the FUH measure.

Lastly, our current regulation at § 438.334(d) requires States to issue *an* annual quality rating (that is, a single rating) to each managed care plan using the Medicaid managed care quality rating system (emphasis added). However, based on feedback we received from beneficiaries, we are proposing to revise that current policy and to require States to issue to each managed care plan a quality rating for each mandatory measure for which the managed care plan is accountable. As proposed at § 438.515(a)(4) for Medicaid, and for separate CHIP by cross-reference through a proposed amendment at § 457.1240(d), States would be required to issue quality ratings as measure performance rates (that is, the individual percentage rates calculated under § 438.515(a)(3)). For example, a managed care plan that furnishes behavioral health services would likely be issued a measure performance rate for each of the proposed behavioral health mandatory measures, depending on the availability of data. We also considered requiring States to calculate and display a performance rating that reflects a national baseline for each mandatory measure, which would align with the practice of States that currently publish managed care quality measures using an individual, percentage rating. However, we chose not to propose this requirement in this rulemaking. We seek comment on our proposal to issue individual performance rates and seek additional input on our decision not to require additional percentage ratings to reflect a national baseline for each mandatory measure.

The proposal to require that States issue quality ratings for individual quality measures is supported by the user testing we conducted during our engagement with interested parties. Beneficiaries stated varying preferences for the level of information that they would like to have, with roughly half preferring more detailed information, 40 percent preferring big picture information, and 10 percent falling in the middle. Many beneficiaries stated interest in quality ratings for specific measures that related to their individual health care needs, especially those that aligned with their understanding of important health indicators identified by trusted health care professionals, such as blood A1c levels for people with diabetes, demonstrating the value of including individual measure quality ratings.

Our user testing suggests that displaying managed care plan quality ratings both at the individual measure and the domain level would be most desirable to beneficiaries. This approach would allow beneficiaries who prefer big picture information to concisely compare plans at the domain-level, while beneficiaries who desire more detailed information could drill down into the domains to understand a plan's performance on the individual quality measures from which the domain score is derived. These findings are discussed in additional detail in section I.B.6.g. of this proposed rule. However, we did not significantly test domain level quality ratings and believe that additional engagement with interested parties and beneficiary testing would be necessary before requiring States to calculate and issue domain-level ratings. Therefore,

we propose at § 438.515(c) for Medicaid, and for separate CHIP by cross-reference through a proposed amendment at § 457.1240(d), that CMS will engage with States, beneficiaries, and other interested parties before proposing to implement domain-level quality ratings for managed care plans. Examples of potential care domains include behavioral health, chronic conditions, infant and children, and preventive care.

We believe that including domain-level quality ratings in the MAC QRS, in addition to measure-level quality ratings, would align best with the informational preferences expressed by beneficiaries who participated in testing of a MAC QRS prototype. We intend to propose the care domains, methodology, and website display requirements in future rulemaking. In calculating domain-level quality ratings, we are considering requiring States to calculate and assign quality ratings for a managed care plan only in those domains that are relevant to the managed care plan. For instance, while most care domains are likely to be relevant to an MCO, a care domain that focuses on infants and children is unlikely to be relevant to a plan that provides long term services and supports to dually eligible individuals. We seek feedback on our proposal to include individual percent scores, intended approach to domain-level ratings, and potential MAC QRS care domains.

To ensure that services provided to all Medicaid beneficiaries are reflected in each managed care plan's quality ratings, we propose at § 438.515(b)(1) that States must ensure that the quality ratings issued under proposed § 438.515(a)(4) include data for all beneficiaries who receive coverage from the managed care plan for a service or action for which data are required to calculate the quality rating. This includes beneficiaries who are dually eligible for Medicare and Medicaid and receive services through the Medicaid managed care plan, subject to the availability of data about the services received by dually eligible individuals. While we recognize that including dually eligible beneficiaries in quality ratings may require additional effort to obtain and analyze Medicare utilization data, especially where dually eligible beneficiaries are not in programs that integrate Medicare and Medicaid, we believe it is important to ensure that these beneficiaries can assess the quality of care furnished by available Medicaid plans for beneficiaries who also are enrolled in Medicare. Furthermore, including dually eligible individuals in MAC QRS quality ratings would align with the Adult and Child Core Sets, as some measures require both Medicaid and Medicare data (see Core Set NPRM, 87 FR at 51317). Under proposed § 438.515(b)(1), only dually eligible individuals who receive full Medicaid benefits would be included in the MAC QRS, because individuals whose Medicaid eligibility is limited to assistance with Medicare premiums and/or cost sharing receive covered services exclusively through Medicare. We intend to provide additional guidance on which beneficiaries must be included in the quality ratings for each MAC QRS mandatory measure in the technical resource manual alongside technical specifications from the mandatory measure's measure steward. For separate CHIP, § 457.310(b)(2) does not allow for concurrent coverage with other health insurance, so our proposed amendment to § 457.1240(d) excludes dually eligible individuals from the scope of the required CHIP managed care quality rating.

In § 438.515(b)(2) for Medicaid, and for separate CHIP by cross-reference through a proposed amendment at § 457.1240(d), we propose that States would be required to calculate quality ratings at the plan level by program. While some States have one managed care program through which they offer all Medicaid services, most States cover Medicaid services through multiple programs that are defined by the population served by the program and the set of benefits covered by the program. For example, a State may have one program that covers behavioral health services while a second program covers physical health services. Other States may choose to provide similar services through different managed care programs that serve different populations. In these States, different programs cover different services to meet the needs of different subpopulations of Medicaid beneficiaries, such as pregnant individuals, children in foster care, or those with disabilities, chronic conditions, or HIV/AIDS. In States with multiple managed care programs, managed care plans may choose which programs they will participate in by contracting with the State. Generally, beneficiaries would then select from the managed care plans participating in each program for which the beneficiary is determined eligible, subject to requirements on access to multiple managed care plans in § 438.52.

Under our proposals, States that offer multiple managed care programs would calculate plan level ratings for each managed care plan participating in a single managed care program using only the service data described in § 438.515(b)(1) of beneficiaries enrolled in that managed care plan under that managed care program. A managed care plan that participates in multiple managed care programs would receive a distinct rating for each of these programs. These ratings would be produced using data only from those beneficiaries enrolled in the managed care plan under the specific managed care program. That is, ratings would be calculated at the plan level but with the plan dividing up its enrolled population based on the specific managed care program(s) that the State has contracted with the plan for coverage. As eligible beneficiaries select from available managed care plans within a program, we believe that plan level quality ratings for each program in which the plan participates will best align with what beneficiaries may expect to receive from each managed care plan participating in that program. This approach is distinguishable from single plan level ratings for all of the programs in which the plan participates, which would be calculated using all data from the plan regardless of the managed care program. We believe such ratings would not provide useful information to potential enrollees because such plan level ratings would reflect the quality of services provided to all beneficiaries covered by the plan, regardless of the program through which the beneficiary receives services from the plan, and may not reflect the performance that a beneficiary could expect based on the beneficiary's enrollment options. The proposed plan level ratings for each managed care program would produce quality ratings that are most representative of the care beneficiaries can expect to experience because each rating would be calculated only from data for beneficiaries enrolled in the same managed care plan under the same program. If a measure cannot be reported for a plan due to low denominator sizes, the plan would be issued an appropriate ''missing data'' message for that measure as the quality rating. We seek comment on how this proposed policy would interact with our proposed minimum enrollment threshold, such as an analysis that assesses the extent to which a State's smaller plans may report missing data messages.

We considered the level at which ratings are assigned in the MA and Part D and QHP quality ratings systems as part of developing our proposal for the MAC QRS. In the MA and Part D quality rating system, quality ratings for most measures are assigned at the contract

level, which consolidates data from all plan benefit packages offered under the contract to calculate a quality rating. Under a contract-level reporting unit, quality ratings would be calculated based on data from all enrollees served under a given contract between a State and a managed care plan. However, we do not believe that contract-level ratings would be as useful to Medicaid beneficiaries and would make it difficult for States to assess the quality of care provided to beneficiaries in separate programs that are often designed to improve the quality of care for a particular subpopulation of beneficiaries with unique care considerations. In the QHP quality rating system, quality ratings are assigned at the product level (for example, Exclusive Provider Organization Plan (EPO), Health Maintenance Organization (HMO), Point of Service (POS), and Preferred Provider Organization (PPO)). These products typically provide coverage of a similar set of comprehensive health care services, but vary in terms of how enrollees are able to access these services and at what cost. If an issuer of health care offered multiple products, each separate product would receive its own ratings. In Medicaid, product level ratings could correlate with ratings assigned at the PIHP, PAHP, or MCO level.

Under our proposal at § 438.515(b)(2), managed care plans that participate in multiple managed care programs would receive separate quality ratings under each program. These separate quality ratings would be calculated from data for only those beneficiaries enrolled in the managed care plan under a given program. We believe that this approach best balances the need for representative ratings with the level of effort States must employ to calculate quality ratings for the MAC QRS, while also accommodating the current way that States structure their overall Medicaid and CHIP program and the need for comparable quality ratings both within and among States. While our proposed reporting unit would require the calculation of more quality ratings than those used by the MA and Part D or QHP quality rating systems, we believe that this additional work will also help States monitor the quality of the managed care programs that they have developed to ensure provision of high-quality, cost-efficient care to their beneficiaries. We seek comment on our proposal to use a program-level reporting unit for the MAC QRS as well as other recommendations for reporting units that would result in quality ratings that are both representative and less burdensome on States.

Finally, it is important to note that States could receive an enhanced match for assistance with quality ratings of MCOs performed by an EQRO, including the calculation and validation of MCO data, under the external quality review optional activity at § 438.358(c)(6), in accordance with § 438.370 and section 1903(a)(3)(C)(ii) of the Act.

g. MAC QRS Website Display (§§ 438.334(e), 438.520, 457.1240(d))

Current regulations at § 438.334(e), which would be redesignated at § 438.520(a) of this proposed rule, require States to prominently display the quality rating issued for each MCO, PIHP, or PAHP on the website required under § 438.10(c)(3) in a manner that complies with the standards in § 438.10(d). Our policies proposed at § 438.520 would establish new requirements for the website display, which were informed by extensive consultation with Medicaid beneficiaries and their caregivers and iterative testing of a MAC QRS website prototype. The consultation and testing revealed that the presentation of quality ratings greatly influences the usability and utility of the MAC QRS as a tool to assist beneficiaries in selecting a plan. Providing information to beneficiaries in a useable way is necessary for compliance with section 1932(a)(5) of the Act regarding provision of information, including comparative information on plan quality, to beneficiaries when a State mandates enrollment in an MCO. The same standards apply under section 2103(f)(3) of the Act to CHIP. To promote the efficient and economical operation of the Medicaid State Plan and CHIP, we apply the same requirements for all managed care programs through our regulations. Our proposed requirements for Medicaid managed care programs in § 438.520 would also be applicable to separate CHIP under this proposal, through a cross-reference in the CHIP regulation at § 457.1240(d).

In our initial round of testing, participants struggled to understand how to use the MAC QRS prototype, and often dismissed or skipped over the quality ratings, noting that they did not understand the ratings or how they translated to member care. Subsequent revisions of our MAC QRS prototype focused on identifying how best to present quality ratings to prospective users in a way that supported beneficiaries' ability to understand and incorporate quality ratings and use them to inform their selection of a health plan. Based on our testing, it was clear that to truly empower beneficiaries as informed health care consumers, quality ratings are best presented as one part of a comprehensive website that efficiently guides the user through the considerations for identifying a quality health plan. We also learned that to be more useful, the website should address factors commonly considered by individuals in selecting a health plan, which include information not traditionally factored into health plan quality ratings, such as what providers are in the network and drug coverage. Using this feedback, we designed, tested, and refined the MAC QRS display components proposed in this rulemaking to align with the stated preferences of our user-testing participants.

The display components identified as most critical are included in proposed § 438.520; these components fall into three categories: (1) information to help navigate and understand the content of the MAC QRS website; (2) information to allow users to identify available managed care plans and features to tailor display information; and (3) features that allow beneficiaries to compare managed care plans on standardized information, including plan performance, cost and coverage of services and pharmaceuticals, and provider network. Based on the feedback we received during prototype testing, we believe that these components are critically important to ensure quality rating information can be readily understood by beneficiaries and used in decision-making. We are therefore proposing at § 438.520 that States display a MAC QRS website that includes: (1) clear information that is understandable and usable for navigating a MAC QRS website; (2) interactive features that allows users to tailor specific information, such as formulary, provider directory, and quality ratings based on their entered data; (3) standardized information so that users can compare managed care programs and plans, based on our identified information; (4) information that promotes beneficiary understanding of and trust in the displayed quality ratings, such as data collection timeframes and validation confirmation; and (5) access to Medicaid and CHIP enrollment and eligibility information, either directly on the website or through external resources.

Importantly, we understand from our engagement with States and interested parties that some display requirements we believe align with the goals discussed in section I.B.6.a. of this proposed rule may require more

technology-intensive implementation, such as the interactive features that allow users to tailor displayed information. We are therefore proposing to implement the proposed website display requirements in two phases. The first phase would be implemented by the end of the fourth year following the release of the final rule, as proposed at § 438.505(a)(2). In this phase, States would develop the MAC QRS website, display quality ratings, and would ensure that users can access information on plan providers, drug coverage, and view quality ratings by sex, race, ethnicity and dual eligibility status from the MAC QRS website. For instance, in lieu of an interactive search tool, the State may simply hyperlink to each managed care plan's existing provider directory and formulary to meet our proposed requirements. This first phase would accomplish the goal of having a one-stop-shop for beneficiaries to access the information we believe is key to their decision-making, but would not require States to develop the interactive tools identified in our research as more beneficial and usable by prospective users. In the second phase, States would be required to modify the website to provide a more interactive user experience with more information readily available to users on the MAC QRS website. This would entail including or moving some of the information required in other parts of 42 CFR part 438 to the MAC QRS website. For example, users could tailor the display of information to their needs and search for plans that cover their providers and medications without leaving the MAC QRS website. We discuss our proposal for phasing-in more interactive features of the website display in more detail later in this section. We seek comment on which requirements should be phased in as well as how much time would be needed.

Given the visual nature of the website display, we are providing two sample MAC QRS prototypes; a simple website (Prototype A) that represents the information we are considering to require by the proposed implementation date in § 438.505(a)(2) and another MAC QRS prototype (Prototype B) that represents an interactive website that includes both the display features from the first implementation phase and the more technology-intensive features we are considering phasing in. These prototypes can be found at *https://www.medicaid.gov/medicaid/quality-of-care/medicaid-managed-care-quality/quality-rating-system/index.html* and are meant to show our overall vision for the progression of the website display. In addition to the two prototypes, we intend to release a MAC QRS design guide following the final rule, which will provide a comprehensive overview of the results of our user testing that States may reference in the design of their MAC QRS website display. These materials would also provide CMS's interpretation of the requirements of the final rule as well as guidance on potential best practices in complying with the rule. We intend the design guide to include several components, including but not limited to: desirable features and content that States can implement at their discretion, plain language descriptions of mandatory measures, and display templates that States would have the option to use in the design of their MAC QRS. In the following paragraphs we discuss the proposed website display requirements and the feedback that led to their inclusion in the proposed website display.

(1) Navigational and Orienting Information (§§ 438.334(e), 438.520(a)(1) and (5), 457.1240(d))

Throughout our engagement, beneficiaries consistently stated the expectation that State Medicaid website and online plan selection processes would be difficult to navigate, and many users shared that they had previously felt confused and overwhelmed during the process of selecting a managed care plan. When reviewing the initial MAC QRS prototype, some beneficiaries reported struggling to understand the purpose of the prototype and how and when the information could be useful. In light of this feedback, we tested a number of features to support users in understanding and navigating potential websites and found that beneficiaries responded positively to live assistance services (such as chat and telephone), and pop-ups and other mechanisms of displaying information to explain content as participants navigated the prototype.

We found that providing upfront clear information about what the MAC QRS is (a State-run, unbiased source of information on managed care plans and their performance) and is not (a sales funnel for a particular managed care plan) and what it can do (help compare available managed care plans and their quality and performance) and what it cannot do (determine eligibility for Medicaid and CHIP or enroll beneficiaries in a health plan) allowed participants to quickly determine the purpose of the MAC QRS and whether the information available would be a useful tool for them when selecting a managed care plan. We also found that some beneficiaries initially needed additional background on relevant programs such as Medicaid, CHIP, and Medicare to understand if they were eligible for, or enrolled in, a plan or program with ratings or information available through the MAC QRS. Once the purpose of the MAC QRS was established, beneficiaries positively responded to features that clearly conveyed how to use the information available in the MAC QRS to select a managed care plan in a simple, easy to understand manner, such as providing the steps to identifying, comparing, and selecting a managed care plan. In our testing prototype, users were wary about entering personal information to help identify and tailor the display of available managed care plans, such as zip code, age, sex, and health conditions—information that can be helpful in navigating a website designed to help individuals select a plan. However, when a clear explanation of how their information would be used, users became more comfortable providing personal information.

Based on these findings from user testing, we are proposing certain navigational requirements for the MAC QRS website display requirements in proposed § 438.520(a)(1). Specifically, we propose in § 438.520(a)(1)(i) that States must provide users with information necessary to understand and navigate the MAC QRS display, including a requirement to provide users with information on the MAC QRS purpose, relevant information on dual eligibility and enrollment through Medicare, Medicaid, and CHIP, and an overview of how the MAC QRS website can be used to select a managed care plan. We propose in § 438.520(a)(1)(ii) that States must provide information on how to access the beneficiary support system required under existing § 438.71 to answer questions related to the MAC QRS (proposed at § 438.505(a)(3) and described in section I.B.6.d. of this proposed rule). Since beneficiary support systems are not required for separate CHIP, our proposed amendment to § 457.1240(d) excludes references to this requirement. We seek comment on whether beneficiary supports similar to those proposed for Medicaid should be required for States for separate CHIP in connection with the MAC QRS information or on a broader basis through future rulemaking. Under proposed § 438.520(a)(1)(iii) for Medicaid, and for separate CHIP by cross-reference through a proposed amendment at § 457.1240(d), States would be required

to inform users of how any information they provide would be used. Finally, under proposed § 438.520(a)(5), States would be required to provide users with information or hyperlinks that direct users to resources on how and where to apply for Medicaid and enroll in a Medicaid or CHIP plan. This requirement ensures that users can easily navigate to the next steps in the plan selection process after reviewing the MAC QRS website.

We believe that States can implement these features by relying on existing public information or expanding current requirements. For instance, States are required to have the beneficiary support system at § 438.71 in place and can train existing staff on the MAC QRS. Through an environmental scan of State Medicaid websites, we found that all States currently have information describing their Medicaid and CHIP programs as well as programs available to those dually eligible for Medicare and Medicaid. In both phases of the website display implementation, States may use these existing resources to comply with the requirements of proposed § 438.520(a)(1)(i) and (ii) either by hyperlinking to these resources from the MAC QRS website or incorporating existing information into the MAC QRS website display. Finally, as part of the MAC QRS design guide, we intend to provide plain language descriptions to illustrate what we would interpret the final rule to require; States may use such examples on their websites to provide an overview of how to use the MAC QRS to select a quality managed care plan.

(2) Tailoring of MAC QRS Display Content (§§ 438.334(e), 438.520(a)(2) and (a)(6), and 457.1240(d))

We also found that testing participants responded positively to features that allowed them to reduce the number of plans displayed to only those that met specific criteria, such as geographic location and eligibility requirements (for example, beneficiary age), so long as their privacy concerns were addressed by providing information on how and why such data would be used. Beneficiaries felt most comfortable providing their age and geographic location to identify health plans and we believe that these data points are likely sufficient to reduce the number of plans available to beneficiaries for comparison while also minimizing burden on States. Furthermore, dually eligible participants responded positively to the ability to easily identify those plans for which they were eligible. Therefore, we are proposing at § 438.520(a)(2)(i) for Medicaid, and for separate CHIP by cross-reference through a proposed amendment at § 457.1240(d), that each State's website must allow users to view available plans for which the user may be eligible based on users' age, geographic location, and dual eligibility status, as well as other demographic data identified by us in display guidance. Under the proposed rule, States would retain the flexibility to allow users to use additional information or eligibility criteria to further narrow down available managed care plans, such as searching by health condition like pregnancy or diabetes. In both phases of the website display implementation, States may meet this requirement by linking to a PDF that clearly indicates plans available to a beneficiary based on the identified factors (see Prototype A at *https://www.medicaid.gov/medicaid/quality-of-care/medicaid-managed-care-quality/quality-rating-system/index.html*). However, States may instead choose to implement an interactive display that allows the beneficiaries to input information upfront, and then tailors which managed care plans' information is displayed based on this information (see Prototype B at *https://www.medicaid.gov/medicaid/quality-of-care/medicaid-managed-care-quality/quality-rating-system/index.html*). In our environmental scan of State Medicaid websites, we identified many States that provide such a feature to help beneficiaries identify plans available to them. We believe this requirement supports the MAC QRS website being a one-stop-shop where beneficiaries can select a plan based on their eligibility information. We have made the judgment that requiring the development and use of the MAC QRS website in this manner is necessary for the proper and efficient operation of State Medicaid plans, and accordingly are proposing this requirement under our authority in section 1902(a)(4) of the Act, because this would support the beneficiary enrollment (and disenrollment) protections established in section 1932(a)(4)(A) of the Act . Based on our testing, the additional context is necessary and appropriate for beneficiaries to effectively use the information on plan quality ratings when choosing a managed care plan. Further, providing this flexibility for beneficiaries to choose how certain comparative information is presented is consistent with the requirement in section 1932(a)(5)(C) of the Act (which we have extended to information about PIHPs and PAHPs as well as MCOs using our authority in section 1902(a)(4) of the Act) for States to provide comparative information to beneficiaries about Medicaid managed care plans.

Participants in our user testing also prioritized confirming whether their current provider or prescriptions would be covered under a plan prior to navigating to other details about the plan. We therefore are proposing at § 438.520(a)(2)(ii) and (iii) for Medicaid, and for separate CHIP by cross-reference through a proposed amendment at § 457.1240(d), to require States to display provider directory and drug coverage information for each managed care plan in phase one of the website display requirements. This information is already required to be available from managed care plans under existing § 438.10(h)(1) and (2) and § 438.10(i), which set forth the general requirements for provider directory and formulary information that plans must make available to beneficiaries. In the first phase, States could satisfy the proposed requirements by providing hyperlinks to existing plan formularies and provider directories required under § 438.10(h) and (i) (See Prototype A); this capability would be required by the general implementation date proposed under § 438.505(a)(2).

As previously mentioned, user-testing participants preferred an integrated search feature that allowed them to identify available plans that offered coverage of specific prescription drugs and providers, rather than being directed via hyperlink to each managed care plan's website, which would require them to conduct multiple searches to identify the plans that cover their prescriptions and providers. When consulted, States generally were supportive of the display requirements we are proposing in § 438.520(a)(2), but noted that a searchable formulary or directory would be difficult to design and implement by the implementation date proposed in § 438.505(a)(2). Under § 431.60(a) of the May 2020 CMS Interoperability and Patient Access final rule,[148] States must implement an application programming interface (API) that permits third-party retrieval of certain data specified by CMS, including information about covered outpatient drugs and preferred drug list information (§ 431.60(b)(4)) and

[148] Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Interoperability and Patient Access for Medicare Advantage Organization and Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans on the Federally-Facilitated Exchanges, and Health Care Providers. CMS–9115–F. (85 FR 25510). Published in the **Federal Register** on May 1, 2020. (available online at *https://www.govinfo.gov/content/pkg/FR-2020-05-01/pdf/2020-05050.pdf).*

provider directory information (§ 431.70(b)). These requirements are applied in Medicaid managed care to MCOs, PIHP, and PAHPs under § 438.242(b)(5) and (6). We therefore believe that burden on managed care plans and States to provide the interactive search tools proposed in § 438.520(a)(2) would be minimized given that the data necessary to offer such tools is the same data that plans must make available through an API as specified in § 438.242(b)(5) and (6) and States could compile and leverage this existing data to offer the search functionality we are proposing. However, we agree that States will need additional time to implement dynamic, interactive website display features. Therefore, we are proposing, at § 438.520(a)(6)(i) and (ii) for Medicaid, and for separate CHIP by cross-reference through a proposed amendment at § 457.1240(d), that States would be given at least two additional years after a State's initial implementation of their MAC QRS (that is, two additional years after the date proposed at § 438.505(a)(2) for initial implementation) to display provider directory and drug coverage information for each managed care plan through an integrated, interactive search feature that allows users to identify plans that cover certain providers and prescriptions (see Prototype B). We seek comment on this phased-in approach and a reasonable timeline for the second phase. In addition, we seek comment on the display requirements and technical assistance needs.

In § 438.520(a)(6)(iii) and (iv), we propose a second phase of implementation for the stratification of quality ratings, in which States would implement an interactive display that allows beneficiaries to view and filter quality ratings for specific mandatory measures identified by CMS by the factors which would already be required in phase one under proposed § 438.520(a)(2)(v) plus additional factors identified by CMS including, but not limited to, age, rural/urban status, disability, and language spoken by the enrollees who have received services (see Prototype B). This proposal would address feedback we received in testing the MAC QRS prototype websites with beneficiaries. We tested dynamic filters that allowed participants to view quality ratings representing services provided only to plan beneficiaries that aligned with participant-selected factors such as race, sex, and age. This feature increased participant positivity and trust in the quality ratings displayed, especially among those who raised concerns about the uniformity of experience among beneficiaries. Similar to our proposal to phase-in interactive plan provider directory and formulary tools, we are proposing to phase in the interactive display of quality ratings stratified by various demographic factors. In § 438.520(a)(2)(v) for Medicaid, and for separate CHIP by cross-reference through a proposed amendment at § 457.1240(d), we therefore are proposing a first phase of implementation for this information that would require States to display quality ratings for mandatory measures stratified by factors including dual eligibility status, race and ethnicity, and sex. To reduce burden on States, we would permit States to report, if finalized, the same measurement and stratification methodologies and classifications as those proposed in the Mandatory Medicaid and CHIP Core Set Reporting proposed rule and the Access proposed rule. Measuring and making available performance reports on a stratified basis will assist in identifying health disparities. Driving improvements in quality is a cornerstone of the CMS approach to advancing health equity and also align with the CMS Strategic Priorities. In the first phase of implementation, a State's website would need to provide access to quality ratings that reflect the quality of care furnished to all of a plan's enrollees, as well as quality ratings that reflect the quality of care furnished to these subpopulations of a plan's enrollees (see Prototype A). This requirement is consistent with current efforts among measure stewards and other Federal reporting programs, such as the Child and Adult Core Sets, to stratify data to ensure that disparities in health outcomes are identified and addressed, not hidden (See Core Set proposed rule, 87 FR 51313). We are selecting these as our initial stratification factors as we believe this information is most likely to be collected as compared to our other proposed stratification factors. Furthermore, many testing participants shared their concern that health outcomes and customer experience may vary when stratified by race, ethnicity, or sex. We also believe that those who are dually eligible to receive Medicare and full Medicaid benefits would find it particularly useful to see quality ratings that focus specifically on the experience of such dually eligible beneficiaries. We believe that such ratings would allow beneficiaries who are dually eligible for Medicare and Medicaid to best identify a high-quality health plan, given the unique access considerations among this population. States would be required to display this information by the general MAC QRS implementation date proposed under § 438.505(a)(2). We seek comment on the feasibility of the proposed factors for stratifying quality ratings by the initial implementation date, and also whether certain mandatory measures may be more feasible to stratify by these factors than others. We are proposing that this interactive tool would be available no earlier than two years after the general MAC QRS implementation date. We request comment on this proposal including the timeline for implementation, technical assistance that may be necessary for States to implement the proposed feature, and the proposed factors by which such quality ratings would be stratified.

(3) Plan Comparison Information (§§ 438.334(e), 438.520(a)(3), and 457.1240(d))

Our prototype testing showed us participants were often frustrated and confused by the need to navigate multiple websites to obtain health plan information, such as out of pocket expenses, plan coverage of benefits, providers, and pharmaceuticals; and health plan metrics such as average time spent waiting for care, weekend and evening hours, and appointment wait times. When compiled into a standardized display along with quality ratings in our website prototype, participants responded positively and found the ability to compare plans on out-of-pocket expenses and covered benefits to be particularly useful. After identifying available plans that aligned with their needs and preferences on these two variables, some participants reflected that they would use quality ratings as an additional way to narrow down and filter their options. When presented alongside quality ratings, this information allowed beneficiaries to better compare plans. Based on this testing, we are proposing in § 438.520(a)(3) for Medicaid, and for separate CHIP by cross-reference through a proposed amendment at § 457.1240(d), to require States to display, for each managed care plan, standardized information identified by CMS that allows users to compare available managed care plans and programs, including the name, website, and customer service telephone hot line of each managed care plan; premium and cost sharing information; a summary of covered benefits; certain metrics of managed care plan access and performance; and whether the managed care plan offers an integrated Medicare-Medicaid plan. Under proposed § 438.520(a)(3)(iii) and (iv), States

would be required to identify comparative information about plans, specifically differences in premiums, cost-sharing, and benefits among managed care plans, to help users quickly identify where managed care plans do and do not differ. We believe that this information should be readily available to States and providing comparative information of this type is consistent with the information disclosure requirements in section 1932(a)(5) of the Act. These requirements are illustrated in Prototype A and B.

Under proposed § 438.520(a)(3)(v), States would also be required to provide on the QRS website certain metrics of managed care plan performance that States must make available to the public under Part 438, subparts B and D regulations, including certain data most recently reported to CMS on each managed care program under § 438.66(e) (Medicaid only) and the results of secret shopper survey proposed at § 438.68(f) in this proposed rule. Proposed paragraph (a)(3)(v) authorizes CMS to specify the metrics that are required to be displayed this way. States already report information related to grievances, appeals, availability and accessibility of covered services under § 438.66(e) and we believe that displaying some of this information would be responsive to input we received from our testing participants and improve transparency for beneficiaries without imposing significant burden on States since the information is already reported to us. States could choose to integrate these metrics into the display of MAC QRS measures on the MAC QRS website or, as illustrated in Prototypes A and B, may choose to hyperlink to an existing page with the identified information from the MAC QRS web page. These proposed requirements also support our goal for the MAC QRS to be a one-stop-shop where beneficiaries can access a wide variety of information on plan quality and performance in a user-friendly format to help inform their decision making. We seek comment on the inclusion of these metrics, and whether we should consider phasing in certain metrics first before others.

Lastly, at § 438.530(a)(3)(vi), we are proposing to require States to indicate when a managed care plan offers an integrated Medicare-Medicaid plan or a highly or fully integrated Medicare Advantage D–SNP and to provide a link to the integrated plan's rating under the MA and Part D quality rating system. The definitions of fully integrated dual eligible special needs plan and highly integrated dual eligible special needs plan are at § 422.2. We believe this is the simplest and most efficient way to help dually eligible users understand how to use the two quality ratings together. Both Prototype A and B illustrate this requirement through a hyperlink to the integrated plan's MA and Part D quality rating. We seek comment on these requirements, including on our proposal to require States to provide standardized information that users may rely on to compare managed care plans and request feedback on the feasibility of providing this information by the date initial implementation date.

(4) Information on Quality Ratings (§§ 438.334(e), 438.520(a)(4) and (c), and 457.1240(d))

Our user testing found that participants were initially skeptical of data provided in the MAC QRS, stating confusion regarding the source of the data used and mistrust in the ratings generated because they were uncertain how they were derived. Additionally, some participants stated that they did not trust information from the health plans. In an effort to improve user trust through data transparency, we tested providing clear and comprehensive information on displayed quality ratings and identified three types of information that together resulted in increased participant trust of the quality ratings. These include descriptions of the quality ratings in plain language, how recent the data displayed are, and how the data were confirmed to be accurate. Based on this user feedback, in § 438.520(a)(4)(i) for Medicaid, and for separate CHIP by cross-reference through a proposed amendment at § 457.1240(d), we propose that States would provide plain language descriptions of the importance and impact of each quality measure. We found that a simple explanation of what a quality measure is assessing, as well as how the measure relates to a beneficiary's health and well-being, were most helpful to users in understanding displayed quality ratings. A simple explanation would satisfy the proposed requirement. Both Prototype A and B include example explanations for our proposed mandatory measures, and we intend to include a sample explanation of the quality ratings for each final mandatory measure in the design guide discussed in section I.B.6.g. of this proposed rule, which States may choose to use.

Users responded positively to information that showed when data were collected and whether data were validated. They appreciated knowing that an external, neutral organization calculated the measures, noting that they would not trust the measures if they were calculated solely by the managed care plan. In § 438.520(a)(4)(ii) for Medicaid, and for separate CHIP by cross-reference through a proposed amendment at § 457.1240(d), we propose that States be required to indicate the measurement period during which data were produced to calculate the displayed quality ratings. In § 438.520(a)(4)(iii) for Medicaid, and for separate CHIP by cross-reference through a proposed amendment at § 457.1240(d), we propose that States must provide on the MAC QRS website when, how, and by whom quality ratings have been validated. This information would be provided in plain language and convey the role of parties (other than the rated plans) in validating data used to calculate the quality ratings, which will promote transparency and trustworthiness in the data. We note that States may use the External Quality Review optional activity described at § 438.358(c)(6) for EQRO assistance with quality ratings and link to the validated data included in the EQR technical reports. We seek comment on the display requirement proposed in § 438.520(a)(4) and request feedback on the feasibility of implementing these requirements by the initial implementation date proposed at§ 438.505(a)(2).

Finally, we believe that user preferences for how information should be displayed may change over time as the available data and the technology that enables website display of available data evolves. To ensure that the MAC QRS website continues to be a useful tool, we intend to periodically engage in additional consultations with MAC QRS users as part of a continuous improvement approach. We are proposing in § 438.520(c) for Medicaid, and for separate CHIP by cross-reference through a proposed amendment at § 457.1240(d), that CMS periodically consult with interested parties, including MAC QRS users such as Medicaid and CHIP beneficiaries and their caregivers, to maintain and update the website display requirements for the information required in proposed § 438.520(a). These consultations may result in proposed changes through rulemaking that add to or refine existing requirements or remove existing requirements that beneficiaries no longer find useful.

(5) Display of additional Measures Not on the Mandatory Measure Set (§§ 438.334(e), 438.520(b), and 457.1240(d))

Under our proposal at § 438.510(a), States would have the option to display

additional measures that are not included in the mandatory measure set if the two requirements set forth in proposed § 438.520(b)(1) and (2) are met. The same standards would apply to separate CHIP as proposed in § 457.1240(d) by cross-referencing part 438, subpart G.

First, we are proposing, in § 438.520(b)(1) to require States to obtain input from prospective MAC QRS users, including beneficiaries, their caregivers, and, if the State enrolls American Indians/Alaska Natives in managed care, consult with Tribes and Tribal Organizations in accordance with the State's Tribal consultation policy. In this proposed rule, we have extensively noted the importance of the prospective user testing we engaged in and the extent to which this feedback directed our design of the MAC QRS framework and selection of the preliminary mandatory measure set. Just as beneficiary participation was, and will continue to be, critical in our design of the MAC QRS, we believe beneficiary participation is critical in the identification of any additional measures included in a State's MAC QRS. States could meet this requirement by ensuring that beneficiary members of the MCAC are present when obtaining input from the State's MCAC, or may engage in direct beneficiary interviews, focus groups, or prototype testing.

Second, we are also proposing at § 438.520(b)(2) that States must document the input received from prospective MAC QRS users on such additional measures, the modifications made to the proposed additional measures in response to the input, and rationale for not accepting input. We are also proposing this documentation to be reported as part of the MAC QRS annual report proposed under § 438.535(a)(3). For States that currently publish a QRS-like website, measures that are not in the mandatory measure set would be considered additional measures and would be subject to this process prior to display. If a State obtained user input for the additional measure prior to displaying the measure on its current website, the State may use this input to meet this requirement.

h. Alternative Quality Rating System (§§ 438.334(c), 438.525, and 457.1240(d))

Current regulations at § 438.334(c) allow States, with CMS approval, to implement an alternative managed care quality system (alternative QRS) that uses different quality measures or applies a different methodology if the conditions set forth in § 438.334(c)(1)(i) through (iii) are met, including that the measure or methodology must be substantially comparable to the measures and methodology established by CMS under the MAC QRS framework. Based on feedback we received during our engagement with States and other interested parties, we are proposing to redesignate § 438.334(c) at § 438.525 for Medicaid, and for separate CHIP by cross-reference through a proposed amendment at § 457.1240(d), and to modify the current policy by narrowing the changes (compared to the MAC QRS framework described in proposed § 438.515) that would require our approval. We are also proposing to apply the same requirements for both Medicaid managed care programs and separate CHIP by revising § 457.1240(d) to require States to comply with § 438.525.

First, we are proposing to remove the language in current § 438.334(c)(1) that includes the use of ''different performance measures'' being subject to our review and approval as part of an alternative QRS. Current regulations at § 438.334(c)(1) require States to submit for our review and approval an alternative QRS request to include measures different than those included in the mandatory measure set identified by CMS. We believe requiring States to obtain our approval to include measures not required by us creates unnecessary administrative burden for both States and CMS. Under the proposed regulation, instead of requiring approval of different measures, we are proposing that States would have the flexibility to add measures that are not mandatory measures without prior approval from CMS.

We highlight here that the measure specifications established by measure stewards for mandatory measures are not considered part of the methodology described in proposed § 438.515 and are therefore not subject to § 438.525. Modifications to these specifications that are approved by the measure steward do not require a State to undergo any part of the alternative QRS process described in this section for the State to use those measure steward approved modifications to produce a rating for a mandatory measure. However, we would consider quality ratings for mandatory measures identified by CMS under § 438.510(a) that are calculated using specifications not approved by a measure steward to be a different measure. We believe that this policy provides flexibility to States while ensuring that the results on the mandatory measures remain comparable among States.

Second, we are proposing to further define the criteria and process for determining if an alternative QRS system is substantially comparable to the MAC QRS methodology described in proposed § 438.515. The current regulations at § 438.334(c)(4) provide that we will issue guidance on the criteria and process for determining if an alternative QRS meets the substantial comparability standard in current § 438.334(c)(1)(ii), redesignated at § 438.525(a)(2). We are proposing to eliminate § 438.334(c)(4) and redesignate as proposed § 438.525(c)(2)(i) through (iii) and specify in proposed § 438.525(c)(2)(iv) that States are responsible for submitting documents and evidence that demonstrates compliance with the substantial comparability standards. We believe that eliminating § 438.334(c)(4) is appropriate as this rulemaking provides an opportunity for States and other interested parties to submit comments on how CMS should evaluate alternative quality rating systems for substantial comparability.

In the future, we intend to issue instructions on the procedures and the dates by which States must submit an alternative QRS request to meet the implementation date specified in proposed § 438.505(a)(2). For requests or modifications made after implementation of the MAC QRS, we are considering accepting rolling requests instead of specifying certain dates or times of year when we will accept alternative QRS requests or modifications. We believe this may be necessary given that States may have different contract cycles with managed care plans. We solicit comment on these different approaches.

Current § 438.334(c)(2) describes the information that States would submit to CMS as part of their request to implement an alternative QRS. We are proposing to redesignate § 438.334(c)(2), with revisions, at § 438.525(c)(2)(iv) to allow States to provide additional supporting documents and evidence that they believe demonstrates that a proposed alternative QRS would yield information regarding managed care plan performance that is substantially comparable to that yielded by the MAC QRS methodology described in § 438.515. Examples of such additional supporting documents could include a summary of the results of a quantitative or qualitative analysis of why the proposed alternative methodology is substantially comparable or calculations of mandatory measures with the alternative methodology and with the methodology required under § 438.515.

We seek comment on these proposals, in particular, the described process and documentation for assessing whether a

proposed alternative QRS framework is substantially comparable, by when States would need alternative QRS guidance, and by when States would need to receive approval of an alternative QRS request to implement the alternative by the implementation date specified in proposed § 438.505(a)(2).

i. Annual Technical Resource Manual (§§ 438.334, 438.530, and 457.1240(d))

We propose at § 438.530(a) for Medicaid, and for separate CHIP by cross-reference through a proposed amendment at § 457.1240(d), that CMS will develop and update annually a Medicaid managed care quality rating system technical resource manual no later than August 1, 2025, and update it annually thereafter. Providing clear and detailed information for reporting on MAC QRS measures not only supports States in implementing their MAC QRS but is also essential for consistent reporting and comparable quality ratings across States and managed care plans. This manual would include information needed by States and managed care plans to calculate and issue quality ratings for all mandatory measures that States would be required to report under this proposed rule. This includes the mandatory measure set, the measure steward technical specifications for those measures, and information on applying our proposed methodology requirements to the calculation of quality ratings for mandatory measures. Under our proposal, we would publish an initial technical resource manual following the final rule, and would update the manual annually thereafter to maintain its relevance. We considered releasing the technical resource manual less frequently than annually, but we do not believe this manual could be properly maintained unless it is updated annually due to the inclusion of updates to the technical specifications for the mandatory measures.

Proposed § 438.530(a) identifies the components of the technical resource manual to be issued by CMS. As described in § 438.530(a)(1), we propose to use the technical resource manual to identify the mandatory measures as well as any measures newly added or removed from the previous year's mandatory measure set. We intend for the first technical resource manual to include details on the initial MAC QRS mandatory measure set that will be finalized after consideration of the public comments received in response to this proposed rule.

These content requirements for the technical resource manual proposed at new § 438.530(a)(1) through (3) include the following:

- The mandatory measure set so States know what they are required to report.
- The specific MAC QRS measures newly added to or removed from the prior year's mandatory set as well as a summary of the engagement and public comments received during the engagement process in § 438.510(b) used for the most recent modifications to the mandatory measure set. To provide a complete picture of any changes being made to the MAC QRS measures, we propose this summary to include a discussion of the feedback and recommendations received, the final modifications and timeline for implementation, and the rationale for recommendations or feedback not accepted.
- The subset of mandatory measures that must be stratified by race, ethnicity, sex, age, rural/urban status, disability, language, or such other factors as may be specified by CMS in the annual technical resource manual as required under § 438.520(a)(2)(v) and (a)(6)(iii). We discuss the rationale for inclusion of stratifiers in section I.B.6.g.2. of this proposed rule.
- How to use the methodology described in § 438.515 to calculate quality ratings for managed care plans. We seek comment on which topics States and health plans would like technical assistance or additional guidance to ensure successful implementation of the rating system.
- Technical specifications for mandatory measures produced by measures stewards as part of the proposed annual technical resource manual. We believe this information would assist States and health plans in the calculation of quality ratings for mandatory measures and aligns with the practices of the Adult and Child Core Set and the MA and Part D and QHP quality rating systems.

Lastly, at § 438.530(b) for Medicaid, and for separate CHIP by cross-reference through a proposed amendment at § 457.1240(d), we are proposing the general rule that CMS take into account stratification guidance issued by the measure steward and other CMS reporting programs when identifying which measures, and by which factors, States must stratify mandatory measures. Under this proposal, we plan to implement a phased-in approach for specifying the mandatory measures for which data must be stratified and the factors by which such data must be stratified. We intend to align with the stratification schedule which is proposed in § 437.10(d) of the Mandatory Medicaid and CHIP Core Set Reporting Proposed Rule (see 87 FR 51327). We believe this alignment with the Core Set stratification would minimize State and health plan burden to report stratified measures. For any MAC QRS measures that are not Core Set measures, we would consider, and align where appropriate, with the stratification policies for the associated measure steward or other CMS reporting programs. Additional information regarding MAC QRS stratification requirements are proposed in section I.B.6.g.2. of this proposed rule.

Based on feedback we received through listening sessions with interested parties, we are considering releasing an updated technical resource manual at least five months prior to the measurement period for which the technical resource manual will apply. This is in alignment with the proposed date for the first technical resource manual of August 1, 2025 for a 2026 measurement year, and would ensure that States have enough time to implement any necessary changes before the measurement period and, if necessary, submit and receive approval for an alternative QRS request. In our listening sessions, interested parties noted that this timeline would align with those used by other measure stewards (for example, NCQA for HEDIS measures) and would ensure that States and managed care plans are able to identify and make necessary contractual, systems, and data collection changes to facilitate additional data collection required for the upcoming measurement period. We seek comment on whether this timing is appropriate for States to implement any changes included in the reporting and technical guidance for the initial measurement year as well as subsequent measurement years.

j. Reporting (§§ 438.334, 438.535, and 457.1240(d))

We are proposing requirements at § 438.535 for States to submit to CMS, upon request, information on their MAC QRS to support our oversight of Medicaid and CHIP and compliance with MAC QRS requirements, to ensure beneficiaries can meaningfully compare ratings between plans, and to help us monitor trends in additional measures and use of permissible modifications to measure specifications used among States, which could inform future additions to the mandatory measures and modifications of our methodology. We are proposing any request for reporting by States would be no more frequently than annually. We are proposing the report would include the following components:

• A list of all measures included in the State's MAC QRS, including a list of the mandatory measures reported and any additional measures a State has chosen to display in their MAC QRS to inform updates to the measures list;
• An attestation that displayed quality ratings for all mandatory measures were calculated and issued in compliance with § 438.515, and a description of the methodology used to calculate any additional measures when it deviates from the methodology proposed in § 438.515;
• If a State chooses to display additional quality measures, a description of and the required documentation for the process required under § 438.520(b);
• The date on which the State publishes or updates their quality ratings for the State's managed care plans;
• The link to the State's MAC QRS website to enable CMS to ensure the MAC QRS ratings are current; and
• The use of any technical specification adjustments to MAC QRS mandatory measures, which are outside the measure steward's allowable adjustment for the mandatory measure, but that the measure steward has approved for use by the State. As discussed in section I.B.6.f. of this proposed rule, we do not consider measure steward technical specifications to be part of the MAC QRS rating methodology, but they are part of the measures. Therefore, we do not require States to submit such adjustments to us for approval as an alternative QRS and believe State reporting is more appropriate to better understand if such adjustments impact plan-to-plan comparability or comparability within and among States.
• A summary of each alternative QRS approved by CMS, including the effective dates (the time period during which the alternative QRS was, has been, or will be applied by the State) for each approved alternative QRS.

We propose these reporting requirements at new § 438.535(a)(1) through (7) for Medicaid, and for separate CHIP by cross-reference through a proposed amendment at § 457.1240(d). We propose in § 438.535(a) the report will be ''in a form and manner determined by CMS'' because we intend to establish an online portal that States could access to easily submit this information to us. At § 438.535(b) for Medicaid, and for separate CHIP by cross-reference through a proposed amendment at § 457.1240(d) we propose that States would be given a minimum of 90 days' notice to provide such a report. We seek comment on whether States prefer one annual reporting date or a date that is relative to their MAC QRS updates.

k. Technical Changes (§§ 438.334, 438 Subpart G, 438.358, and 457.1240(d))

We are proposing several technical changes to conform our regulations with other parts of our proposed rule, which include:
• Redesignating the regulations under current § 438.334(a) to 42 CFR part 438, subpart G, § 438.505;
• In current § 438.358(c)(6), changing the reference for this EQR optional activity from § 438.334 to part 438, subpart G to align with the proposed redesignating of § 438.334;
• In current § 438.334(a)(1), redesignated to § 438.505(a)(1)(i), changing the ''Medicaid managed care quality rating system developed by CMS in accordance with paragraph (b) of this section'' to ''QRS framework'' to align with the proposed definition of QRS framework in new § 438.500;
• In current § 438.334(a)(2), redesignated to § 438.505(a)(2)(ii), changing ''in accordance with paragraph (c) of this section'' to ''in accordance with § 438.525 of this subpart'' to align with the proposed alternative QRS requirements in new § 438.525;
• Modifying current § 438.334(a)(3), redesignated to § 438.505(a)(2), to use the term ''the final rule'' instead of ''a final notice'' to refer to the proposed rules herein, if finalized;
• Modifying current § 438.334(c)(1), redesignated to § 438.525(a), by replacing ''different methodology'' with ''alternative methodology'' to better align with the proposed terminology used in the new proposed § 438.525);
• In current § 438.334(b)(1), redesignated to § 438.505(c), replacing ''related CMS quality rating approaches'' with ''similar CMS quality measurement and rating initiatives'' to better describe how we are aligning the QRS framework;
• Redesignating current § 438.334(c)(3)(i) to § 438.525(c)(2)(i) and modifying by removing ''alternative quality rating system framework, including the quality measures'' to align with our proposal under new § 438.525;

Unless otherwise noted, these technical changes are equally proposed for separate CHIP by cross-reference through a proposed amendment at § 457.1240(d).

II. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 *et seq.*), we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. For the purpose of the PRA and this section of the preamble, ''collection of information'' is defined under 5 CFR 1320.3 of the PRA's implementing regulations. To fairly evaluate whether a collection of information should be approved by OMB, section 3506(c)(2)(A) of the PRA requires that we solicit comment on the following issues:

• The need for the information collection and its usefulness in carrying out the proper functions of our agency.
• The accuracy of our estimate of the information collection burden.
• The quality, utility, and clarity of the information to be collected.
• Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements. Comments, if received, will be responded to within the subsequent final rule.

A. Wage Estimates

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' May 2021 National Occupational Employment and Wage Estimates for all salary estimates (*https://www.bls.gov/oes/current/oes_nat.htm*). Table 3 presents BLS' mean hourly wage, our estimated cost of fringe benefits and overhead (calculated at 100 percent of salary), and our adjusted hourly wage.

TABLE 3—NATIONAL OCCUPATIONAL EMPLOYMENT AND WAGE ESTIMATES

Occupation title	Occupation code	Mean hourly wage ($/hr)	Fringe benefits and overhead ($/hr)	Adjusted hourly wage ($/hr)
All Occupations	00–0000	28.01	n/a	n/a

TABLE 3—NATIONAL OCCUPATIONAL EMPLOYMENT AND WAGE ESTIMATES—Continued

Occupation title	Occupation code	Mean hourly wage ($/hr)	Fringe benefits and overhead ($/hr)	Adjusted hourly wage ($/hr)
Accountant	13–2011	40.37	40.37	80.74
Actuary	15–2011	60.24	60.24	120.48
Business Operations Specialist, All Other	13–1199	38.64	38.64	77.28
Computer Programmer	15–1251	54.68	54.68	109.36
Customer Service Rep	43–4051	18.79	18.79	37.58
Database Administrator	15–1242	49.25	49.25	98.50
General and Operations Manager	11–1021	55.41	55.41	110.82
Medical Records Specialist	29–2072	23.23	23.23	46.46
Office Clerk, General	43–9061	18.98	18.98	37.96
Statistician	15–2041	47.81	47.81	96.62
Registered Nurse	29–1141	39.78	39.78	79.56
Web Developer	15–1245	39.09	39.09	78.18

States and the Private Sector: As indicated, we are adjusting our employee hourly wage estimates by a factor of 100 percent. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly from employer to employer, and because methods of estimating these costs vary widely from study to study. Nonetheless, we believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

Beneficiaries: To derive average costs for beneficiaries we believe that the burden will be addressed under All Occupations (BLS occupation code 00–0000) at $28.01/hr. Unlike our State and private sector wage adjustments, we are not adjusting beneficiary wages for fringe benefits and overhead since the individuals' activities would occur outside the scope of their employment.

B. Proposed Information Collection Requirements (ICRs)

To estimate the burden for the requirements in part 438, we utilized State submitted data by States for enrollment in managed care plans for CY 2020. The enrollment data reflected 58,521,930 enrollees in MCOs, 37,692,501 enrollees in PIHPs or PAHPs, and 6,089,423 enrollees in PCCMs, for a total of 67,836,622 Medicaid managed care enrollees. This includes duplicative counts when enrollees are enrolled in multiple managed care plans concurrently. These data also showed 43 States that contract with 467 MCOs, 11 States that contract with 162 PIHPs or PAHPs, 19 States that contract with 21 non-emergency transportation PAHPs, and 13 States with 26 PCCM or PCCM entities. The estimates below reflect deduplicated State counts as data permitted.

To estimate the burden for these requirements in part 457, we utilized State submitted data for enrollment in managed care plans for CY 2017. The enrollment data reflected 4,580,786 Medicaid expansion CHIP and 2,593,827 separate CHIP managed care enrollees. These data also showed that 32 States use managed care entities for CHIP enrollment contracting with 199 MCOs, PIHPs, and PAHPs, as well as 17 PCCMs.

1. ICRs Regarding Standard Contract Requirements (§ 438.3 and 457.1203)

The following proposed changes to § 438.3 will be submitted to OMB for review under control number 0938–TBD (CMS–10856). At this time the OMB control number has not been determined, but it will be assigned by OMB upon their clearance of our proposed collection of information request. The control number's expiration date will be issued by OMB upon their approval of our final rule's collection of information request. The following proposed changes to § 457.1203 will be submitted to OMB for review under control number 0938–1282 (CMS–10554).

The proposed amendments to §§ 438.3(i) and 457.1203(f) would require that MCOs, PIHPs, and PAHPs report provider incentive payments based on standard metrics for provider performance. The proposed amendments to § 438.8(e)(2) would define the provider incentive payments that could be included in the MLR calculation; however, the administrative burden for these changes is attributable to the managed care contracting process, so we are attributing these costs to the contracting requirements in § 438.3(i). Approximately half (or 315 Medicaid contracts and 100 CHIP contracts) of all MCO, PIHP, and PAHP contracts would require modification to reflect these changes. For the contract modifications, we estimate it would take 2 hours at $77.28/hr for a business operations specialist and 1 hour at $110.82/hr for a general operations manager. In aggregate for Medicaid for § 438.3(i), we estimate a one-time State burden of 945 hours (315 contracts × 3 hr) at a cost of $83,595 [315 contracts × ((2 hr × $77.28/hr) + (1 hr × $110.82/hr))]. As this would be a one-time requirement, we annualize our time and cost estimates to 315 hours and $9,288. The annualization divides our estimates by three (3) years to reflect OMB's likely approval period. We are annualizing the one-time burden estimates since we do not anticipate any additional burden after the 3-year approval period expires.

In aggregate for CHIP for § 457.1203(f) we estimate a one-time State burden of 300 hours (100 contracts × 3 hr) at a cost of $26,538 [100 contracts × ((2 hr × $77.28/hr) + (1 hr × $110.82/hr))]. As this would be a one-time requirement, we annualize our time and cost estimates to 66 hours and $8,819. The annualization divides our estimates by three (3) years to reflect OMB's likely approval period. We are annualizing the one-time burden estimates since we do not anticipate any additional burden after the 3-year approval period expires.

To report provider incentive payment based on standard metrics, MCOs, PIHP, and PAHPs would need to select standard metrics, develop appropriate payment arrangements, and then modify the affected providers' contracts. We estimate it would take 120 hours consisting of: 80 hours × $77.28/hr for a business operations specialist and 40 hours × $110.82/hr for a general and operations manager. In aggregate for Medicaid for § 438.3(i), we estimate a one-time private sector burden of 37,800 hours (315 contracts × 120 hr) at a cost of $3,343,788 [315 contracts × ((80 hr × $77.28/hr) + (40 hr × $110.82/hr))]. As this would be a one-time requirement, we annualize our time and cost

estimates to 12,600 hours and $1,114,596. The annualization divides our estimates by three (3) years to reflect OMB's likely approval period. We are annualizing the one-time burden estimates since we do not anticipate any additional burden after the 3-year approval period expires.

In aggregate for CHIP for § 457.1203(f) we estimate a one-time private sector burden of 12,000 hours (100 contracts × 120 hr) at a cost of $1,061,520 [100 contracts × ((80 hr × $77.28/hr) + (40 hr × $110.82/hr))].

To do the annual reconciliations needed to make the incentive payments and include the expenditures in their annual report required by 438.8(k), we estimate MCOs, PIHPs, and PAHPs would take 1 hour at $77.28/hr for a business operations specialist. In aggregate for Medicaid we estimate an annual private sector burden of 315 hours (315 contracts × 1 hr) at a cost of $24,343 (315 contracts × 1 hr × $77.28/hr).

In aggregate for CHIP, we estimate an annual private sector burden of 100 hours (100 contracts × 1 hr) and $7,728 (100 contracts × 1 hr × $77.28/hr).

2. ICRs Regarding Special Contract Provisions Related to Payment (§ 438.6)

The following proposed changes will be submitted to OMB for review under control number 0938–TBD (CMS–10856). At this time the OMB control number has not been determined, but it will be assigned by OMB upon their clearance of our proposed collection of information request. The control number's expiration date will be issued by OMB upon their approval of our final rule's collection of information request.

The proposed amendments to § 438.6(c)(2) would require all SDP expenditures under paragraphs (c)(1)(i) and (ii) and (c)(1)(iii)(C) through (E) (that is, the SDPs that require prior written approval under this proposed rule) must be submitted and have written approval by CMS prior to implementation.

Initially, we estimate that 38 States would submit 50 new proposals for minimum/maximum fee schedules, value-based payment, or uniform fee increases. We estimate that it would take 2 hours at $120.48/hr for an actuary, 6 hours at $77.28/hr for a business operations specialist, and 2 hours at $110.82/hr for a general and operations manager for development and submission. We estimate an annual State burden of 500 hours (50 proposals × 10 hr) at a cost of $46,314 [50 proposals × ((2 hr × $120.48/hr) + (6 hr × $77.28/hr) + (2 hr × $110.82/hr))].

Thereafter, we estimate that 38 States would submit 150 renewal or amendment proposals per year. We estimate also it would take 1 hour at $77.28/hr for a business operations specialist, 1 hour at $120.48/hr for an actuary, and 1 hour at $110.82/hr for a general and operations manager for any proposal updates or renewals. In aggregate, we estimate an annual State burden of 450 hours (150 proposals × 3 hr) and $46,287 [150 renewal/amendment proposals × ((1 hr × $77.28/hr) + (1 hr × $110.82/hr) + (1 hr × 120.48/hr))].

The proposed amendments to § 438.6(c)(2)(iii) would require that all SDPs subject to prior approval under paragraphs (c)(1)(i) through (iii) for inpatient hospital services, outpatient hospital services, nursing facility services, and qualified practitioner services at an academic medical center, include a written analysis, showing that the total payment for such services does not exceed the average commercial rate. We estimate that 38 States will develop and submit 60 of these SDPs that include a written analysis to CMS. We also estimate it would take 6 hours at $120.48/hr for an actuary, 3 hours at $110.82/hr for a general and operations manager, and 6 hours at $109.36/hr for a computer programmer for each analysis. In aggregate we estimate an annual State burden of 900 hours (60 SDPs × 15 hr) and at a cost of $102,690 [60 certifications × ((6 hr × $120.48/hr) + (3 hr × $110.82/hr) + (6 hr × $109.36/hr))].

Section 438.6(c)(2)(iv) would require that SDPs under paragraphs (c)(1)(i) and (ii) and (c)(1)(iii)(C) through (E) must prepare and submit a written evaluation plan to CMS. The evaluation plan must include specific components under this proposal and is intended to measure the effectiveness of those State directed payments in advancing at least one of the goals and objectives in the quality strategy on an annual basis and whether specific performance targets are met. We estimate that 38 States would submit 50 written evaluation plans for new proposals. We also estimate it would take 5 hours at $109.36/hour for a computer programmer, 2.5 hours at $110.82/hr for a general and operations manager, and 2.5 hours at $77.28/hr for a business operations specialist for each new evaluation plan. In aggregate, we estimate an annual State burden of 500 hours (50 evaluation plans × 10 hr) and at a cost of $50,853 [50 evaluation plans × ((5 hr × 109.36/hr) + (2.5 hr × $110.82) + (2.5 hr × $77.28/hr))].

Thereafter, we estimate that 38 States would prepare and submit 150 written evaluation plans for amendment and renewal proposals. We also estimate it would take 2 hours at $109.36/hr for a computer programmer, 2 hours at $110.82/hr for a general and operations manager and 2 hours at $77.28/hr for a business operations specialist for each evaluation plan amendment and renewal. In aggregate we estimate an annual State burden of 900 hours (150 evaluation plans × 6 hr) at a cost of $89,238 [150 evaluation plans × ((2 hr × 109.36/hr) + (2 hr × $110.82) + (2 hr × $77.28/hr))].

Section 438.6(c)(2)(v) would require for all SDPs under paragraphs (c)(1)(i) and (ii) and (c)(1)(iii)(C) through (E) that have an actual Medicaid managed care spending percentage greater than 1.5 must complete and submit an evaluation report using the approved evaluation plan to demonstrate whether the SDP results in achievement of the State goals and objectives in alignment with the State's evaluation plan.

We estimate 38 States will submit 47 evaluation reports. We also estimate it would take 3 hours at $109.36/hr for a computer programmer, 1 hour at $110.82/hour for a general and operations manager, and 2 hours at $77.28/hr for a business operations specialist for each report. In aggregate we estimate an annual State burden of 282 hours (47 reports × 6 hr) at a cost of $27,893 [47 reports × ((3 hr × $109.36/hr) + (1hr × $110.82/hr) + (2 hr × $77.28/hr)].

The proposal at § 438.6(c)(7) would require States to submit a final SDP cost percentage as a separate actuarial report concurrently with the rate certification only if a State wishes to demonstrate that the final SDP cost percentage is below 1.5 percent. We anticipate that 10 States would need: 5 hours at $120.48/hr for an actuary, 5 hours at $109.36/hr for a computer programmer, and 7 hours at $77.28/hr for a business operations specialist. In aggregate, we estimate an annual State burden of 170 hours (17 hr × 10 States) at a cost of $16,902 (10 States × [(5 hr × $120.48/hr) + (5 hr × $109.36/hr) + (7 hr × $77.28/hr)]).

3. ICRs Regarding Rate Certification Submission (§ 438.7)

The following proposed changes will be submitted to OMB for review under control number 0938–TBD (CMS–10856). At this time the OMB control number has not been determined, but it will be assigned by OMB upon their clearance of our proposed collection of information request. The control number's expiration date will be issued by OMB upon their approval of our final rule's collection of information request.

The proposed amendments to § 438.7 set out revisions to the submission and

documentation requirements for all managed care actuarial rate certifications. The certification would be reviewed and approved by CMS concurrently with the corresponding contract(s). Currently, § 438.7(b) details certain requirements for documentation in the rate certifications. We believe these requirements are consistent with actuarial standards of practice and previous Medicaid managed care rules.

We estimate that 44 States would develop 225 certifications at 250 hours for each certification. Of the 250 hours, we estimate that it would take 110 hours at $120.48/hr for an actuary, 15 hours at $110.82/hr for a general and operations manager, 53 hours at $109.36/hr for a computer programmer, 52 hours at $77.28/hr for a business operations specialist, and 20 hours at $37.96/hr for an office and administrative support worker. In aggregate we estimate an annual State burden of 56,250 hours (250 hr × 225 certifications) at a cost of $5,735,012 [225 certifications × ((110 hr × $120.48/hr) + (15 hr × $110.82/hr) + (53 hr × $109.36/hr) + (52 hr × $77.28/hr) + (20 hr × $37.96/hr))].

4. ICRs Regarding Medical Loss Ratio Standards (§§ 438.3, 438.8, 438.74, and 457.1203)

The following proposed changes will be submitted to OMB for review under control number 0938–TBD (CMS–10856). At this time the OMB control number has not been determined, but it will be assigned by OMB upon their clearance of our proposed collection of information request. The control number's expiration date will be issued by OMB upon their approval of our final rule's collection of information request. The following proposed changes to § 457.1203 will be submitted to OMB for review under control number 0938–1282 (CMS–10554).

This rule's proposed amendments to §§ 438.8 and 457.1203 would require that MCOs, PIHPs, and PAHPs report to the State annually their total expenditures on all claims and non-claims related activities, premium revenue, the calculated MLR, and, if applicable, any remittance owed.

We estimate the total number of MLR reports that MCOs, PIHPs, and PAHPs were required to submit to States amount to 629 Medicaid contracts and 199 CHIP contracts. All MCOs, PIHPs, and PAHPs need to report the information specified under §§ 438.8 and 457.1203 regardless of their credibility status.

The proposed amendments to § 438.8(k) would require that MCOs, PIHPs, and PAHPs include expenditures for State directed payments on a separate line in their annual report to the State. We anticipate that the one-time system change would take 4 hr at $77.28/hr for a business operations specialist and 2 hr at $109.36/hr for a computer programmer. In aggregate for Medicaid for § 438.8(k), we estimate a one-time private sector burden of 3,774 hours (629 contracts × 6 hr) at a cost of $332,011 [629 contracts × ((4 hr × $77.28/hr) + (2 hr × $109.36/hr))]. As this would be a one-time requirement, we annualize our time and cost estimates to 1,258 hours and $110,670. The annualization divides our estimate by three (3) years to reflect OMB's likely approval period. We are annualizing the one-time burden estimates since we do not anticipate any additional burden after the 3-year approval period expires.

The proposed amendments to §§ 438.8(k)(1)(vii) and 457.1203(f) would require that MCOs, PIHPs, and PAHPs develop their annual MLR reports compliant with the proposed expense allocation methodology.[149] To meet this requirement we anticipate it would take: 1 hr at $80.74/hr for an accountant, 1 hr at $77.28/hr for a business operations specialist, and 1 hr at $110.82/hr for a general operations manager. In aggregate for Medicaid for § 438.8(k)(1)(vii), we estimate an annual private sector burden of 1,887 hours (629 contracts × 3 hr) at a cost of $169,100 [629 contracts × ((1 hr × $80.74/hr) + (1 hr × $77.28/hr) + (1 hr × $110.82/hr))]. In aggregate for CHIP for § 457.1203(f), we estimate an annual private sector burden of 597 hours (199 contracts × 3 hr) at a cost of $53,499 [199 contracts × ((1 hr × $80.74/hr) + (1 hr × $77.28/hr) + (1 hr × $110.82/hr))].

The proposed amendments to §§ 438.74 and 457.1203(e) would require States to comply with data aggregation requirements for their annual reports to CMS. We estimate that only 5 States would need to resubmit MLR reports to comply with the proposed data aggregation changes. We anticipate that it would take 5 hours × $77.28/hr for a business operations specialist. In aggregate, for Medicaid for § 438.74, we estimate a one-time State burden of 25 hours (5 States × 5 hr) at a cost of $1,932 (5 States × 5 hr × $77.28/hr). As this would be a one-time requirement, we annualize our time and cost estimates to 8 hours and $644. In aggregate for CHIP for § 457.1203(e) we estimate a one-time State burden of 25 hours (5 States × 5 hr) at a cost of $1,932 (5 States × 5 hr × $77.28/hr). As this would be a one-time requirement, we annualize our time and cost estimates for CHIP to 8 hours and $644. The annualization divides our estimates by three (3) years to reflect OMB's likely approval period. We are annualizing the one-time burden estimates since we do not anticipate any additional burden after the 3-year approval period expires.

The proposed amendments to § 438.74 would require States to submit a summary report of the State directed payment data submitted by their managed care plans under § 438.8(k). The proposed changes to § 438.74 would apply to 43 States. To accommodate the new data from plans resulting from proposed changes to § 438.74, we anticipate it would take 4 hours at $77.28/hr for a business operations specialist to implement the proposed SDP reporting changes in their MLR summary reports. In aggregate, we estimate an annual State burden of 172 hours (43 States × 4 hr) at a cost of $13,292 (43 States × 4 hr × $77.28/hr).

5. ICRs Regarding Information Requirements (§§ 438.10 and 457.1207)

The following proposed changes to § 438.10 will be submitted to OMB for review under control number 0938–TBD (CMS–10856). At this time the OMB control number has not been determined, but it will be assigned by OMB upon their clearance of our proposed collection of information request. The control number's expiration date will be issued by OMB upon their approval of our final rule's collection of information request. The following proposed changes to § 457.1207 will be submitted to OMB for review under control number 0938–1282 (CMS–10554).

The proposed amendments to §§ 438.10(c)(3) and 457.1207 would require States to operate a website that provides the information required in § 438.10(f). We propose to require that States include required information on one page, use clear labeling, and verify correct functioning and accurate content at least quarterly. We anticipate it would take 20 hours at $109.36/hr once for a computer programmer to place all required information on one page and ensure the use of clear and easy to understand labels on documents and links.

In aggregate for Medicaid for § 438.10(c)(3), we estimate a one-time State burden of 900 hours (45 States × 20 hr) at a cost of $98,424 (900 hr × $109.36/hr). As this would be a one-time requirement, we annualize our time and cost estimates to 300 hours and $32,808. In aggregate for CHIP for § 457.1207, we estimate a one-time State burden of 640 hours (32 States × 20 hr) at a cost of $69,990 (640 hr × $109.36/

[149] Methodology(ies) for allocation of expenditures as described at 45 CFR 158.170(b).

hr). As this would be a one-time requirement, we annualize our time and cost estimates to 213 hours and $23,294. The annualization divides our estimates by three (3) years to reflect OMB's likely approval period. We are annualizing the one-time burden estimates since we do not anticipate any additional burden after the 3-year approval period expires.

We also anticipate that it would take 40 hr at $109.36/hr for a computer programmer to periodically add and verify the function and content on the site at least quarterly (10 hours/quarter). In aggregate for Medicaid for we estimate an annual State burden of 1,800 hours (45 States × 40 hr) at a cost of $196,848 (1,800 hr × $109.36/hr). Due to the additional proposal to post summary enrollee experience survey results by separate CHIP managed care plan on the State's website, we estimate an additional 1 hour at $109.36/hr for a computer programmer to post these comparative data annually for a total of 41 hours. For CHIP, we estimate an annual State burden of 1,312 hours (32 States × 41 hr) at a cost of $143,480 (1,312 hr × $109.36/hr).

6. ICRs Regarding ILOS Contract and Supporting Documentation Requirements (§§ 438.16 and 457.1201)

The following proposed changes at § 438.16 will be submitted to OMB for review under control number 0938–TBD (CMS–10856). At this time the OMB control number has not been determined, but it will be assigned by OMB upon their clearance of our proposed collection of information request. The control number's expiration date will be issued by OMB upon their approval of our final rule's collection of information request. The following proposed changes to § 457.1201 will be submitted to OMB for review under control number 0938–1282 (CMS–10554).

The proposals at §§ 438.16 and 457.1201 would require States that provide ILOSs, with the exception of short term IMD stays, to comply with additional information collection requirements. 44 States utilize MCOs, PIHPs and PAHPs in Medicaid managed care programs. We do not have current data readily available on the number of States that utilize ILOSs and the types of ILOSs in Medicaid managed care. We believe it is a reasonable estimate to consider that half of the States with MCOs, PIHPs and PAHPs (22 States) may choose to provide non-IMD ILOSs. Similarly, for CHIP, we estimate that half of the States with MCOs, PIHPs, and PAHPS (16 States) provide ILOSs and would be subject to the additional information collection requirements.

The proposal at § 438.16(c)(4)(i) would require States to submit a projected ILOS cost percentage to CMS as part of the rate certification. The burden for this proposal is accounted for in ICR #2 (above) for § 438.7 Rate Certifications.

The proposal at § 438.16(c)(5)(ii) would require States to submit a final ILOS cost percentage and summary of actual MCO, PIHP and PAHP ILOS costs as a separate actuarial report concurrently with the rate certification. We anticipate that 22 States would need: 5 hours at $120.48/hr for an actuary, 5 hours at $109.36/hr for a computer programmer, and 7 hours at $77.28/hr for a business operations specialist. In aggregate, we estimate an annual State burden of 374 hours (17 hr × 22 States) at a cost of $37,184 (22 States × [(5 hr × $120.48/hr) + (5 hr × $109.36/hr) + (7 hr × $77.28/hr)]).

Proposals at §§ 438.16(d)(1) and 457.1201(e) would require States that elect to use ILOS to include additional documentation requirements in their managed care plan contracts. We anticipate that 22 States for Medicaid and 16 States for CHIP would need 1 hour at $77.28/hr for a business operations specialist to amend 327 Medicaid MCO, PIHP, and PAHP contracts and 100 CHIP contracts annually. In aggregate for Medicaid for § 438.16(d)(1), we estimate an annual State burden of 327 hours (327 contracts × 1 hr) at a cost of $25,271 (327 hr × $77.28/hr). In aggregate for CHIP for § 457.1201(e) we estimate an annual State burden of 100 hours (100 contracts × 1 hr) at a cost of $7,728 (100 hr × $77.28/hr).

Proposals at §§ 438.16(d)(2) and 457.1201(e) would require some States to provide to CMS additional documentation to describe the process and supporting data the State used to determine each ILOS to be a medically appropriate and cost-effective substitute. This additional documentation would be required for States with a projected ILOS cost percentage greater than 1.5 percent. We anticipate that approximately 5 States may be required to submit this additional documentation. We estimate it would take 2 hours at $77.28/hr for a business operations specialist to provide this documentation. In aggregate for Medicaid for § 438.16(d)(2), we estimate an annual State burden of 10 hours (5 States × 2 hr) at a cost of $773 (10 hr × $77.28/hr). In aggregate for CHIP for § 457.1201(e) we estimate the same annual State burden of 10 hours (5 States × 2 hr) at a cost of $773 (10 hr × $77.28/hr).

Proposals at §§ 438.16(e)(1) and 457.1201(e) would require States with a final ILOS cost percentage greater than 1.5 percent to submit an evaluation for ILOSs to CMS. We anticipate that approximately 5 States may be required to develop and submit an evaluation. We estimate it would take 25 hours at $77.28/hr for a business operations specialist. In aggregate for Medicaid for § 438.16(e)(1), we estimate an annual State burden of 125 hours (5 States × 25 hr) at a cost of $9,660 (125 hr × $77.28/hr). In aggregate for CHIP for § 457.1201(e), we estimate the same annual State burden of 125 hours (5 States × 25 hr) at a cost of $9,660 (125 hr × $77.28/hr).

An ILOS may be terminated by either a State, a managed care plan, or by CMS. Proposals as §§ 438.16(e)(2)(iii) and 457.1201(e) would require States to develop an ILOS transition of care policy. We believe all States with non-IMD ILOSs should proactively prepare a transition of care policy in case an ILOS is terminated. We estimate both a one-time burden and an annual burden for these proposals. We believe there is a higher one-time burden as all States that currently provide non-IMD ILOSs would need to comply with this proposed requirement by the applicability date, and an annual burden is estimated for States on an on-going basis. We estimate for a one-time burden, it would take: 2 hours at $109.36/hr for a computer programmer and 2 hours at $77.28/hr for a business and operations specialist for initial development of a transition of care policy. In aggregate for Medicaid for § 438.16(e)(2)(iii), we estimate a one-time State burden 88 hours (22 States × 4 hr) at a cost of $8,212 (22 States × [(2 hr × $109.36/hr) + (2 hr × $77.28/hr)]). As this would be a one-time requirement, we annualize our time and cost estimates to 30 hours and $2,799. In aggregate for CHIP for § 457.1201(e), we estimate a one-time State burden 64 hours (16 States × 4 hr) at a cost of $5,973 (16 States × [(2 hr × $109.36/hr) + (2 hr × $77.28/hr)]). As this would be a one-time requirement, we annualize our time and cost estimates to 21 hours and $1,991. The annualization divides our estimates by three (3) years to reflect OMB's likely approval period. We are annualizing the one-time burden estimates since we do not anticipate any additional burden after the 3-year approval period expires.

For updates to reflect specific ILOSs, we also estimate that this proposed ILOS transition of care policy would have an annual burden of 1 hour at $77.28/hr for a business operations specialist per State. In aggregate for

Medicaid for § 438.16(e)(2)(iii), we estimate an annual State burden of 22 hours (22 States × 1 hr) at a cost of $1,700 (22 hr × $77.28/hr). In aggregate for CHIP for § 457.1201(e), we estimate an annual State burden of 16 hours (16 States × 1 hr) at a cost of $1,237 (16 hr × $77.28/hr).

For MCOs, PIHPs, or PAHPs that would need to implement a transition policy when an ILOS is terminated, we estimate that on an annual basis, 20 percent of managed care plans (65 plans for Medicaid and 40 plans for CHIP) may need to implement this policy. We estimate an annual managed care plan burden of 2 hours at $77.28/hr for a business operations specialist to implement the policy. In aggregate for Medicaid for § 438.16(e)(2)(iii)(B) we estimate an annual burden of 130 hours (65 plans × 2 hr) at a cost of $10,046 (130 hr × $77.28/hr). In aggregate for CHIP for § 457.1201(e), we estimate an annual burden of 80 hours (40 plans × 2 hr) at a cost of $6,182 (80 hr × $77.28/hr).

7. ICRs Regarding State Monitoring Requirements (§ 438.66)

The following proposed changes will be submitted to OMB for review under control number 0938–TBD (CMS–10856). At this time the OMB control number has not been determined, but it will be assigned by OMB upon their clearance of our proposed collection of information request. The control number's expiration date will be issued by OMB upon their approval of our final rule's collection of information request.

The proposed amendments to § 438.66(c) would require States to conduct, or contract for, an enrollee experience survey annually. We believe most, if not all, States will use a contractor for this task and base our burden estimates on that assumption. In the first year, for procurement, contract implementation and management, and analysis of results, we estimate 85 hours at $77.28/hr for a business operations specialist and 25 hours at $110.82/hr for general operations manager. In aggregate for § 438.66(c), we estimate a one-time State burden of 5,390 hours (49 States × 110 hr) at a cost of $457,626 (49 States × [(85 hr × $77.28/hr) + (25 hr × $110.20)]). As this would be a one-time requirement, we annualize our time and cost estimates to 1,796 hours and $152,542. The annualization divides our estimates by three (3) years to reflect OMB's likely approval period. We are annualizing the one-time burden estimates since we do not anticipate any additional burden after the 3-year approval period expires.

In subsequent years, for contract management and analysis of experience survey results, we estimate 50 hours at $77.28/hr for a business operations specialist and 15 hours at $110.82/hr for general operations manager. In aggregate, we estimate an annual State burden of 3,185 hr (49 States × 65 hr) at a cost of $270,789 (49 States × [(50 hr × $77.28/hr) + (15 hr × $110.20/hr)]).

Amendments to § 438.66(e)(1) and (2) would require that States submit an annual program assessment report to CMS covering the topics listed in § 438.66(e)(2). The data collected for § 438.66(b) and the utilization of the data in § 438.66(c), including reporting as proposed in § 438.16, would be used to complete the report. We anticipate it would take 80 hours at $77.28/hr for a business operations specialist to compile and submit this report to CMS. In aggregate, we estimate an annual State burden of 3,920 hours (49 States × 80 hr) at a cost of $302,938 (3,920 hr × $77.28/hr).

8. ICRs Regarding Network Adequacy Standards (§§ 438.68 and 457.1218)

The following proposed changes to § 438.66 will be submitted to OMB for review under control number 0938–TBD (CMS–10856). At this time the OMB control number has not been determined, but it will be assigned by OMB upon their clearance of our proposed collection of information request. The control number's expiration date will be issued by OMB upon their approval of our final rule's collection of information request. The following proposed changes to § 457.1218 will be submitted to OMB for review under control number 0938–1282 (CMS–10554).

Sections 438.68(e) and 457.1218 would require States with MCO, PIHP, and PAHPs to develop appointment wait time standards for four provider types. We anticipate it would take: 20 hours at $77.28/hr for a business operations specialist for development and 10 hours at $77.28/hr a business operations specialist for ongoing enforcement of all network adequacy standards. In aggregate for Medicaid for § 438.68(e), we estimate a one-time State burden of 880 hours (44 States × 20 hr) at a cost of $68,006 (880 hr × $77.28/hr) and an annual State burden of 440 hours (44 States × 10 hr) at a cost of $34,003 (440 hr × $77.28/hr).

In aggregate for CHIP for § 457.1218, we estimate a one-time State burden of 640 hours (32 States × 20 hr) at a cost of $49,459 (640 hr × $77.28/hr) and an annual State burden of 320 hours (32 States × 10 hr) at a cost of $24,730 (320 hr × $77.28/hr). As this would be a one-time requirement, we annualize our time and cost estimates to 320 hours and $24,729. The annualization divides our estimates by three (3) years to reflect OMB's likely approval period. We are annualizing the one-time burden estimates since we do not anticipate any additional burden after the 3-year approval period expires.

Amendments to §§ 438.68(f) and 457.1218 would require States with MCO, PIHPs, or PAHPs to contract with an independent vendor to perform secret shopper surveys of plan compliance with appointment wait times and accuracy of provider directories and send directory inaccuracies to the State within three days of discovery. In the first year, for procurement, contract implementation, and management, we anticipate it would take: 85 hours at $77.28/hr for a business operations specialist and 25 hours at $110.82/hr for general operations manager. In aggregate for Medicaid for § 438.68(f), we estimate a one-time State burden of 4,840 hours (44 States × 110 hr) at a cost of $410,929 (44 States × [(85 hr × $77.28/hr) + (25 hr × $110.82/hr)]). As this would be a one-time requirement, we annualize our time and cost estimates to 1,614 hours and $136,976. In aggregate for CHIP for § 457.1218, we estimate a one-time State burden of 3,520 hours (32 States × 110 hr) at a cost of $298,858 (32 States × [(85 hr × $77.28/hr) + (25 hr × $110.82/hr)]). As this would be a one-time requirement, we annualize our time and cost estimates to 1441 hours and $129,228. The annualization divides our estimates by three (3) years to reflect OMB's likely approval period. We are annualizing the one-time burden estimates since we do not anticipate any additional burden after the 3-year approval period expires.

In subsequent years, for contract management and analysis of results, we anticipate it would take 50 hours at $77.28/hr for a business operations specialist and 15 hours at $110.82/hr for general operations manager. In aggregate for Medicaid for § 438.68(c), we estimate an annual State burden of 2,860 hours (44 States × 65 hr) at a cost of $243,157 (44 States × [(50 hr × $77.28/hr) + (15 hr × $110.82)]).

In aggregate for CHIP for § 457.1218 we estimate an annual State burden of 2,080 hours (32 States × 65 hr) at a cost of $176,842 (32 States × [(50 hr × $77.28/hr) + (15 hr × $110.82/hr)]).

9. ICRs Regarding Assurance of Adequate Capacity and Services (§§ 438.207 and 457.1230)

The following proposed changes to § 438.207 will be submitted to OMB for

review under control number 0938–TBD (CMS–10856). At this time the OMB control number has not been determined, but it will be assigned by OMB upon their clearance of our proposed collection of information request. The control number's expiration date will be issued by OMB upon their approval of our final rule's collection of information request. The following proposed changes to § 457.1230 will be submitted to OMB for review under control number 0938–1282 (CMS–10554).

The proposed amendments to §§ 438.207(b) and 457.1230(b) would require MCOs, PIHPs, and PAHPs to submit documentation to the State of their compliance with § 438.207(a). As we propose in this rule to add a reimbursement analysis at § 438.207(b)(3) (and at § 457.1230(b) for separate CHIP), we estimate a one-time plan burden of: 50 hours at $77.28/hr for a business operations specialist, 20 hours at $110.82/hr for a general operations manager, and 80 hours at $109.36/hr for a computer programmer. In aggregate for Medicaid for § 438.207(b), we estimate a one-time private sector burden of 94,350 hours (629 MCO, PIHPs, and PAHPs × 150 hr) at a cost of $9,327,567 (629 MCOs, PIHPs, and PAHPs × [(50 hr × $77.28/hr) + (20 hr × $110.20/hr) + (80 hr × $109.36/hr)]). As this would be a one-time requirement, we annualize our time and cost estimates to 31,450 hours and $3,460,800. The annualization divides our estimates by three (3) years to reflect OMB's likely approval period. We are annualizing the one-time burden estimates since we do not anticipate any additional burden after the 3-year approval period expires.

In aggregate for CHIP for § 457.1230(b), we estimate a one-time private sector burden of 29,850 hours (199 MCO, PIHPs, and PAHPs × 150 hr) at a cost of $2,948,543 (199 MCOs, PIHPs, and PAHPs × [(50 hr × $77.28/hr) + (20 hr × $110.20/hr) + (80 hr × $109.36/hr)]). As this would be a one-time requirement, we annualize our time and cost estimates to 9,950 hours and $982,848. The annualization divides our estimates by three (3) years to reflect OMB's likely approval period. We are annualizing the one-time burden estimates since we do not anticipate any additional burden after the 3-year approval period expires.

For ongoing analyses and submission of information that would be required by amendments to § 438.207(b), we estimate it would take: 20 hours at $77.28/hr for a business operations specialist, 5 hours at $110.82/hr for a general operations manager, and 20 hours at $109.36/hr for a computer programmer. In aggregate for Medicaid, we estimate a one-time private sector burden of 28,305 hours (629 MCO, PIHPs, and PAHPs × 45 hr) at a cost of $2,696,460 (629 MCO, PIHPs, and PAHPs × [(20 hr × $77.28/hr) + (5 hr × $110.20/hr) + (20 hr × $109.36/hr)]).

In aggregate for CHIP, we estimate a one-time private sector burden of 8,955 hours (199 MCO, PIHPs, and PAHPs × 45 hr) at a cost of $852,476 (199 MCO, PIHPs, and PAHPs × [(20 hr × $77.28/hr) + (5 hr × $110.20/hr) + (20 hr × $109.36/hr)]).

Amendments to §§ 438.207(d) and 457.1230(b) would require States to submit an assurance of compliance to CMS that their MCOs, PIHPs, and PAHPs meet the State's requirements for availability of services. The submission to CMS must include documentation of an analysis by the State that supports the assurance of the adequacy of the network for each contracted MCO, PIHP or PAHP and the accessibility of covered services. Including the proposals in this rule at § 438.68(f) and § 438.208(b)(3), we anticipate it would take 40 hours at $77.28/hr for a business operations specialist. Although States may need to submit a revision to this report at other times during a year (specified at § 438.207(c)), we believe these submissions will be infrequent and require minimal updating to the template; therefore, the burden estimated here in inclusive of occasional revisions. In aggregate for Medicaid, we estimate an annual State burden of 1,760 hours (44 States × 40 hr) at a cost of $136,013 (1,760 hr × $77.28/hr).

Due to the additional proposal to include enrollee experience survey results in the State's separate CHIP analysis of network adequacy, we anticipate an additional 4 hours at $77.28/hr for a business operations specialist to analyze these data for a total of 44 hours annually. In aggregate for CHIP, we estimate an annual State burden of 1,408 hours (32 States x 44 hr) at a cost of $108,810 (1,408 hr × $77.28/hr).

10. ICRs Regarding External Quality Review Results (§§ 438.364 and 457.1250)

The following proposed changes to § 438.364 will be submitted to OMB under control number 0938–0786 (CMS–R–305), and the proposed changes to § 457.1250 will be submitted to OMB for review under control number 0938–1282 (CMS–10554).

Amendments to § 438.360(a)(1) would remove the requirement that plan accreditation must be from a private accrediting organization recognized by CMS as applying standards at least as stringent as Medicare under the procedures in § 422.158. Eliminating this requirement would simplify the plan accreditation process. We assume that States would apply the non-duplication provision to 10 percent of MCOs, PIHPs, and PAHPs, we anticipate that this provision would offset the burden associated with § 438.358(b)(1)(i) through (iii) for 65 MCOs, PIHPs, and PAHPs (since these activities will no longer be necessary for these 65 plans). Consistent with the estimates used in § 438.358(b)(1)(i) through (iii), we estimate an aggregated offset of annual State burden of minus 26,606 hours [(−65 MCOs, PIHPs × 409.33 hr)] and minus $2,056,146 (−26,606.45 hr × $77.28/hr).

The proposed amendments to § 438.364(a)(2)(iii) for Medicaid, and through an existing cross-reference at § 457.1250(a) for separate CHIP, would (1) require that the EQR technical reports include ''any outcomes data and results from quantitative assessments'' for the applicable EQR activities in addition to whether or not the data has been validated, and (2) add the mandatory network adequacy validation activity to the types of EQR activities to which the requirement to include data in the EQR technical report applies. For Medicaid § 438.364, we assume 44 States and 654 MCOs, PIHPs and PAHPs will be subject to the EQR provisions. For CHIP, we assume 32 States and 199 MCOs, PIHPs and PAHPs will be subject to the proposed EQR provisions.

We estimate it would take 1 hour at $77.28/hr for a business operations specialist to describe the data and results from quantitative assessments and 30 minutes at $37.96/hr for an office clerk to collect and organize data. In aggregate for Medicaid we estimate an annual State burden of 981 hours (654 MCOs, PIHPs, and PAHPs yearly reports × 1.5 hr) at a cost of $62,954 (654 reports × [(1 hr × $77.28/hr) + (0.5 hr × $37.96/hr)]). In aggregate for CHIP for § 457.1250(a), we estimate an annual State burden of 299 hours (199 MCOs, PIHPs, and PAHPs yearly reports × 1.5 hr) at a cost of $19,156 (199 reports × [(1 hr × $77.28/hr) + (0.5 hr × $37.96/hr)]).

Amendments to § 438.364(c)(1) for Medicaid, and through an existing cross-reference at § 457.1250(a) for separate CHIP, shifts the date in which States must finalize their annual EQR technical report. Previously, EQR annual reports had to be posted by April 30th, but under this new provision, EQR technical reports must be posted on the website required under §§ 438.10(c)(3)

and 457.1207 by December 31st of each year. We estimate it would take 1 hour at $77.28/hr for a business operations specialist and 30 minutes at $110.82/hr a general operations manager to amend vendor contracts to reflect the new reporting date. In aggregate for Medicaid, we estimate an annual State burden of 981 hours (654 MCOs, PIHPs, and PAHPs yearly reports × 1.5 hr) at a cost of $86,779 (654 contracts [(1 hr × $77.28/hr) + (0.5 hr × $110.82/hr)]). In aggregate for CHIP, we estimate an annual State burden of 299 hours (199 MCOs, PIHPs, and PAHPs yearly reports × 1.5 hr) and $26,405 (199 contracts [(1 hr × $77.28/hr) + (0.5 hr × $110.82/hr)]). Amendments to § 438.364(c)(2)(i) for Medicaid, and through an existing cross-reference at § 457.1250(a) for separate CHIP, would require States to notify CMS within 14 calendar days of posting their EQR technical reports on their quality website and provide CMS with a link to the report. Previously States were not required to notify CMS when reports were posted. We estimate it would take 30 minutes at $77.28/hr for a business operations specialist to notify CMS of the posted reports. In aggregate for Medicaid we estimate an annual State burden of 22 hours (44 States × 0.5 hr) at a cost of $1,700 (22 hr × $77.28/hr). In aggregate for CHIP, we estimate an annual State burden of 16 hours (32 States × 0.5 hr) at a cost of $1,236 (16 hr × $77.28/hr).

Amendments to § 438.364(c)(2)(iii) for Medicaid, and through an existing cross-reference at § 457.1250(a) for separate CHIP, would require States to maintain an archive of at least the previous 5 years of EQR technical reports on their websites. Currently, almost half of States maintain an archive of at least 2 years' worth of EQR reports. Initially, we assume 75 percent of reports completed within the previous 5 years need to be archived on State websites. We estimate it would take 5 minutes (0.0833 hr) at $77.28/hr for a business operations specialist to collect and post a single EQR technical report to a State website. In aggregate for Medicaid for § 438.364(c)(2)(iii), we estimate a one-time burden of 204 hours (654 MCOs, PIHPs, and PAHPs yearly reports × 0.75 × 5 years × 0.0833 hr) at a cost of $15,765 (204 hr × $77.28/hr). As this will be a one-time requirement, we annualize our time and cost estimates to 68 hours and $5,255. In aggregate for CHIP for § 457.1250(a), we estimate a one-time burden of 62 hours [(199 MCOs, PIHPs, and PAHPs yearly reports × 0.75 × 5 years × 0.0833 hr) at a cost of $4,791 (62 hr × $77.28/hr). As this would be a one-time requirement, we annualize our time and cost estimates to 21 hours and $1,597. The annualization divides our estimates by three (3) years to reflect OMB's likely approval period. We are annualizing the one-time burden estimates since we do not anticipate any additional burden after the 3-year approval period expires.

11. ICRs Regarding Requirements for PCCMs (§§ 438.310(c)(2), 438.350, and 457.1250)

The following proposed changes will be submitted to OMB for review under control number 0938–0786 (CMS–R–305). The following proposed changes to § 457.1250 will be submitted to OMB for review under control number 0938–1282 (CMS–10554).

The proposed amendments to §§ 438.310(c)(2), 438.350, and 457.1250(a) would remove PCCMs from the managed care entities subject to EQR. We estimate the burden on States of completing EQR mandatory and optional activities which include:

Mandatory EQR activities include the validation of performance measures and a compliance review. We assume States validate 3 performance measures each year and conduct a compliance review once every 3 years. We expect it would take 53 hours at $77.28/hr for a business operations specialist to complete each performance measure validation and 361 hours at $77.28/hr for a business operations specialist to conduct a compliance review. Alleviating this burden would result in an annual State Medicaid savings of minus 2,793 hours (10 PCCM entities × [(53 hr/validation × 3 performance measure validations) + (361 hr/3 years compliance review)]) and minus $215,843 (− 2,793 hr × $77.28/hr). For CHIP for § 457.1250(a), we estimate an annual State savings of minus 4,749 hours (17 PCCM entities × [(53 hr/validation × 3 performance measure validations) + (361 hr/3 years compliance review)]) and minus $367,003 (−4,749 hr × $77.28/hr).

Optional EQR activities include: (1) validation of client level data (such as claims and encounters); (2) administration or validation of consumer or provider surveys; (3) calculation of performance measures; (4) conduct of PIPs; (5) conduct of focused studies; and (6) assist with the quality rating of MCOs, PIHPs, and PAHPs consistent with §§ 438.334 and 457.1240(d). Based on our review of recent EQR technical report submissions we estimate and assume that each year 10 percent of PCCM entities would be subject to each of the optional EQR-related activities. Regarding the administration or validation of consumer or provider surveys, we assume that half would administer surveys while half (29) would validate surveys. We also estimate that a mix of professionals would work on each optional EQR-related activity: 20 percent by a general and operations manager at $110.82/hr; 25 percent by a computer programmer at $92.92/hr; and 55 percent by a business operations specialist at $77.28/hr. Alleviating this burden would result in an annual State Medicaid savings of minus 999 hours (−350+−75 hr + −25 hr + −159 hr + −195 hr + −195 hr) and minus $87,810 [(−999 hr × 0.20 × $110.82/hr) + (−999 hr × 0.25 × $92.92/hr) + (−999 hr × 0.55 × $77.28/hr)]. For CHIP, we estimate annual State savings of minus 649 hours (−75 hr + −25 hr + −159 hr + −195 hr + −195 hr) and minus $57,045.80 [(−649 hr × 0.20 × $110.82/hr) + (−649 hr × 0.25 × $92.92/hr) + (−649 hr × 0.55 × $77.28/hr)].

Per § 438.364(c)(2)(ii), each State agency would provide copies of technical reports, upon request, to interested parties such as participating health care providers, enrollees and potential enrollees of the MCO, PIHP, or PAHP, beneficiary advocacy groups, and members of the general public. This change would eliminate the burden on States to provide PCCM EQR reports. We estimate an annual State burden of 5 minutes (on average) or 0.0833 hours at $37.96/hr for an office clerk to disclose the reports (per request), and that a State would receive five requests per PCCM entity. Alleviating this burden would result in an annual Medicaid State savings of minus 4 hours (10 PCCM entities × 5 requests × 0.0833 hr) and minus $152 (−4 hr × $37.96/hr). For CHIP for § 457.1250(a), we estimate an annual State savings of minus 0.833 hours (50 minutes) (2 PCCM entities × 5 requests × 0.833 hr) and minus $32 (−0.833 hr × $37.96/hr).

For the mandatory and optional EQR activities, in aggregate, we estimate an annual State savings of minus 3,796 hours (−2,793 hr + −999 hr + −4 hr) and minus $303,805 ($215,843 + $87,810 + $152).

Additionally, the burden associated with § 438.358(b)(2) also includes the time for a PCCM entity (described in § 438.310(c)(2)) to prepare the information necessary for the State to conduct the mandatory EQR-related activities. Given the estimate of 200 hr for an MCO, PIHP, or PAHP, and that there are only 2 mandatory EQR-related activities for PCCM entities (described in § 438.310(c)(2)), we estimate it would take 100 hr to prepare the documentation for these 2 activities, half (50 hr) at $77.28/hr by a business operations specialist and half (50 hr) at

$37.96/hr by an office clerk. In aggregate for Medicaid, we estimate an annual private sector savings of minus 1,000 hours (10 PCCM entities × 100 hr) and minus $57,620 [(− 500 hr × $77.28/hr) + (− 500 hr × $37.96/hr)]. In aggregate for CHIP for § 457.1250(a), we estimate an annual private sector savings of minus 200 hours (2 PCCM entities × 100 hr) and minus $11,524 [(− 100 hr × $77.28/hr) + (− 100 hr × $37.96/hr)].

Amendments to §§ 438.364(c)(7) and 457.1250(a) add a new optional EQR activity to assist in evaluations for In Lieu of Services, quality strategies and State Directed Payments that pertain to outcomes, quality, or access to health care services. Based on our review of recent EQR technical report submissions we estimate and assume that each year 10 percent of MCOs, PIHPs and PAHPs will be subject to each of the optional EQR-related activities, though we note that the exact States and number vary from year to year. We also estimate that a mix of professionals will work on each optional EQR-related activity: 20 percent by a general and operations manager at $110.82/hr; 25 percent by a computer programmer at $109.36/hr; and 55 percent by a business operations specialist at $77.28/hr. To assist in evaluations, we estimate an annual State burden of 80 hours per MCO, PIHP and PAHP. In aggregate for Medicaid, the annual State burden to assist in evaluations is 4,640 hours (58 MCOs, PIHPs and PAHPs × 80 hr) at a cost of $426,917 [(4,640 hr × 0.20 × $110.82/hr) + (4,640 hr × 0.25 × $103.36/hr) + (4,640 hr × 0.55 × $77.28/hr)]. In aggregate for CHIP for § 457.1250(a), the annual State burden to assist in evaluations is 1,600 hours (20 MCOs, PIHPs and PAHPs × 80 hr) at a cost of $147,213 [(1,600 hr × 0.20 × $110.82/hr) + (1,600 hr × 0.25 × $109.36/hr) + (1,600 hr × 0.55 × $77.28/hr)].

12. ICRs Regarding Quality Rating System Measure Collection (§§ 438.515 and 457.1240)

The following proposed changes will be submitted to OMB for review under control number 0938–1281 (CMS–10553). The following proposed changes to § 457.1240 will be submitted to OMB for review under control number 0938–1282 (CMS–10554).

The proposed amendments to §§ 438.515(a)(1) and 457.1240(d) would revise the existing QRS requirements by mandating that the State collect specified data from each managed care plan with which it contracts that has 500 or more enrollees on July 1 of the measurement year. Based on the data collected, the State would calculate and issue an annual quality rating to each managed care plan. The State would also collect data from Medicare and the State's fee-for-service providers, if all data necessary to issue an annual quality rating cannot be provided by the managed care plans. Annual quality ratings will serve as a tool for States, plans and beneficiaries. The annual quality ratings will hold States and plans accountable for the care provided to Medicaid and CHIP beneficiaries, provide a tool for States to drive improvements in plan performance and the quality of care provided by their programs, and empower beneficiaries with useful information about the plans available to them. States would be required to collect data using the framework of a mandatory QRS Measure Set. We used the proposed mandatory measure set, found in Table 1, as the basis for the measure collection burden estimate. The proposed mandatory measure set consists of 18 measures, including CAHPS survey measures, and reflects a wide range of preventive and chronic care measures representative of Medicaid and CHIP beneficiaries. For Medicaid managed care, we assume 629 MCOs, PIHPs and PAHPs and 44 States to be subject to the proposed mandatory QRS measure set collection and reporting provision. For CHIP managed care, we assume 199 MCOs, PIHPs and PAHPs and 32 States to be subject to the proposed mandatory QRS measure set collection and reporting provision. We assume that plans with CHIP populations will report the subset of QRS measures which apply to beneficiaries under 19 years of age and to pregnant and postpartum adults, where applicable.

For Medicaid, we expect reporting the QRS non-survey measures would take: 680 hours at $109.36/hr for a computer programmer to program and synthesize the data; 212 hours at $77.28/hr for a business operations specialist to manage the data collection process; 232 hours at $37.96/hr for an office clerk to input the data; 300 hours at $79.56/hr for a registered nurse to review medical records for data collection; and 300 hours at $46.46/hr for medical records and health information analyst to compile and process medical records. For Medicaid, for one managed care entity we estimate an annual private sector burden of 1,724 hours (680 hr + 212 hr + 232 hr + 300 hr + 300 hr) at cost of $137,361 ([680 hr × $109.36/hr] + [252 hr × $77.28/hr] + [328 hr x $37.96/hr] + [300 hr × $79.56/hr] + [300 hr × $46.46/hr]).

For Medicaid, we also estimate that conducting the QRS survey measures comprised of the CAHPS survey would take: 20 hours at $77.28/hr for a business operations specialist to manage the data collection process; 40 hours at $37.96/hr for an office clerk to input the data; and 32 hours at $95.62/hr for a statistician to conduct data sampling. For one Medicaid managed care entity we estimate an annual private sector burden of 92 hours (20 hr + 40 hr + 32 hr) at cost of $6,124 ([20 hr × $77.28/hr] + [40 hr × $37.96/hr] + [32 hr × $95.62]).

For one Medicaid managed care entity, for mandatory QRS non-survey and survey measures we estimate an annual private sector burden of 1,816 hours (1,724 hr +92 hr) at a cost of $143,485 ($137,361 + $6,124). In aggregate, for Medicaid, we estimate an annual private sector burden of 1,142,264 hours (629 Medicaid MCOs, PIHPs and PAHPs × 1,816 hours) and $90,252,065 (629 Medicaid MCOs, PIHPs and PAHPs × $143,485).

For CHIP for § 457.1240(d), we expect reporting non-survey QRS measures would take: 400 hours at $109.36/hr for a computer programmer to program and synthesize the data; 148 hours at $77.28/hr for a business operations specialist to manage the data collection process; 152 hours at $37.96/hr for an office clerk to input the data; 60 hours at $79.56/hr for a registered nurse to review medical records for data collection; and 60 hours at $46.46/hr for medical records specialist to compile and process medical records. For one CHIP managed care entity we estimate an annual private sector burden of 820 hours (400 hr + 148 hr + 152 hr + 60 hr +60 hr) at cost of $68,513 ([400 hr × $109.36/hr] + [148 hr × $77.28/hr] + [152 hr × $37.96/hr] + [60 hr × $79.56/hr] + [60 hr × $46.46/hr])

For CHIP for § 457.1240(d), we also estimate that conducting the survey measures (comprised of the CAHPS survey and secret shopper) would take: 20 hours at $77.28/hr for a business operations specialist to manage the data collection process; 56 hours at $37.96/hr for an office clerk to input the data; and 32 hours at $95.62/hr for a statistician to conduct data sampling. For one CHIP managed care entity we estimate an annual private sector burden of 108 hours (20 hr + 56 hr + 32 hr) at cost of $6,731 ([20 hr × $77.28/hr] + [56 hr × $37.96/hr] + [32 hr × $95.62]).

For one CHIP managed care entity, for mandatory QRS non-survey and survey measures, we estimate an annual private sector burden of 928 hours (820 hr +108 hr) at a cost of $75,244 ($68,513 + $6,731). In aggregate, for CHIP for § 457.1240(d), we estimate an annual private sector burden of 184,672 hours (199 CHIP MCOs, PIHPs and PAHPs × 928 hours) and $14,973,556 (199 CHIP MCOs, PIHPs and PAHPs × $75,244).

The CAHPS survey measures also include a new burden on Medicaid beneficiaries. Beneficiaries complete the survey via telephone or mail. Response rates vary slightly by survey population. The adult CAHPS survey aims for 411 respondents out of a 1,350-person sampling and the Child CAHPS survey aims for 411 respondents out of a 1,650-person sampling. For Medicaid, the survey would be conducted twice, once for children and once for adults. For CHIP, the survey would be conducted once for children and once for pregnant or postpartum adults, as applicable. We estimate it would take 20 minutes (0.33 hr) at $28.01/hr for a Medicaid or CHIP beneficiary to complete the CAHPS Health Plan Survey. For Medicaid, in aggregate, we estimate a new beneficiary burden of 172,346 hours (629 MCOs, PIHPs and PAHPs × 0.33 hr per survey response × 822 beneficiary responses) at a cost of $4,827,411 (172,346 hr × $28.01/hr). For CHIP for § 457.1240(d), in aggregate, we estimate a new beneficiary burden of 27,263 hours (199 MCOs, PIHPs, and PAHPs × 0.33 hr per survey response × 411 beneficiary responses) at a cost of $763,637 (27,263 hr × $28.01/hr).

Additionally, amendments to § 438.515(a)(1)(i), reporting QRS measures would require States to update existing managed care contracts. We estimate it would take 1 hour at $77.28/hr for a business operations specialist and 30 minutes at $110.82/hr a general operations manager to amend vendor contracts to reflect the new reporting requirements. In aggregate for Medicaid, we estimate a one-time State burden of 944 hours (629 MCOs, PIHPs, and PAHPs × 1.5 hours) at a cost of $83,462 (629 contracts × [(1 hr × $77.28/hr) + (0.5 hr × $110.82/hr)]). As this would be a one-time requirement, we annualize our time and cost estimates to 315 hours and $27,821. The annualization divides our estimates by three (3) years to reflect OMB's likely approval period. We are annualizing the one-time burden estimates since we do not anticipate any additional burden after the 3-year approval period expires. In aggregate for CHIP for § 457.1240(d), we estimate a one-time State burden of 299 hours (199 MCOs, PIHPs, and PAHPs × 1.5 hours) at a cost of $26,405 (199 contracts × [(1 hr × $77.28/hr) + (0.5 hr × $110.82/hr)]). As this would be a one-time requirement, we annualize our time and cost estimates to 99 hours and $8,820. The annualization divides our estimates by three (3) years to reflect OMB's likely approval period. We are annualizing the one-time burden estimates since we do not anticipate any additional burden after the 3-year approval period expires.

Amendments to § 438.515(a)(1)(ii) require States to collect data from Medicare and the State's fee-for-service providers, if all data necessary to issue an annual quality rating cannot be provided by the managed care plans and the data are available for collection by the State without undue burden. We expect a that subset of States would need to collect Medicare data or State Medicaid fee-for-service data to report the mandatory quality measures. We assume that plans have access to Medicare data for their members and have included this burden in the cost of data collection described above. However, we assume Medicaid fee-for-service data would need to be provided and that this requirement would impact 5 States. For a State to collect the fee-for-service data needed for QRS reporting, we expect it would take: 120 hours at $109.36/hr for a computer programmer to program and synthesize the data and 20 hours at $77.28/hr for a business operations specialist to manage the data collection process. In aggregate for Medicaid, we estimate an annual State burden of 700 hours (5 States × [120 hr + 20 hr]) at a cost of $73,344 ([120 hr × $109.36/hr] + [20 hr × $77.28/hr]).

Amendments to §§ 438.515(a)(2) and 457.1240(d) require the QRS measure data to be validated. We estimate it would take 16 hours at $77.28/hr for a business operations specialist to review, analyze and validate measure data. In aggregate for Medicaid, we estimate an annual private sector burden of 10,064 hours (629 MCOs, PIHPs, PAHPs and PCCMs × 16 hr) at a cost of $777,746 (10,064 hr × $77.28/hr). In aggregate for CHIP for § 457.1240(d), we estimate an annual private sector burden of 3,184 hours (199 MCOs, PIHPs and PAHPs × 16 hr) at a cost of $246,060 (3,184 hr × $77.28/hr).

13. ICRs Regarding Requirements for QRS Website Display (§§ 438.520(a) and 457.1240)

The following proposed changes will be submitted to OMB for review under control number 0938–1281 (CMS–10553). The following proposed changes to § 457.1240 will be submitted to OMB for review under control number 0938–1282 (CMS–10554).

The proposed amendments to §§ 438.520(a) and 457.1240(d) would require the State to prominently post an up-to-date display on its website that provides information on available MCOs, PIHPs and PAHPs. The display must: allow users to view tailored information, compare managed care plans, provide information on quality ratings and directs users to resources on how to enroll in a Medicaid or CHIP plan. Additionally, the display must offer consumer live assistance services. After the display is established, the State would need to maintain the display by populating the display with data collected from the mandatory QRS measure set established as proposed in this proposed rule. The proposed rule outlines a phase-in approach to the QRS website display requirements; however, the burden estimate reflects the full implementation of the website. We recognize this may results is an overestimate during the initial phase of the website display but believe the estimate is representative of the longer-term burden associated with the QRS website display requirements.

To develop the initial display, we estimate it would take: 600 hours at $109.36/hr for a computer programmer to create and test code; 600 hours at $78.18/hr for a web developer to create the user interface; 80 hours at $77.28/hr for a business operations specialist to manage the display technical development process; and 450 hours at $98.50/hr for a database administer to establish the data structure and organization. We estimate that 44 States for Medicaid and 32 States for CHIP will develop QRS website displays. For one State, we estimate a burden of 1,730 hours (600 hr + 600 hr + 80 hr + 450 hr) at a cost of $163,031 ([600 hr × $109.36/hr] + [600 hr × $78.18/hr] + [80 hr × $77.28/hr] + [450 hr × $98.50/hr]). In aggregate for Medicaid, we estimate a one-time State burden of 76,120 hours (44 States × 1,730 hr) at a cost of $7,173,364 (44 States × $163,031). In aggregate for CHIP for § 457.1240(d), we estimate a one-time State burden of 55,360 hours (32 States × 1,730 hr) and $5,216,992 (32 States × $163,031). As this would be a one-time requirement, we annualize our time and cost estimates for CHIP to 18,453 hours and $48,330,202. The annualization divides our estimates by three (3) years to reflect OMB's likely approval period. We are annualizing the one-time burden estimates since we do not anticipate any additional burden after the 3-year approval period expires.

To maintain the QRS display annually, we estimate it would take: 384 hours at $109.36/hr for a computer programmer to modify and test code; 256 hours at $78.18/hr to update and maintain the user interface; 120 hours at $77.28/hr for a business operations specialist to manage the daily operations of the display; and 384 hours at $98.50/hr for a database administer to organize data. We estimate that 44

States for Medicaid and 32 States for CHIP will maintain QRS displays annually. For one State, we estimate a burden of 1,144 hours (384 hr + 256 hr + 120 hr + 384 hr) at a cost of $109,106 ([384 hr × $92.92/hr] + [256 hr × $78.18/hr] + [120 hr × $77.28/hr] + [384 hr × $98.50/hr]). In aggregate for Medicaid, we estimate an annual State burden of 50,336 hours (1,144 hours × 44 States) at a cost of $4,800,664 ($109,106 × 44 States). In aggregate for CHIP for § 457.1240(d), we estimate an annual State burden of 103,168 hours (1,144 hr × 32 States) at a cost of $3,491,392 ($109,106 × 32 States).

The amendments to §§ 438.520(a)(2)(iv) and 457.1240(d) would require the display to include quality ratings for mandatory measures which may be stratified by factors determined by CMS. We estimate it would take 24 hours at $109.36/hr for a computer programmer to develop code to stratify plan data. In aggregate for Medicaid (§ 438.520(a)(2)(iv)), we estimate an annual private sector burden of 15,096 hours (629 MCOs, PIHPs and PAHPs × 24 hr) at a cost of $1,650,899 (15,096 hr × $109.36/hr). In aggregate for CHIP for § 457.1240(d), we estimate an annual private sector burden of 4,776 hours (199 MCOs, PIHPs and PAHPs × 24 hr) at a cost of $522,303 (4,776 hr × $109.36/hr).

The amendments to § 438.520(a)(3)(v) would require the QRS website display to include certain managed care plan performance metrics, as specified by CMS including the results of the secret shopper survey specified in § 438.68(f). The secret shopper survey is currently accounted for by OMB under control number 0938–TBD (CMS–10856). Plans would complete the secret shopper independent of the QRS requirements. To meet QRS requirements, States would enter data collected from the secret shopper survey and display the results of the survey on the QRS. Since the burden for the secret shopper survey is accounted for under a separate control number, for the purposes of MAC QRS, we account for the incremental burden associated with meeting the QRS requirements. We estimate it would take 16 hours at $37.96/hr for an office clerk to enter the results from the secret shopper survey into the QRS. In aggregate for Medicaid § 438.520(a)(3)(v), we estimate an annual private sector burden of 10,064 hours (629 MCOs, PIHPs and PAHPs × 16 hr) at a cost of $382,029 (10,064 hr × $37.96/hr). In aggregate for CHIP for § 457.1240(d), we estimate an annual private sector burden of 3,184 hours (199 MCOs, PIHPs and PAHPs × 16 hr) at a cost of $120,865 (3,184 hr × $37.96/hr).

14. ICRs Regarding QRS Annual Reporting Requirements (Part 438 Subpart G and §§ 438.520(a) and 457.1240)

The following proposed changes will be submitted to OMB for review under control number 0938–1281 (CMS–10553). The following proposed changes to § 457.1240 will be submitted to OMB for review under control number 0938–1282 (CMS–10554).

The proposed amendments to §§ 438.535(a) and 457.1240(b) would mandate that on an annual basis, the State submit a Medicaid managed care quality rating system report in a form and manner determined by CMS. We estimate that 44 States for Medicaid and 32 States for CHIP will submit annual MAC QRS reports. We estimate it would take 24 hours at $77.28/hr for a business operations specialist to compile the required documentation to complete this report and attestation that the State is in compliance with QRS standards. In aggregate for Medicaid for § 438.535(a), we estimate an annual State burden of 1,056 hours (44 States × 24 hr) at a cost of $81,608 (1,056 hr × $77.28/hr). In aggregate for CHIP for § 457.1240(b), we estimate an annual State burden of 768 hours (32 States × 24 hr) at a cost of $59,351 (768 hr × $77.28/hr).

The addition of 438 subpart G for Medicaid, and through a proposed amendment at § 457.1240(d) for separate CHIP, would revise the quality rating system requirements and associated burden previously promulgated under § 438.334. Given the QRS requirements have substantively changed, our currently approved burden estimates for making changes to an approved alternative Medicaid managed care QRS are no longer applicable.

Therefore, alleviating this burden would result in an annual Medicaid State reduction of minus 116.7 hours [(10 States × 35 hr)/3 years] and minus $8,361 (10 States × [(5 hr × $37.96/hr) + (30 × $77.28/hr)]/3 years). Similarly, we estimate an annual CHIP State savings of minus 116.7 hours [(10 States × 35 hr)/3 years] and minus $8,361 [(10 States × ((5 hr × $37.96/hr) + (30 × $77.28/hr))/3 years)].

To implement an alternative Medicaid managed care QRS, we estimate it would take: 5 hours at $37.96/hr for an office and administrative support worker, 25 hours at $77.28/hr for a business operations specialist to complete the public comment process, and 5 additional hours at $77.28/hr for a business operations specialist to seek and receive approval from CMS for the change. We assume that a subset of States will opt for an alternative QRS and that the subset will revise their QRS once every three years.

15. ICRs Regarding Program Integrity Requirements Under the Contract (§§ 438.608 and 457.1285)

The following proposed changes to § 438.608 will be submitted to OMB for review under control number 0938–TBD (CMS–10856). At this time the OMB control number has not been determined, but it will be assigned by OMB upon their clearance of our proposed collection of information request. The control number's expiration date will be issued by OMB upon their approval of our final rule's collection of information request. The following proposed changes to § 457.1285 will be submitted to OMB for review under control number 0938–1282 (CMS–10554).

The proposed amendments to §§ 438.608 and 457.1285 would require States to update all MCO, PIHP, and PAHP contracts to require managed care plans to report overpayments to the State within 10 business days of identifying or recovering an overpayment. We estimate that the proposed changes to the timing of overpayment reporting (from timeframes that varied by State to 10 business days for all States) would apply to all MCO, PIHP, and PAHP contracts, including contracts for NEMT, that is, a total of 654 contracts for Medicaid, and 199 contracts for CHIP. We estimate it would take: 2 hours at $77.28/hr for a business operations specialist and 1 hour at $110.82/hr for a general and operations manager to modify State contracts with plans. In aggregate for Medicaid for *§* 438.608, we estimate a one-time State burden of 1,962 hours (654 contracts × 3 hr) at a cost of $173,559 [654 contracts × ((2 hr × $77.28/hr) + (1 hr × $110.82/hr))]. As this would be a one-time requirement, we annualize our time and cost estimates to 654 hours and $57,853.

In aggregate for CHIP for § 457.1285, we estimate a one-time State burden of 597 hours (199 contracts × 3 hr) at a cost of $52,811 [199 contracts × ((2 hr × $77.28/hr) + (1 hr × $110.82/hr))]. As this would be a one-time requirement, we annualize our time and cost estimates to 199 hours and $17,604. The annualization divides our estimates by three (3) years to reflect OMB's likely approval period. We are annualizing the one-time burden estimate since we do not anticipate any additional burden after the 3-year approval period expires.

We also estimate that it would take MCOs, PIHPs, and PAHPs 1 hour at

$109.36/hr for a computer programmer to update systems and processes already used to meet the previous requirement for ''prompt'' reporting. In aggregate for Medicaid for §438.608, we estimate a one-time private sector burden of 654 hours (654 contracts × 1 hr) at a cost of $71,521 (654 hr × $109.36/hr). As this would be a one-time requirement, we annualize our time and cost estimates to 218 hours and $23,840. In aggregate for CHIP for § 457.1285, we estimate a one-time private sector burden of 199 hours (199 contracts × 1 hr) at a cost of $21,763 (199 contracts × $109.36/hr). As this would be a one-time requirement, we annualize our time and cost estimates to 218 hours and $7,947. The annualization divides our estimates by three (3) years to reflect OMB's likely approval period. We are annualizing the one-time burden estimate since we do not anticipate any additional burden after the 3-year approval period expires.

C. Summary of Collection of Information Requirements and Associated Burden Estimates

TABLE 4: Summary of Proposed Medicaid Requirements and Burden

Regulatory Section in Title 42 of the CFR	OMB Control Number (CMS ID No.)	# of Respondents	Total # of Responses	Time per Response (hours)	Total Time (hours)	Labor Rate ($/hr)	Total cost ($)	Frequency	Annualized Time (hours)	Annualized Costs ($)
438.3(i)	0938–0920 (CMS–10856)	315	315	2	630	77.28	48,686	Once	210	16,229
438.3(i)	0938–0920 (CMS–10856)	315	315	1	315	110.82	34,908	Once	105	11,636
438.3(i)	0938–0920 (CMS–10856)	315	315	80	25,200	77.28	1,947,456	Once	8,400	649,152
438.3(i)	0938–0920 (CMS–10856)	315	315	40	12,600	110.82	1,396,332	Once	4,200	465,444
438.6(c)(2)(ii)	0938–0920 (CMS–10856)	38	50	2	100	120.48	12,048	Annual	n/a	n/a
438.6(c)(2)(ii)	0938–0920 (CMS–10856)	38	50	6	300	77.28	23,184	Annual	n/a	n/a
438.6(c)(2)(ii)	0938–0920 (CMS–10856)	38	50	2	100	110.82	11,082	Annual	n/a	n/a
438.6(c)(2)(ii)	0938–0920 (CMS–10856)	38	150	1	150	110.82	16,623	Annual	n/a	n/a
438.6(c)(2)(ii)	0938–0920 (CMS–10856)	30	150	1	150	120.48	18,072	Annual	n/a	n/a
438.6(c)(2)(ii)	0938–0920 (CMS–10856)	38	150	1	150	77.28	11,592	Annual	n/a	n/a
438.6(c)(2)(iii)	0938–0920 (CMS–10856)	38	60	6	360	120.48	43,373	Once	120	14,458
438.6(c)(2)(iii)	0938–0920 (CMS–10856)	38	60	3	180	110.82	19,948	Once	60	6,649
438.6(c)(2)(iii)	0938–0920 (CMS–10856)	38	60	6	360	109.36	39,370	Once	120	13,123
438.6(c)(2)(iv)	0938–0920 (CMS–10856)	38	50	5	250	109.36	27,340	Annual	n/a	n/a
438.6(c)(2)(iv)	0938–0920 (CMS–10856)	38	50	2.5	125	110.82	13,853	Annual	n/a	n/a
438.6(c)(2)(iv)	0938–0920 (CMS–10856)	38	50	2.5	125	77.28	9,660	Annual	n/a	n/a

Regulatory Section in Title 42 of the CFR	OMB Control Number (CMS ID No.)	# of Respondents	Total # of Responses	Time per Response (hours)	Total Time (hours)	Labor Rate ($/hr)	Total cost ($)	Frequency	Annualized Time (hours)	Annualized Costs ($)
438.6(c)(2)(v)	0938–0920 (CMS–10856)	38	47	3	141	109.36	15,420	Annual	n/a	n/a
438.6(c)(2)(v)	0938–0920 (CMS–10856)	38	47	1	47	110.82	5,209	Annual	n/a	n/a
438.6(c)(2)(v)	0938–0920 (CMS–10856)	38	47	2	94	77.28	7,264	Annual	n/a	n/a
438.6(c)(7)	0938-0920 (CMS-10856)	10	10	5	15	120.48	6,024	Annual	n/a	n/a
438.6(c)(7)	0938-0920 (CMS-10856)	10	10	5	15	109.36	5,468	Annual	n/a	n/a
438.6(c)(7)	0938-0920 (CMS-10856)	10	10	7	70	77.28	5,410	Annual	n/a	n/a
438.7(b)	0938–0920 (CMS–10856)	44	225	110	24,750	120.48	2,981,880	Annual	n/a	n/a
438.7(b)	0938–0920 (CMS–10856)	44	225	15	3,375	110.82	374,018	Annual	n/a	n/a
438.7(b)	0938–0920 (CMS–10856)	44	225	53	11,925	109.36	1,304,118	Annual	n/a	n/a
438.7(b)	0938–0920 (CMS–10856)	44	225	52	11,700	77.28	904,176	Annual	n/a	n/a
438.7(b)	0938–0920 (CMS–10856)	44	225	20	4,500	37.96	170,820	Annual	n/a	n/a
438.8(k)	0938–0920 (CMS–10856)	629	629	4	2,516	77.28	194,437	Once	839	64,812
438.8(k)	0938–0920 (CMS–10856)	629	629	2	1,258	109.36	137,575	Once	419	45,858
438.8(k)	0938–0920 (CMS–10856)	629	629	1	629	80.74	50,785	Annual	n/a	n/a
438.8(k)	0938–0920 (CMS–10856)	315	315	1	315	77.28	24,343	Annual	n/a	n/a
438.8(k)	0938–0920 (CMS–10856)	629	629	1	629	110.82	69,706	Annual	n/a	n/a
438.8(k)	0938-0920 (CMS-10856)	629	629	1	629	77.28	48,609	Annual	n/a	n/a
438.10(c)(3)	0938–0920 (CMS–10856)	45	45	20	900	109.36	98,424	Once	300	32,808
438.10(c)(3)	0938–0920 (CMS–10856)	45	45	40	1800	109.36	196,848	Annual	n/a	n/a
438.16(c)(5)(ii)	0938–0920 (CMS–10856)	22	22	5	110	120.48	13,253	Annual	n/a	n/a

Regulatory Section in Title 42 of the CFR	OMB Control Number (CMS ID No.)	# of Respondents	Total # of Responses	Time per Response (hours)	Total Time (hours)	Labor Rate ($/hr)	Total cost ($)	Frequency	Annualized Time (hours)	Annualized Costs ($)
438.16(c)(5)(ii)	0938–0920 (CMS–10856)	22	22	7	154	77.28	11,901	Annual	n/a	n/a
438.16(c)(5)(ii)	0938–0920 (CMS–10856)	22	22	5	110	109.36	12,030	Annual	n/a	n/a
438.16(d)(1)	0938–0920 (CMS–10856)	22	327	1	327	77.28	25,271	Annual	n/a	n/a
438.16(d)(2)	0938–0920 (CMS–10856)	5	5	2	10	77.28	773	Annual	n/a	n/a
438.16(e)(1)	0938–0920 (CMS–10856)	5	5	25	125	77.28	9,660	Annual	n/a	n/a
438.16(e)(2)(iii)	0938–0920 (CMS–10856)	22	22	2	44	77.28	3,400	Once	15	1,159
438.16(e)(2)(iii)	0938–0920 (CMS–10856)	22	22	2	44	109.36	4,812	Once	15	1,640
438.16(e)(2)(iii)	0938–0920 (CMS–10856)	22	22	1	44	77.28	1,700	Annual	n/a	n/a
438.16(e)(2)(iii)	0938–0920 (CMS–10856)	65	65	2	130	77.28	10,046	Annual	n/a	n/a
438.66(c)	0938–0920 (CMS–10856)	49	49	85	4,165	77.28	321,871	Once	1,388	107,290
438.66(c)	0938–0920 (CMS–10856)	49	49	25	1,225	110.82	135,755	Once	408	45,252
438.66(c)	0938–0920 (CMS–10856)	49	49	50	2,450	77.28	189,336	Annual	n/a	n/a
438.66(c)	0938–0920 (CMS–10856)	49	49	15	735	110.82	81,453	Annual	n/a	n/a
438.66(e)	0938–0920 (CMS–10856)	49	49	80	3,920	77.28	302,938	Annual	n/a	n/a
438.68(e)	0938–0920 (CMS–10856)	44	44	20	880	77.28	68,006	Once	293	22,669
438.68(e)	0938–0920 (CMS–10856)	44	44	10	440	77.28	34,003	Annual	n/a	n/a
438.68(f)	0938–0920 (CMS–10856)	44	44	85	3,740	77.28	289,027	Once	1,247	96,342
438.68(f)	0938–0920 (CMS–10856)	44	44	25	1,100	110.82	121,902	Once	367	40,634
438.68(f)	0938–0920 (CMS–10856)	44	44	50	2,200	77.28	170,016	Annual	n/a	n/a
438.68(f)	0938–0920 (CMS–10856)	44	44	15	660	110.82	73,141	Annual	n/a	n/a

Regulatory Section in Title 42 of the CFR	OMB Control Number (CMS ID No.)	# of Respondents	Total # of Responses	Time per Response (hours)	Total Time (hours)	Labor Rate ($/hr)	Total cost ($)	Frequency	Annualized Time (hours)	Annualized Costs ($)
438.74	0938–0920 (CMS–10856)	5	5	5	25	77.28	1,932	Once	8	644
438.74	0938–0920 (CMS–10856)	43	43	4	172	77.28	13,292	Annual	n/a	n/a
438.207(b)(3)	0938–0920 (CMS–10856)	629	629	50	31,450	77.28	3,485,289	Once	10,483	1,161,763
438.207(b)(3)	0938–0920 (CMS–10856)	629	629	20	12,580	110.82	1,394,116	Once	4,193	464,705
438.207(b)(3)	0938–0920 (CMS–10856)	629	629	80	50,320	109.36	5,502,995	Once	16,773	1,834,332
438.207(b)(3)	0938–0920 (CMS–10856)	629	629	20	12,580	77.28	972,182	Annual	n/a	n/a
438.207(b)(3)	0938–0920 (CMS–10856)	629	629	5	3,145	110.82	348,529	Annual	n/a	n/a
438.207(b)(3)	0938–0920 (CMS–10856)	629	629	20	12,580	109.36	1,375,749	Annual	n/a	n/a
438.207(d)	0938–0920 (CMS–10856)	44	44	40	1,760	77.28	136,013	Annual	n/a	n/a
438.310(c)(2), 438.350	0938-0786 (CMS-R-305)	10	10	379.6	-3,796	varies	-303,805	Annual	n/a	n/a
438.334(c)(1)(a)	0938-0786 (CMS-R-305)	10	-10	-35	-117	varies	-8,361	Annual	n/a	n/a
438.358(b)(2)	0938-0786 (CMS-R-305)	10	-10	-100	-1000	varies	-57,620	Annual	n/a	n/a
438.360(a)(1)	0938-0786 (CMS-R-305)	65	-65	-409.33	-26,606	77.28	-2,056,146	Annual	n/a	n/a
438.364(a)(2)(iii)	0938-0786 (CMS-R-305)	654	654	1.5	981	varies	62,954	Annual	n/a	n/a
438.364(c)(1)	0938-0786 (CMS-R-305)	44	654	1.5	981	Varies	86,779	Once	327	28,926
438.364(c)(2)(i)	0938-0786 (CMS-R-305)	44	44	0.5	22	77.28	1,700	Annual	n/a	n/a
438.364(c)(2)(iii)	0938-0786 (CMS-R-305)	44	2452.5	0.0833	204	77.28	15,765	Once	68	5,255
438.364(c)(7)	0938-0786 (CMS-R-305)	58	58	80	4640	Varies	426,917	Annual	n/a	n/a
438.515(a)(1)	0938-1282 (CMS-10553)	629	629	1816	1,142,264	Varies	90,252,065	Annual	n/a	n/a
438.515(a)(1)(i)	0938-1282 (CMS-10553)	44	629	1.5	944	Varies	83,462	Once	315	27,821

Regulatory Section in Title 42 of the CFR	OMB Control Number (CMS ID No.)	# of Respondents	Total # of Responses	Time per Response (hours)	Total Time (hours)	Labor Rate ($/hr)	Total cost ($)	Frequency	Annualized Time (hours)	Annualized Costs ($)
438.515(a)(1)(ii)	0938-1282 (CMS-10553)	5	5	140	700	varies	73,344	Annual	n/a	n/a
438.515(a)(2)	0938-1282 (CMS-10553)	629	629	16	10,064	77.28	777,745	Annual	n/a	n/a
438.520(a)	0938-1282 (CMS-10553)	44	44	1730	76120	varies	7,173,364	Once	25,373	2,391,121
438.520(a)	0938-1282 (CMS-10553)	44	44	1,144	50336	varies	4,800,664	Annual	n/a	n/a
438.520(a)(2)(iv)	0938-1282 (CMS-10553)	629	629	24	15,096	109.36	1,650,899	Annual	n/a	n/a
438.520(a)(3)(v)	0938-1282 (CMS-10553)	629	629	16	10,064	37.96	382,029	Annual	n/a	n/a
438.540(a)	0938-1282 (CMS-10553)	44	44	24	1056	77.28	81,608	Annual	n/a	n/a
438.608(a)(2)	0938–0920 (CMS–10856)	654	654	2	1308	77.28	101,082	Once	436	33,694
438.608(a)(2)	0938–0920 (CMS–10856)	654	654	1	654	110.82	72,476	Once	218	24,159
438.608(a)(2)	0938–0920 (CMS–10856)	654	654	1	654	109.36	71,521	Once	218	23,840
Total		Varies	20,977	Varies	1,538,197	Varies	129,072,871	Varies	76,918	7,631,425

TABLE 5: Summary of Proposed CHIP Requirements and Burden

Regulatory Section in Title 42 of the CFR	OMB Control Number (CMS ID No.)	# of Respondents	Total # of Responses	Time per Response (hours)	Total Time (hours)	Labor Rate ($/hr)	Total cost ($)	Frequency	Annualized Time (hours)	Annualized Cost ($)
457.1201(c)	0938-1282 (CMS-10554)	16	100	1	100	77.28	7,728	annual	n/a	n/a
457.1201(e)	0938-1282 (CMS-10554)	5	5	2	10	77.28	773	annual	n/a	n/a
457.1201(e)	0938-1282 (CMS-10554)	5	5	25	125	77.28	9,660	annual	n/a	n/a
457.1201(e)	0938-1282 (CMS-10554)	16	16	2	32	109.36	3,500	once	11	1167
457.1201(e)	0938-1282 (CMS-10554)	16	16	2	32	77.28	2,473	once	11	824
457.1201(e)	0938-1282 (CMS-10554)	16	16	1	16	77.28	1,236	annual	n/a	n/a
457.1203(f)	0938-1282 (CMS-10554)	32	100	2	100	77.28	15,456	once	33	5,125
457.1203(f)	0938-1282 (CMS-10554)	32	100	1	100	110.82	11,082	once	33	3,694
457.1203(e)	0938-1282 (CMS-10554)	32	5	5	25	77.28	1,932	once	8	644
457.1207	0938-1282 (CMS-10554)	32	32	20	640	109.36	69,990	once	213	23,294
457.1207	0938-1282 (CMS-10554)	32	32	41	1,312	109.36	143,480	annual	n/a	n/a
457.1218	0938-1282 (CMS-10554)	32	32	20	640	77.28	49,459	once	213	16,486
457.1218	0938-1282 (CMS-10554)	32	32	10	320	77.28	24,730	once	107	8,243
457.1218	0938-1282 (CMS-10554)	32	32	85	2,720	77.28	210,202	once	1174	99,676
457.1218	0938-1282 (CMS-10554)	32	32	25	800	110.82	88,656	once	267	29,552
457.1218	0938-1282 (CMS-10554)	32	32	50	1,600	77.28	123,648	annual	n/a	n/a
457.1218	0938-1282 (CMS-10554)	32	32	15	480	110.82	53,194	annual	n/a	n/a
457.1230(b)	0938-1282 (CMS-10554)	32	32	44	1,408	77.28	108,810	annual	n/a	n/a
457.1240(d)	0938-1282 (CMS-10554)	32	199	1	199	77.28	15,379	once	66	5,126
457.1240(d)	0938-1282	32	199	.5	100	110.82	11,082	once	33	3,694

Regulatory Section in Title 42 of the CFR	OMB Control Number (CMS ID No.)	# of Respondents	Total # of Responses	Time per Response (hours)	Total Time (hours)	Labor Rate ($/hr)	Total cost ($)	Frequency	Annualized Time (hours)	Annualized Cost ($)
	(CMS-10554)									
457.1240(d)	0938-1282 (CMS-10554)	32	32	600	19,200	109.36	2,099,712	once	6,400	699,904
457.1240(d)	0938-1282 (CMS-10554)	32	32	600	19,200	78.18	1,501,056	once	6,400	500,352
457.1240(d)	0938-1282 (CMS-10554)	32	32	80	2,560	77.28	197,837	once	853	65,946
457.1240(d)	0938-1282 (CMS-10554)	32	32	450	14,400	98.50	141,192,000	once	4,800	47,064,000
457.1240(d)	0938-1282 (CMS-10554)	32	32	384	12,288	109.36	1,343,816	once	4,096	447,939
457.1240(d)	0938-1282 (CMS-10554)	32	32	256	8,192	78.18	640,451	once	2,731	213,484
457.1240(d)	0938-1282 (CMS-10554)	32	32	120	3,840	78.28	300,595	annual	n/a	n/a
457.1240(d)	0938-1282 (CMS-10554)	32	32	384	12,288	98.50	1,210,368	annual	n/a	n/a
457.1240(d)	0938-1282 (CMS-10554)	32	32	24	768	77.28	59,351	annual	n/a	n/a
457.1240(d)	0938-1282 (CMS-10554)	(10)	(10)	(5)	(50)	(37.96)	(1,898)	annual	n/a	n/a
457.1240(d)	0938-1282 (CMS-10554)	(10)	(10)	(30)	(300)	(77.28)	(23,184)	annual	n/a	n/a
457.1250(a)	0938-1282 (CMS-10554)	32	199	1	199	77.28	15,379	annual	n/a	n/a
457.1250(a)	0938-1282 (CMS-10554)	32	199	.5	100	37.96	3,777	annual	n/a	n/a
457.1250(a)	0938-1282 (CMS-10554)	32	32	.5	16	77.28	1,236	annual	n/a	n/a
457.1250(a)	0938-1282 (CMS-10554)	32	149	.0833	62	77.28	4,791	once	21	1597
457.1250(a)	0938-1282 (CMS-10554)	32	199	1	199	77.28	15,379	annual	n/a	n/a
457.1250(a)	0938-1282 (CMS-10554)	32	199	.5	100	110.82	11,027	annual	n/a	n/a
457.1250(a)	0938-1282 (CMS-10554)	(17)	(17)	(1298)	(22066)	(110.82)	(2,445,354)	annual	n/a	n/a
457.1250(a)	0938-1282 (CMS-10554)	(17)	(17)	(162)	(2758)	(92.92)	(256,297)	annual	n/a	n/a
457.1250(a)	0938-1282 (CMS-10554)	(17)	(17)	(357)	(6068)	(77.28)	(468,947)	annual	n/a	n/a

Regulatory Section in Title 42 of the CFR	OMB Control Number (CMS ID No.)	# of Respondents	Total # of Responses	Time per Response (hours)	Total Time (hours)	Labor Rate ($/hr)	Total cost ($)	Frequency	Annualized Time (hours)	Annualized Cost ($)
457.1250(a)	0938-1282 (CMS-10554)	(3)	(17)	(279.33)	(4,749)	(77.28)	(366,977)	annual	n/a	n/a
457.1250(a)	0938-1282 (CMS-10554)	(2)	(10)	(.0833)	(0.833)	(37.96)	(32)	annual	n/a	n/a
457.1250(a)	0938-1282 (CMS-10554)	20	20	16	320	110.82	35,462	annual	n/a	n/a
457.1250(a)	0938-1282 (CMS-10554)	20	20	20	400	109.36	43,744	annual	n/a	n/a
457.1250(a)	0938-1282 (CMS-10554)	20	20	44	880	77.28	68,006	annual	n/a	n/a
457.1285	0938-1282 (CMS-10554)	32	199	2	398	77.28	30,757	once	133	10,252
457.1285	0938-1282 (CMS-10554)	32	199	1	199	110.82	22,053	once	66	7,351
Total		Varies	2,674	Varies	70376	Varies	146,186,578	Varies	27,382	49,198,887

D. Submission of PRA-Related Comments

We have submitted a copy of this proposed rule to OMB for its review of the rule's information collection requirements. The requirements are not effective until they have been approved by OMB.

To obtain copies of the supporting statement and any related forms for the proposed collections discussed above, please visit the CMS website at *www.cms.hhs.gov/PaperworkReductionActof1995*, or call the Reports Clearance Office at 410–786–1326.

We invite public comments on these potential information collection requirements. If you wish to comment, please submit your comments electronically as specified in the **DATES** and **ADDRESSES** section of this proposed rule and identify the rule (CMS–2439–P), the ICR's CFR citation, and OMB control number.

III. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

IV. Regulatory Impact Analysis

A. Statement of Need

This proposed rule would advance CMS' efforts to improve access to care, quality and health outcomes, and better address health equity issues for Medicaid and CHIP managed care enrollees. The proposed rule would specifically address standards for timely access to care and States' monitoring and enforcement efforts, reduce burden for State directed payments and certain quality reporting requirements, add new standards that would apply when States use in lieu of services and settings (ILOSs) to promote effective utilization and identify the scope and nature of ILOS, specify medical loss ratio (MLR) requirements, and establish a quality rating system (QRS) for Medicaid and CHIP managed care plans.

B. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Section 3(f) of Executive Order 12866, as amended by Executive Order 14094, defines a ''significant regulatory action'' as an action that is likely to result in a rule: (1) having an annual effect on the economy of $200 million or more in any 1 year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments or communities; (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising legal or policy issues for which centralized review would meaningfully further the President's priorities or the principles set forth in the Executive Order.

A regulatory impact analysis (RIA) must be prepared for major rules. Based on our estimates, OMB's Office of Information and Regulatory Affairs has determined this rulemaking is ''significant'' under Section 3(f)(1) as measured by the $200 million threshold, and hence also a major rule under Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (also known as the Congressional Review Act). Accordingly, we have prepared a Regulatory Impact Analysis that to the best of our ability presents the costs and benefits of the rulemaking. Therefore, OMB has reviewed these proposed regulations, and the Departments have provided the following assessment of their impact.

C. Detailed Economic Analysis

We have examined the proposed provisions in this rule and determined that most of the proposed revisions to part 438 and part 457 outlined in this proposed rule are expected to minimally or moderately increase administrative burden and associated costs as we note in the COI (see section II. of this proposed rule). Aside from our analysis on burden in the COI, we believe that certain provisions in this proposed rule should specifically be analyzed in this regulatory impact analysis as potentially having a significant economic impact. Those proposed provisions include State directed payments, MLR reporting standards, and ILOS due to the impact these proposed provisions could have on the associated and corresponding managed care payments.

1. State Directed Payments (SDPs) (§§ 438.6, 438.7)

Neither the May 6, 2016 final rule (81 FR 27830) nor the November 13, 2020 final rule (85 FR 72754) included a regulatory impact analysis that discussed the financial and economic effects of SDPs. At the time the 2016 final rule was published and adopted regulations explicitly governing State directed payments, we believed that States would use the SDPs in three broad ways to: (1) transition previous pass-through payments into formal arrangements as SDPs; (2) add or expand provider payment requirements to promote access to care; and (3) implement quality or value payment models that include Medicaid managed care plans. However, since § 438.6(c) was issued in the 2016 final rule, States have requested approval for an increasing number of SDPs. The scope, size, and complexity of the SDPs being submitted by States for approval has also grown steadily. In calendar year 2017, CMS received 36 preprints for our review and approval from 15 States; in calendar year 2021, CMS received 223 preprints from 39 States. For calendar year 2022, CMS received 309 preprints from States. As of March 2023, CMS has reviewed more than 1,100 SDP proposals and approved more than 1,000 proposals since the 2016 final rule was issued. To accommodate these requests from States, CMS applied discretion in interpreting and applying § 438.6(c) in reviewing and approving SDPs. The 2016 final rule required criteria to determine if provider payment rates are ''reasonable, appropriate, and attainable'' and that SDPs must relate to utilization, quality, or other goals described in § 438.6(c). CMS has interpreted these sections of the regulation broadly, and therefore, the amount of SDP payments has grown significantly over time.

SDPs also represent a substantial amount of State and Federal spending. The Medicaid and CHIP Payment and Access Commission (MACPAC) reported that CMS approved SDPs in 37

States, with spending exceeding more than $25 billion.[150] The U.S. Government Accountability Office (GAO) also reported that at least $20 billion has been approved by CMS for preprints with payments to be made on or after July 1, 2021, across 79 proposals.[151]

We have tracked SDP spending trends as well. Using the total spending captured for each SDP through the end of fiscal year 2022, we calculate that SDP payments in 2022 were at least $52.2 billion. there may be some SDPs for which CMS does not have projected or actual spending data. In addition, our data reporting and collection is not standardized, and in some cases may be incomplete, so spending data for some SDP approvals may be less accurate. CMS began collecting total dollar estimates for SDPs incorporated through adjustments to base rates as well as those incorporated through separate payment terms with the revised preprint form published in January 2021; States were required to use the revised preprint form for rating periods beginning on or after July 1, 2021. We estimate that SDP spending comprises approximately 11.3 percent of total managed care payments in 2022 ($461.6 billion) and 6.6 percent of total Medicaid benefit expenditures ($794.5 billion). SDP spending varies widely across States. Thirty-nine (39) States reported the use of one or more SDPs in 2022. In these States, the percentage of Medicaid managed care spending paid through SDPs ranged from 1 percent to 58 percent, with a median of 8 percent; as a share of total Medicaid spending, SDPs ranged from 0 percent to 33 percent, with a median of 3 percent.

From 2016 through 2022, SDPs were a significant factor in Medicaid expenditure growth. Total benefit spending increased at an average annual rate of 6.3 percent per year from 2016 through 2022; excluding SDPs, benefit spending grew at an average rate of 5.1 percent. Managed care payments grew 9.2 percent on average over 2016 to 2022, but excluding SDPs, the average growth rate was 7.0 percent. While some SDP spending may have been included in managed care payments prior to 2016 (either as a pass-through payment or some other form of payment), by 2022 we expect that much of this is new spending.

In 2022, we estimate that about 75 percent of SDP spending went to hospitals for inpatient and outpatient services, and another 5 percent went to academic medical centers. The remaining 20 percent of SDP spending went to nursing facilities, primary care physicians, specialty physicians, HCBS and personal care service providers, behavioral health service providers, and dentists.

The data available do not allow us to determine how much of this baseline SDP spending was incorporated into managed care expenditures prior to the 2016 final rule, or reflected historical transfers from prior payment arrangements. For example, States transitioned pass-through payments to SDPs or transferred spending from fee-for-service payments (for example, supplemental payments) to SDPs. Some States indicate that the SDP has had no net impact on rate development while other States have reported all estimated spending for the services and provider class affected by the SDP. Based on our experience working with States, we believe much of the earlier SDP spending was largely existing Medicaid spending that was transitioned to managed care SDPs. However, in more recent years, we believe that most SDP spending reflects new expenditures. For context, States reported $6.7 billion in pass-through payments after the 2016 final rule.[152] States also have reported only a small decrease in fee-for-service supplemental payments since 2016 (from $28.7 billion in 2016 to $27.5 billion in 2022).[153] SDP spending in 2022 significantly exceeds the originally reported pass-through payments and the changes in fee-for-service supplemental payments.

The proposals in this rule are intended to ensure the following policy goals: (1) Medicaid managed care enrollees receive access to high-quality care under SDPs; (2) SDPs are appropriately linked to Medicaid quality goals and objectives for the providers participating in the SDPs; and (3) CMS has the appropriate fiscal and program integrity guardrails in place to strengthen the accountability and feasibility of SDPs.

The proposal expected to have the most significant economic impact is setting a payment ceiling at 100 percent of the ACR for SDPs for inpatient hospital services, outpatient hospital services, nursing facility services, and qualified practitioner services at academic medical centers. As discussed in section I.B.2.f. of this proposed rule, we have used the ACR as a benchmark for total payment levels for all SDP reviews since 2018 and have not knowingly approved an SDP that includes payment rates that are projected to exceed the ACR. Based on the available data, we estimate that $11.6 billion of SDPs in 2022 reflect payments at or near the ACR. It is difficult to determine the amounts of these payments due to data quality and inconsistent reporting of these details. For example, if payment data are aggregated across multiple providers or provider types, it can be difficult to determine if providers are being paid at different levels. Additionally, many SDPs report payment rates relative to Medicare instead of ACR; for some SDPs, the payment rates relative to Medicare suggest effective payment rates would be near the ACR. These would include SDPs with effective payment rates of 150 percent or more of the Medicare rate (with several over 200 percent and as high as 450 percent).

Under current policy, we project that SDP spending would increase from $52 billion in 2022 (or 11.3 percent of managed care spending) to about $91 billion by 2028 (or 15 percent of managed care spending).

TABLE 6—PROJECTED MEDICAID MANAGED CARE AND STATE DIRECTED SPENDING UNDER CURRENT POLICY, FY 2022–2028

[In billions of dollars]

	2022	2023	2024	2025	2026	2027	2028
Managed care spending	$461.6	$502.2	$479.4	$502.9	$536.6	$571.1	$607.7

[150] Medicaid and CHIP Payment and Access Commission, ''Report to Congress on Medicaid and CHIP,'' June 2022, available at *https://www.macpac.gov/wp-content/uploads/2022/06/MACPAC_June2022-WEB-Full-Booklet_FINAL-508-1.pdf.*

[151] U.S. Government Accountability Office, ''Medicaid: State Directed Payments in Managed Care,'' June 28, 2022, available at *https://www.gao.gov/assets/gao-22-105731.pdf.*

[152] Our data reflects documentation provided from 15 States with pass-through payments in rating periods beginning from July 1, 2017 through June 30, 2018.

[153] CMS–64. *https://www.medicaid.gov/medicaid/financial-management/state-expenditure-reporting-for-medicaid-chip/expenditure-reports-mbescbes/index.html.*

TABLE 6—PROJECTED MEDICAID MANAGED CARE AND STATE DIRECTED SPENDING UNDER CURRENT POLICY, FY 2022–2028—Continued

[In billions of dollars]

	2022	2023	2024	2025	2026	2027	2028
SDP spending	$52.2	$66.1	$67.5	$73.1	$79.2	$85.7	$91.2
SDP as share of managed care	11.3%	13.2%	14.1%	14.5%	14.8%	15.0%	15.0%

Estimating the impact of the proposed SDP provisions is challenging for several reasons. First, as noted previously, the projected and actual spending data that we collect from States is not standardized, and in some cases aggregated across providers. It is also often difficult to determine how payment rates compare, especially when States use different benchmarks for payment (for example, comparing SDPs using Medicare payment rates to those using ACR payment rates). In addition, there is frequently limited information on ACR payment rates. It is difficult to determine how the ACR may be calculated and how the calculation may vary across different States and providers. Furthermore, it may be difficult to determine how many more providers are not paid under SDPs and how much they could be paid if SDPs were expanded to them.

Second, it is difficult to determine how much providers are paid in managed care programs without SDPs. These data appear to be less frequently reported, and we have virtually no information about provider payments when the State does not use an SDP. This information is important when estimating the impact of changes in SDPs, because the initial payment rate matters as much as the final rate. In some cases, the initial payment rates for existing SDPs are significantly low (for example, there are several SDPs where the reported initial payment rates are 10 to 20 percent of ACR or commercial rates, 25 to 30 percent of Medicare rates, or 10 to 35 percent of Medicaid State plan rates). In other cases, the initial payment rates are relatively higher. Thus, it may be difficult to determine how large new SDPs would be.

Third, there is significant variation in the use of SDPs across States. States have significant discretion in developing SDPs (including which providers receive SDPs and the amounts of the payments), and it is challenging to predict how States would respond to changes in policy. Some States may add more SDPs or expand spending in existing SDPs. Moreover, as many SDPs are funded through sources other than State general revenues (such as intergovernmental transfers or provider taxes), decisions about SDPs may be dependent on the availability of these funding sources.

For these reasons, we believe it is prudent to provide a range of estimated impacts for this section of the proposed rule. The following estimates reflect a reasonable expectation of the impacts of this proposed rule on Medicaid expenditures, but do not include all possible outcomes.

We estimate that the low end of the range for the proposed changes would have zero impact on Medicaid expenditures. That is, we assume that the new policies in the rule would have no bearing on States' future decisions on SDPs. Future growth in Medicaid spending on SDPs would be the same as currently projected. This estimate also assumes that there would be no reduction in expenditures from limiting effective payment rates to ACR rates.

We believe this is a reasonable estimate of the low end of this range. SDPs are already growing rapidly and several States already have SDPs with effective payment rates at or near the ACR. In addition, SDP spending is projected to continue to grow as a share of Medicaid managed care spending over the next several years, which suggests that other States may add SDPs or increase the payment rates within the SDPs. Thus, one possible outcome is that States would use SDPs the same way under current policy and under the proposed rule.

The estimate of the upper end of the range is based on the expectation that the provisions of the proposed rule would prompt States to increase SDP spending. We believe that by setting the payment limit at the ACR rates for certain services, States may increase the size and scope of future SDPs to approach this limit. In particular, there are many SDPs that currently have effective reimbursement rates at or around 100 percent of Medicare reimbursement rates, and others with rates below 100 percent of ACR, and that States may potentially increase payments associated with these SDPs.

For the high scenario, we assume that Medicaid SDP spending would increase at a faster rate than projected under current law. Under current law, Medicaid SDP spending is projected to reach 15 percent of managed care spending by 2027; we assume in the high scenario that SDP spending would reach about 17.5 percent of managed care spending in 2027. Under this scenario, SDP spending would increase by approximately 20 percent by 2027 (or about $16 billion). From 2024 through 2026, SDP spending would increase somewhat faster than assumed under current law to reach those levels. This increase would include additional spending from current SDPs increasing payment rates to the ACR, and may also include new or expanded SDPs. We would also expect that this would occur mostly among SDPs for hospitals and academic medical centers, as those are currently the providers that receive the majority of SDPs. We have not estimated a breakdown of impacts by provider type or by State in this analysis. The estimated impacts are provided in Table 7.

TABLE 7—PROJECTED MEDICAID STATE DIRECTED PAYMENT SPENDING UNDER PROPOSED RULE, HIGH SCENARIO, FY 2024–2028

[In billions of dollars]

	2024	2025	2026	2027	2028
Current law	$67.5	$73.1	$79.2	$85.7	$91.2
Proposed rule	72.2	81.7	91.8	101.9	108.5
Impact	4.7	8.6	12.6	16.2	17.3

In Table 8, we provide estimates of the impacts on the Federal government and on States.

TABLE 8—PROJECTED MEDICAID STATE DIRECTED PAYMENT SPENDING UNDER PROPOSED RULE BY PAYER, HIGH SCENARIO, FY 2024–2028

[in billions of dollars]

	2024	2025	2026	2027	2028
Total impact	$4.7	$8.6	$12.6	$16.2	$17.3
Federal government	3.1	5.6	8.2	10.5	11.1
States	1.6	3.0	4.4	5.7	6.2

We project that the Federal government would pay an additional $11.1 billion in 2028, with the States paying an additional $6.2 billion in the high scenario. We would note that for the States, they would have discretion of whether or not to increase SDP spending (through existing or new SDPs), and that the source of the non-Federal share may vary. Many States already use sources other than State general revenues (such as IGTs and provider taxes, as noted previously), and therefore the direct impact to State expenditures may be less than projected.

As noted previously, there is a wide range of possible outcomes of this proposed rule on SDP expenditures. The actual changes in spending may be difficult to determine, as there is uncertainty in the future amount of spending through SDPs in the baseline. The specific impacts could also vary over time, by State, and by provider type. We believe actual impacts can reasonably be expected to fall within the range shown here.

There are additional proposals in this rule that may also slightly increase SDP spending. This includes allowing States to:

(1) Direct expenditures for non-network providers;

(2) Set the amount and frequency for VBP SDPs;

(3) Recoup unspent funds for VBP SDPs; and

(4) Exempting minimum fee schedules at the Medicare rate from prior approval.

We do not have quantitative data to analyze the impact of these provisions. However, based on a qualitative analysis of our work with States, we believe these regulatory changes would have much more moderate effects on the economic impact in comparison to the ceiling on payment levels described above. Allowing States to direct expenditures for non-network providers will likely increase the number of State contract provisions; however, we anticipate that most States will want to require minimum fee schedules tied to State plan rates, which will likely result in very small changes from existing rate development practices. Regarding the proposal to remove the existing regulatory requirements for setting the amount and frequency for VBP SDPs and recouping unspent funds for VBP SDPs, we anticipate this will change the types of SDPs States seek, encouraging them to pursue VBP models, that would replace existing VBPs, though a few States may pursue new models. The proposed regulatory requirement to exempt minimum fee schedules tied to Medicare rates will likely cause some increase in spending as more States may take up this option, but again, we do not anticipate this to have as significant impact on rate development.

There are a few proposals in this rule that are likely to exert some minor downward pressure on the rate of growth in SDP spending, such as the enhanced evaluation requirements, requirements related to financing of the non-Federal share, and eliminating States' ability to use reconciliation processes. We expect that these provisions would not have any significant effect on Medicaid expenditures.

Aside from spending, we believe many of the proposals in section I.B.2. of this proposed rule would have significant qualitative impacts on access, quality, and transparency. One example is our proposal to permit the use of SDPs for non-network providers (section I.B.2.d. of this proposed rule). One of the most frequently used non-network provider types is family planning. Permitting States to use SDPs for family planning providers could greatly improve access and ease access for enrollees consistent with the statutory intent of section 1902(a)(23)(B) of the Act. Our proposal to permit States to set the frequency and amount of SDP payments (section I.B.2.h. of this proposed rule) should remove unnecessary barriers for States implementing VBP SDPs. This should have direct impacts on quality of care as States will be more inclined to use VBP SDPs. It will allow the payments to be more closely linked to the services provided in a timely fashion, and it will allow States to establish strong parameters and operational details that define when and how providers will receive payment to support robust provider participation. Lastly, our proposal (section I.B.2.b. of this proposed rule) to require specific information in managed care plan contracts would improve accountability to ensure that the additional funding included in the rate certification is linked to a specific service or benefit provided to a specific enrollee covered under the contract.

Taken together, we believe our SDP related proposals in this rule would enable us to ensure that SDPs would be used to meet State and Federal policy goals to improve access and quality, used for the provision of services to enrollees under the contract, and improve fiscal safeguards and transparency. The proposals in this rule would provide a more robust set of regulations for SDPs and are informed by six years of experience reviewing and approving SDP preprints. We believe the resulting regulations would enable more efficient and effective use of Medicaid managed care funds.

2. Medical Loss Ratio (MLR) Standards (§§ 438.8, 438.74, 457.1201, 457.1203, 457.1285)

We propose to amend §§ 438.3(i), 438.8(e)(2), 457.1201, and 457.1203 to specify that only those provider incentives and bonuses that are tied to clearly defined, objectively measurable, and well-documented clinical or quality improvement standards that apply to providers may be included in incurred claims for MLR reporting. In States that require managed care plans to pay remittances back to the State for not meeting a minimum MLR, and where remittance calculations are based on the MLR standards in § 438.8, the remittance amounts may be affected. If managed care plans currently include

(in reported incurred claims) payments to providers that significantly reduce or eliminate remittances while providing no value to consumers, the proposed clarification would result in transfers from such managed care plans to States in the form of higher remittances or lower capitation rates. Although we do not know how many managed care plans currently engage in such reporting practices or the amounts improperly included in MLR calculations, using information from a prior CCIIO RIA analysis,[154] we estimate the impact of the proposed clarification by assuming that provider incentive and bonus payments of 1.06 percent or more paid claims (the top 5 percent of such observations) may represent incentives based on MLR or similar metrics. Based on this assumption and the Medicaid MLR data for 2018, *the proposed clarification would increase remittances paid by managed care plans to States by approximately $12 million per year* (total computable).

We propose to amend §§ 438.8(e)(3) and 457.1203(c) to specify that only expenditures directly related to activities that improve health care quality may be included in QIA expenses for MLR reporting. In States that require managed care plans to pay remittances back to the State for not meeting a minimum MLR, and where the remittance calculations are based on the MLR standards in § 438.8, the remittance amounts may be affected. This proposed change would result in transfers from managed care plans that currently include indirect expenses in QIA to States in the form of higher remittances or lower capitation rates. Although we do not know how many managed care plans include indirect expenses in QIA, using information from a previous CCIIO RIA analysis,[155] we estimate the impact of the proposed change by assuming that indirect expenses inflate QIA by 41.5 percent (the midpoint of the 33 percent to 50 percent range observed during CCIIO MLR examinations) for half of the issuers that report QIA expenses (based on the frequency of QIA-related findings in CCIIO MLR examinations). Based on these assumptions and the Medicaid MLR data for 2018, *the proposed clarification would increase remittances paid by managed care plans to States by approximately $49.8 million per year.*

We propose to amend §§ 438.608(a)(2) and (d)(3), and 457.1285 to require States' contracts with managed care plans to include a provision requiring managed care plans to report any overpayment (whether identified or recovered) to the State. In States that require managed care plans to pay remittances back to the State for not meeting a minimum MLR, and where the remittance calculations are based on the MLR standards in § 438.8, the remittance amounts may be affected. Given that States do not provide this level of payment reporting to CMS, we are unable to quantify the benefits and costs of this proposed change; however, this proposed change may result in transfers from managed care plans to States in the form of higher remittances or lower capitation rates.

We propose to amend 438.8(k) to require managed care plans to report SDPs to States as a line item in their MLR reports. In States that require managed care plans to pay remittances back to the State for not meeting a minimum MLR, and the remittance calculation arrangements are based on § 438.8, the remittance amounts may be affected. Given that CMS does not have data on actual revenue and expenditure amounts for SDPs that would allow for modeling the effect of the line item reporting on remittances, we are unable to quantify the benefits and costs of this proposed change. We expect that this proposed change may result in transfers from States to managed care plans in the form of lower remittances or higher capitation rates.

3. In Lieu of Services and Settings (ILOSs) (§§ 438.2, 438.3, 438.16, 457.1201, 457.120)

In the May 6, 2016 final rule (81 FR 27830), the regulatory impact analysis addressed the financial and economic effects of allowing FFP for capitation payments made for enrollees that received inpatient psychiatric services during short-term stays in an institution for mental disease (IMD) as an ILOS; however, it did not address other potential ILOS (see 81 FR 27840 and 27841 for further details). When we analyzed the May 6, 2016 final rule for the regulatory impact analysis, we concluded that the financial and economic effects of all other ILOSs would be offset by a decrease in expenditures for the State plan-covered services and settings for which ILOSs are a medically appropriate and cost effective substitute. The use of ILOSs is a longstanding policy in managed care given the flexibility that managed care plans have historically had in furnishing care in alternate settings and services in a risk-based delivery system, if cost effective, on an optional basis and to the extent that the managed care plan and the enrollee agree that such setting or service would provide medically appropriate care. States and managed care plans historically have utilized ILOSs that are immediate substitutes for covered services and settings under the State plan, such as a Sobering Center as a substitute for an emergency department visit. More recently, a few States and managed care plans have begun utilizing ILOSs as longer term substitutes for covered services and settings under the State plan. On January 7, 2021, CMS published a State Health Official (SHO) letter (SHO# 21–001) [156] that described opportunities under Medicaid and CHIP to better address social determinants of health (SDOH). Additionally, on January 4, 2023, CMS published a State Medicaid Director (SMD) letter (SMD# 23–001) [157] that outlined additional guidance for ILOSs in Medicaid managed care. Since CMS published this guidance, States have been working to implement changes in their Medicaid managed care programs to meet the HRSNs of Medicaid beneficiaries more effectively, including partnering with community-based organizations that routinely address HRSNs.

We believe that expanding the definition of what is allowable as ILOSs in Medicaid managed care would likely lead to an increase in Medicaid expenditures. Many of these services intended to address HRSNs may not have been previously eligible for coverage under Medicaid as an ILOS. While guidance requires these to be cost effective, the proposed rule does not require cost effectiveness to be ''budget neutral.'' Moreover, for ILOSs that are intended to be in lieu of some future service, the cost effectiveness may need to be measured over years.

Data on ILOS is extremely limited, and CMS does not currently collect any data (outside of ILOS spending for IMDs as part of the managed care rate contract). Moreover, there is limited information on the additional ILOSs that States may use. Therefore, we are providing a range of potential impacts for this section as well.

At the low end of the range, we project that there would be no impact on Medicaid expenditures. In these cases, we would assume (1) the use of new ILOSs are relatively lower; and (2) additional ILOS spending is offset by savings from other Medicaid services.

[154] 87 FR 703.

[155] 87 FR 703.

[156] Opportunities in Medicaid and CHIP to Address Social Determinants of Health, *https://www.medicaid.gov/federal-policy-guidance/downloads/sho21001.pdf.*

[157] Additional Guide on Use of In Lieu of Services and Settings in Medicaid Managed Care, *https://www.medicaid.gov/federal-policy-guidance/downloads/smd23001.pdf.*

At the high end of the range, we project that there would be some increase in Medicaid spending. We make the following assumptions for the high scenario: (1) half of States would use new ILOSs; (2) States would increase use of ILOSs to 2 percent of total Medicaid managed care spending; and (3) additional ILOSs would offset 50 percent of new spending. Table 9 shows the impacts in the high scenario.

TABLE 9—PROJECTED MEDICAID ILOS SPENDING UNDER PROPOSED RULE BY PAYER, HIGH SCENARIO, FY 2024–2028

[In billions of dollars]

	2024	2025	2026	2027	2028
Total impact	$2.4	$2.5	$2.7	$2.9	$3.0
Federal government	1.6	1.6	1.7	1.9	2.0
States	0.8	0.9	1.0	1.0	1.0

We also believe it is important for CMS to begin to capture data on ILOS expenditures as a portion of total capitation payments that are eligible for FFP to ensure appropriate fiscal oversight, as well as detail on the managed care plans' ILOS costs. Therefore, we proposed reporting related to the final ILOS cost percentage and actual MCO, PIHP and PAHP ILOS costs in §§ 438.16(c) and 457.1201(c). This will also aid us in future regulatory impact analyses.

4. Regulatory Review Cost Estimation

If regulations impose administrative costs on private entities, such as the time needed to read and interpret this proposed rule, we should estimate the cost associated with regulatory review. Due to the uncertainty involved with accurately quantifying the number of entities that will review the rule, we assume that the total number of unique commenters on the 2016 final rule will be the number of reviewers of this proposed rule. We received 879 unique comments on the 2016 final rule. We acknowledge that this assumption may understate or overstate the costs of reviewing this rule. It is possible that not all commenters reviewed the 2016 rule in detail, and it is also possible that some reviewers chose not to comment on the proposed rule. For these reasons, we thought that the number of past commenters would be a fair estimate of the number of reviewers of this rule. We welcome any comments on the approach in estimating the number of entities which will review this proposed rule.

We also recognize that different types of entities are in many cases affected by mutually exclusive sections of this proposed rule, and therefore, for the purposes of our estimate, we assume that each reviewer reads approximately 50 percent of the rule. We seek comments on this assumption.

Using the wage information from the BLS for medical and health service managers (Code 11–9111), we estimate that the cost of reviewing this rule is $115.22 per hour, including overhead and fringe benefits *https://www.bls.gov/oes/current/oes_nat.htm.* Assuming an average reading speed, we estimate that it would take approximately 20 hours for the staff to review half of this proposed rule. For each entity that reviews the rule, the estimated cost is $2,304. Therefore, we estimate that the total cost of reviewing this regulation is $2 million.

D. Alternatives Considered

1. State Directed Payments (SDPs)

As discussed in section I.B.2.f. of this proposed rule on provider payment limits, we are considering alternatives to the ACR as a total payment rate limit for inpatient hospital services, outpatient hospital services, nursing facility services, and qualified practitioner services at an academic medical center for each SDP. The alternatives we are considering include the Medicare rate, some level between Medicare and the ACR, or a Medicare equivalent of the ACR. We are also considering an alternative that would establish a total payment rate limit for any SDPs described in paragraphs (c)(1)(i) and (ii) that are for any of these four services, at the ACR, while limiting the total payment rate for any SDPs described in paragraph § 438.6(c)(1)(iii)(C) through (E), at the Medicare rate. We are also considering and seek public comment on establishing a total payment rate limit for all services for all SDP arrangements described in § 438.6(c)(1)(i) and (ii), and 438.6(c)(1)(iii)(C) through (E) at the Medicare rate. For each of these alternatives, we acknowledge that some States currently have SDPs that have total payment rates up to the ACR. Therefore, these alternative proposals could be more restrictive, and States could need to reduce funding from current levels, which could have a negative impact on access to care and health equity initiatives.

2. Medical Loss Ratio (MLR) Standards

For all MLR-related proposed changes, except those relating to SDP reporting, the only alternative considered was no change. We considered alternatives to requiring actual SDP amounts as part of MLR reports, including creating a new separate reporting process for SDPs or modifying existing reporting processes to include SDPs. We determined that creating a new separate reporting process specific to SDPs would impose significant burden on States as it would require State staff to learn a new process and complete an additional set of documents for SDP reporting. We considered modifying other State managed care reporting processes, for example, MCPAR, to include SDPs but, unlike MLR reporting, those processes were not specific to reporting financial data. We propose integrating SDP reporting in the MLR as the current MLR process requires reporting of financial data from managed care plans, and in turn, States provide a summary of these reports to CMS in the form of the annual MLR summary report. The integration of managed care plan and State SDP reporting using current MLR processes will encourage States to add the monitoring and oversight of SDPs as a part of a State's established MLR reporting process.

3. In Lieu of Services and Settings (ILOSs) (§§ 438.2, 438.3, 438.16, 457.1201, 457.120)

One alternative we considered was leaving the 2016 final rule as it is today; however, since the rule was finalized in 2016, we continue to hear of increased State and plan utilization and innovation in the use of ILOSs, and we do not believe the current regulation ensures appropriate enrollee and fiscal protections. As a result, we propose many additional safeguards in this rule. The ILOS proposals seek to ensure appropriate safeguards while also specifying that States and managed care plans can consider both short term and

longer term substitutes for State plan-covered services and settings. Additionally, we considered including enrollee protections and ILOS transparency without the 5 percent limit on the ILOS cost percentage and the ILOS evaluation, when applicable. However, we have concerns regarding the potential unrestrained growth of ILOS expenditures.

E. Accounting Statement and Table

As required by OMB Circular A–4 (available at *https://www.whitehouse.gov/wp-content/uploads/legacy_drupal_files/omb/circulars/A4/a-4.pdf*), we have prepared an accounting statement in Table 10 showing the classification of the impact associated with the provisions of this proposed rule. In the case *of* SDPs, we categorize these *as transfers* from the Federal government *and* States to health care providers. For ILOSs, we categorize these as transfers from the Federal government and States to beneficiaries in the form of additional services. Finally, for MLR requirements, we categorize these as transfers from managed care organizations to the Federal government and States.

This provides our best estimates of the transfer payments outlined in the ''Section C. Detailed Economic Analysis'' above. We detail our estimates of the low and high end of the ranges in this section, and the primary estimate is the average of the low and high scenario impacts. This reflects a wide range of possible outcomes, but given the uncertainty *in* the ways and degrees to which States may use the SDPs and ILOSs, we believe that *this* is a reasonable estimate of the potential impacts under this proposed rule. For the MLR provisions, we have not provided a range given the relatively small size of the estimated impact.

These impacts are discounted at seven percent and three percent, respectively, as reflected in Table 10.

TABLE 10—ACCOUNTING STATEMENT

[In millions of 2024 dollars]

Benefits						
Non-Quantified	This proposed rule would support many benefits to the Medicaid program, including to align State and Federal efforts to improve timely access to care for Medicaid managed care enrollees, enhance and improve quality-based provider payments to better support care delivery, and support better quality improvement throughout the Medicaid managed care program.					
Transfers						
Annual monetized transfers	Primary estimate	Low estimate	High estimate	Units		
				Year dollars	Discount rate (percent)	Period covered
From Federal Government to Providers	3,384	0	6,767	2024	7	2024–2028
	3,449	0	6,899	2024	3	2024–2028
From States to Providers	1,846	0	3,692	2024	7	2024–2028
	1,882	0	3,764	2024	3	2024–2028
From Federal Government to Beneficiaries	809	0	1,617	2024	7	2024–2028
	809	0	1,619	2024	3	2024–2028
From States to Beneficiaries	428	0	856	2024	7	2024–2028
	429	0	858	2024	3	2024–2028
From Managed Care Plans to Federal Government	62	62	62	2024	7	2024–2028
	62	62	62	2024	3	2024–2028
From Managed Care Plans to States	34	34	34	2024	7	2024–2028
	34	34	34	2024	3	2024–2028

F. Regulatory Flexibility Act (RFA)

Effects on MCOs, PIHPs or PAHPs (referred to as ''managed care plans'') will not have a significant economic impact. As outlined in section II.B. of this proposed rule, we utilized data submitted by States for enrollment in Medicaid managed care plans for CY 2020. The enrollment data reflected 58,521,930 enrollees in MCOs, 37,692,501 enrollees in PIHPs or PAHPs, and 6,089,423 enrollees in PCCMs, for a total of 67,836,622 Medicaid managed care enrollees.[158] This includes duplicative counts when enrollees are enrolled in multiple managed care plans concurrently. This data also showed 43 States that contract with 467 MCOs, 11 States that contract with 162 PIHPs or PAHPs, 19 States that contract with 21 non-emergency transportation PAHPs, and 13 States with 26 PCCM or PCCM entities. For CHIP, we utilized State submitted data for enrollment in managed care plans for CY 2017. The enrollment data reflected 4,580,786 Medicaid expansion and 2,593,827 separate CHIP managed care enrollees.[159] These data also showed that 32 States use managed care entities for CHIP enrollment contracting with 199 managed care entities.[160]

[158] Medicaid Managed Care Enrollment and Program Characteristics (2020).

[159] Centers for Medicare and Medicaid Services, Statistical Enrollment Data System (2017), Quarterly Enrollment Data Form 21E: Number of Children Served in Separate CHIP Program/ Quarterly Enrollment Data Form 64.21E: Number of Children Served in CHIP Medicaid Expansion Program/Quarterly Enrollment Data Form 21PW: Number of Pregnant Women Served, accessed December 5, 2022.

[160] Results of managed care survey of States completed by Centers for Medicare and Medicaid Services, Center for Medicaid and CHIP Services, Children and Adults Health Programs Group, Division of State Coverage Programs, 2017.

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, we estimate that some managed care plans may be small entities as that term is used in the RFA. We believe that only a few managed care plans may qualify as small entities. Specifically, we believe that approximately 14–25 managed care plans may be small entities. We believe that the remaining managed care plans have average annual receipts from Medicaid and CHIP contracts and other business interests in excess of $41.5 million; therefore, we do not believe that this proposed rule will have a significant economic impact on a substantial number of small businesses.

For purposes of the RFA, approximately 0.04 percent of Medicaid managed care plans may be considered small businesses according to the Small Business Administration's size standards with total revenues of $8 million to $41.5 million in any 1 year. Individuals and States are not included in the definition of a small entity. The cost impact on Medicaid managed care plans on a per entity basis is approximately $54,500. This proposed rule will not have a significant impact measured change in revenue of 3 to 5 percent on a substantial number of small businesses or other small entities.

The proposed rule would specifically address standards for (1) timely access to care and States' monitoring and enforcement efforts; (2) reduce burden for State directed payments (SDPs) and certain quality reporting requirements; (3) add new standards that would apply when States use in lieu of services and settings (ILOSs) to promote effective utilization and identify the scope and nature of ILOS; (4) specify medical loss ratio (MLR) requirements; and (5) establish a quality rating system (QRS) for Medicaid and CHIP managed care plans. As outlined, these efforts do not impact small entities.

As its measure of significant economic impact on a substantial number of small entities, HHS uses a change in revenue of more than 3 to 5 percent. We do not believe that this threshold will be reached by the requirements in this proposed rule. Therefore, the Secretary has certified that this proposed rule will not have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. We do not anticipate that the provisions in this proposed rule will have a substantial economic impact on most hospitals, including small rural hospitals. Provisions include some proposed new standards for State governments and managed care plans but no direct requirements on providers, including hospitals. The impact on individual hospitals will vary according to each hospital's current and future contractual relationships with Medicaid managed care plans, but any additional burden on small rural hospitals should be negligible. We invite comment on our proposed analysis of the impact on small rural hospitals regarding the provisions of this proposed rule. We have determined that we are not preparing analysis for either the RFA or section 1102(b) of the Act because we have determined, and the Secretary certifies, that this proposed rule will not have a significant economic impact on a substantial number of small entities or a significant impact on the operations of a substantial number of small rural hospitals in comparison to total revenues of these entities.

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2023, that is approximately $177 million. This proposed rule does not contain any Federal mandate costs resulting from (A) imposing enforceable duties on State, local, or tribal governments, or on the private sector, or (B) increasing the stringency of conditions in, or decreasing the funding of, State, local, or tribal governments under entitlement programs. We have determined that this proposed rule does not impose any mandates on State, local, or tribal governments, or the private sector that will result in an annual expenditure of $177 million or more.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. We believe this proposed regulation gives States appropriate flexibility regarding managed care standards (for example, setting network adequacy standards, setting credentialing standards, EQR activities), while also aligning Medicaid and CHIP managed care standards with those for plans in the Marketplace and MA to better streamline the beneficiary experience and to reduce administrative and operational burdens on States and health plans across publicly-funded programs and the commercial market. We have determined that this proposed rule would not significantly affect States' rights, roles, and responsibilities.

G. Unfunded Mandates Reform Act (UMRA)

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2023, that threshold is approximately $177 million. This proposed rule would not impose a mandate that will result in the expenditure by State, local, and Tribal Governments, in the aggregate, or by the private sector, of more than $177 million in any one year.

H. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. This proposed rule will not have a substantial direct effect on State or local governments, preempt States, or otherwise have a Federalism implication.

Chiquita Brooks-LaSure, Administrator of the Centers for Medicare & Medicaid Services, approved this document on April 24, 2023.

List of Subjects

42 CFR Part 430

Administrative practice and procedure, Grant programs-health, Medicaid, Reporting and recordkeeping requirements.

42 CFR Part 438

Citizenship and naturalization, Civil rights, Grant programs-health, Individuals with disabilities, Medicaid, Reporting and recordkeeping requirements, Sex discrimination.

42 CFR Part 457

Administrative practice and procedure, Grant programs-health,

Health insurance, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR chapter IV as set forth below:

PART 430—GRANTS TO STATES FOR MEDICAL ASSISTANCE PROGRAMS

■ 1. The authority citation for part 430 is revised to read as follows:

Authority: 42 U.S.C. 1302.

■ 2. Amend § 430.3 by revising the introductory text and adding paragraph (d) to read as follows:

§ 430.3 Appeals under Medicaid.

Four distinct types of disputes may arise under Medicaid.

* * * * *

(d) Disputes that pertain to disapproval of written prior approval by CMS of State directed payments under 42 CFR 438.6(c)(2)(i) are also heard by the Board in accordance with procedures set forth in 45 CFR part 16. 45 CFR part 16, appendix A, lists all the types of disputes that the Board hears.

PART 438—MANAGED CARE

■ 3. The authority citation for part 438 continues to read as follows:

Authority: 42 U.S.C. 1302.

■ 4. Amend § 438.2 by—

■ a. Adding the definition of ''In lieu of service or setting (ILOS)'' in alphabetical order; and

■ b. Revising paragraph (9) in the definition of ''Primary care case management entity (PCCM entity)''.

The addition and revision read as follows:

§ 438.2 Definitions.

* * * * *

In lieu of service or setting (ILOS) is a service or setting that is provided to an enrollee as a substitute for a covered service or setting under the State plan in accordance with § 438.3(e)(2). An ILOS can be used as an immediate or longer-term substitute for a covered service or setting under the State plan, or when the ILOS can be expected to reduce or prevent the future need to utilize the covered service or setting under the State plan.

* * * * *

Primary care case management entity (PCCM entity) * * *

(9) Coordination with mental and substance use disorder health systems and providers.

* * * * *

■ 5. Amend § 438.3 by:

■ a. Revising paragraphs (c)(1)(ii) and (e)(2);

■ b. Adding paragraphs (i)(3) and (4); and

■ c. Revising paragraph (v).

The additions and revisions read as follows:

§ 438.3 Standard contract requirements.

* * * * *

(c) * * *

(1) * * *

(ii) The final capitation rates must be based only upon services covered under the State plan, ILOS, and additional services deemed by the State to be necessary to comply with the requirements of subpart K of this part (applying parity standards from the Mental Health Parity and Addiction Equity Act), and represent a payment amount that is adequate to allow the MCO, PIHP or PAHP to efficiently deliver covered services to Medicaid-eligible individuals in a manner compliant with contractual requirements.

* * * * *

(e) * * *

(2) An MCO, PIHP or PAHP may cover, for enrollees, an ILOS as follows:

(i) The State determines that the ILOS is a medically appropriate and cost effective substitute for the covered service or setting under the State plan;

(ii) The enrollee is not required by the MCO, PIHP, or PAHP to use the ILOS, and the MCO, PIHP or PAHP must comply with the following requirements:

(A) An enrollee who is offered or utilizes an ILOS offered as a substitute for a covered service or setting under the State plan retains all rights and protections afforded under part 438, and if an enrollee chooses not to receive an ILOS, they retain their right to receive the service or setting covered under the State plan on the same terms as would apply if an ILOS was not an option; and

(B) An ILOS may not be used to reduce, discourage, or jeopardize an enrollee's access to services and settings covered under the State plan, and an MCO, PIHP or PAHP may not deny access to a service or setting covered under the State plan, on the basis that the enrollee has been offered an ILOS as an optional substitute for a service or setting covered under the State plan, is currently receiving an ILOS as a substitute for a service or setting covered under the State plan, or has utilized an ILOS in the past;

(iii) The approved ILOS is authorized and identified in the MCO, PIHP or PAHP contract, and will be offered to enrollees at the option of the MCO, PIHP or PAHP;

(iv) The utilization and actual cost of the ILOS is taken into account in developing the component of the capitation rates that represents the covered State plan services and settings, unless a statute or regulation explicitly requires otherwise; and

(v) With the exception of a short term stay as specified in § 438.6(e) in an Institution for Mental Diseases (IMD), as defined in § 435.1010 of this chapter, for inpatient mental health or substance use disorder treatment, an ILOS must also comply with the requirements in § 438.16.

* * * * *

(i) * * *

(3) The State, through its contracts with an MCO, PIHP, and PAHP must require that incentive payment contracts between the MCO, PIHP, and PAHP and network providers:

(i) Have a defined performance period that can be tied to the applicable MLR reporting periods.

(ii) Be signed and dated by all appropriate parties before the commencement of the applicable performance period.

(iii) Include well-defined quality improvement or performance metrics that the provider must meet to receive the incentive payment.

(iv) Specify a dollar amount that can be clearly linked to successful completion of the metrics defined in the incentive payment contract, including a date of payment.

(4) The State through its contracts with an MCO, PIHP, and PAHP must:

(i) Define the documentation that must be maintained by the MCO, PIHP, and PAHP to support the provider incentive payments.

(ii) Prohibit the use of attestations as supporting documentation for data that factor into the MLR calculation.

(iii) Require the MCO, PIHP, and PAHP to make incentive payment contracts, and any documentation in paragraph (e)(4)(i), available to the State upon request and at any routine frequency established in the State's contract with the MCO, PIHP, and PAHP.

* * * * *

(v) *Applicability date.* Paragraphs (e)(2)(v), (i)(3), and (i)(4) of this section apply to the first rating period for contracts with MCOs, PIHPs and PAHPs beginning on or after 60 days following [EFFECTIVE DATE OF THE FINAL RULE].

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§ 438.6 Special contract provisions related to payment.

■ 6. Amend § 438.6—

■ a. In paragraph (a) by:

■ i. Revising the introductory text;

■ ii. Adding definitions for ''Academic medical center'', ''Average commercial rate'', ''Condition-based payment'', ''Final State directed payment cost percentage'', ''Inpatient hospital services'', ''Maximum fee schedule'', ''Minimum fee schedule'', ''Outpatient hospital services'', ''Nursing facility services'', ''Performance measure'', ''Population-based payment'', ''Qualified practitioner services at an academic medical center'', ''Separate payment term'', ''Total payment rate'', ''Total published Medicare payment rate'', and ''Uniform increase'' in alphabetical order;

■ b. By revising paragraph (c) paragraph heading and paragraphs (c)(1)(iii),(c)(2) and (c)(3).

■ c. By adding paragraphs (c)(4) through (8); and

■ d. By revising paragraph (e).

The revisions and additions read as follows:

§ 438.6 Special contract provisions related to payment.

(a) *Definitions.* As used in this section, the following terms have the indicated meanings:

Academic medical center means a facility that includes a health professional school with an affiliated teaching hospital.

Average commercial rate means the average rate paid for services by the highest claiming third-party payers for specific services as measured by claims volume.

* * * * *

Condition-based payment means a prospective payment for a defined set of Medicaid covered service(s) that are tied to a specific condition and delivered to Medicaid managed care enrollees.

Final State directed payment cost percentage means the annual amount calculated, in accordance with paragraph (c)(7)(iii) of this section, for each State directed payment for which written prior approval is required under paragraph (c)(2)(i) of this section and for each managed care program.

* * * * *

Inpatient hospital services means the same as specified at § 440.10.

Maximum fee schedule means any State directed payment where the State requires an MCO, PIHP, or PAHP to pay no more than a certain amount for a covered service(s).

Minimum fee schedule means any State directed payment where the State requires an MCO, PIHP, or PAHP to pay no less than a certain amount for a covered service(s).

Outpatient hospital services means the same as specified in § 440.20(a).

Nursing facility services means the same as specified in § 440.40(a).

* * * * *

Performance measure means, for State directed payments, a quantitative measure with a numerator and denominator that is used to monitor performance at a point in time or track performance over time, of provider service delivery, quality of care, or outcomes as defined in § 438.320 for enrollees.

Population-based payment means a prospective payment for a defined set of Medicaid service(s) for a population of Medicaid managed care enrollees covered under the contract attributed to a specific provider or provider group.

Qualified practitioner services at an academic medical center means professional services provided by both physicians and non-physician practitioners affiliated with or employed by an academic medical center.

* * * * *

Separate payment term means a pre-determined and finite funding pool that the State establishes and documents in the Medicaid managed care contract for a State directed payment for which the State has received written prior approval under § 438.6(c)(2)(i). Payments made from this funding pool are made by the State to the MCOs, PIHPs or PAHPs exclusively for State directed payments for which the State has received written prior approval under § 438.6(c)(2)(i) and are made separately and in addition to the capitation rates identified in the contract as required under § 438.3(c)(1)(i).

State directed payment (SDP) means a contract arrangement that directs an MCO's, PIHP's, or PAHP's expenditures under paragraphs (c)(1)(i) through (iii) of this section.

* * * * *

Total payment rate means the aggregate for each managed care program of:

(i) The average payment rate paid by all MCOs, PIHPs, or PAHPs to all providers included in the specified provider class for each service identified in the State directed payment;

(ii) The effect of the State directed payment on the average rate paid to providers included in the specified provider class for the same service for which the State is seeking prior approval under paragraph (c)(2)(i) of this section;

(iii) The effect of any and all other State directed payments on the average rate paid to providers included in the specified provider class for the same service for which the State is seeking prior approval under paragraph (c)(2)(i) of this section; and

(iv) The effect of any and all allowable pass-through payments, as defined in paragraph (a) of this section, paid to any and all providers included in the provider class specified in the State directed payment for which the State is seeking prior approval under paragraph (c)(2)(i) of this section on the average payment rate to providers in the specified provider class.

Total published Medicare payment rate means amounts calculated as payment for specific services that have been developed under Title XVIII Part A and Part B.

Uniform increase means any State directed payment that directs the MCO, PIHP, or PAHP to pay the same amount (the same dollar amount or the same percentage increase) per Medicaid covered service(s) in addition to the rates the MCO, PIHP or PAHP negotiated with the providers included in the specified provider class for the service(s) identified in the State directed payment.

* * * * *

(c) *State directed payments under MCO, PIHP, or PAHP contracts—*

(1) * * *

(iii) The State may require the MCO, PIHP, or PAHP to:

(A) Adopt a minimum fee schedule for providers that provide a particular service under the contract using State plan approved rates.

(B) Adopt a minimum fee schedule for providers that provide a particular service under the contract using a total published Medicare payment rate that was in effect no more than 3 years prior to the start of the rating period and the minimum fee schedule to be used by the MCO, PIHP, or PAHP is equivalent to 100 percent of the specified total published Medicare payment rate.

(C) Adopt a minimum fee schedule for providers that provide a particular service under the contract using rates other than the State plan approved rates or one or more total published Medicare payment rates described in paragraph (c)(1)(iii)(B) of this section.

(D) Provide a uniform dollar or percentage increase for providers that provide a particular service under the contract.

(E) Adopt a maximum fee schedule for providers that provide a particular service under the contract, so long as the MCO, PIHP, or PAHP retains the ability to reasonably manage risk and has discretion in accomplishing the goals of the contract.

(2) *Standards for State directed payments.* (i) State directed payments

specified in paragraphs (c)(1)(i) and (ii) and (c)(1)(iii)(C) through (E) of this section must have written prior approval that the standards and requirements in this section are met.

(ii) Each State directed payment must meet the following standards. Specifically, each State directed payment must:

(A) Be based on the utilization and delivery of services;

(B) Direct expenditures equally, and using the same terms of performance, for a class of providers providing the service under the contract;

(C) Expect to advance at least one of the goals and objectives in the quality strategy in § 438.340;

(D) Have an evaluation plan that measures the degree to which the State directed payment advances at least one of the goals and objectives in the quality strategy in § 438.340 and includes all of the elements outlined in paragraph (c)(2)(iv) of this section;

(E) Not condition provider participation in State directed payments on the provider entering into or adhering to intergovernmental transfer agreements;

(F) Result in achievement of the stated goals and objectives in alignment with the State's evaluation plan;

(G) Comply with all Federal legal requirements for the financing of the non-Federal share, including but not limited to, 42 CFR 433, subpart B;

(H) Ensure that each provider receiving payment under a State directed payment attests that it does not participate in any hold harmless arrangement with respect to any health care-related tax as specified in § 433.68(f)(3) of this subchapter in which the State or other unit of government imposing the tax provides for any direct or indirect payment, offset, or waiver such that the provision of the payment, offset, or waiver directly or indirectly guarantees to hold the provider harmless for all or any portion of the tax amount, and ensure that such attestations are available upon CMS request;

(I) Ensure that the total payment rate for each service and provider class included in the State directed payment must be reasonable, appropriate and attainable and, upon request from CMS, the State must provide documentation demonstrating the total payment rate for each service and provider class; and

(J) Be developed in accordance with § 438.4, and the standards specified in §§ 438.5, 438.7, and 438.8.

(iii) The total payment rate projected for each State directed payment for which written prior approval is required under paragraph (c)(2)(i) of this section for inpatient hospital services, outpatient hospital services, nursing facility services, or qualified practitioner services at an academic medical center must not exceed the average commercial rate. To demonstrate compliance with this paragraph, States must submit:

(A) The average commercial rate demonstration, for which States must use payment data that:

(*1*) Is specific to the State;

(*2*) Is no older than from the three most recent and complete years prior to the rating period of the initial request following the applicability date of this section;

(*3*) Is specific to the service(s) addressed by the State directed payment;

(*4*) Includes the total reimbursement by the third-party payer and any patient liability, such as cost sharing and deductibles;

(5) Excludes payments to FQHCs, RHCs, and from any non-commercial payers, such as Medicare; and

(*6*) Excludes any payment data for services or codes that the applicable Medicaid MCOs, PIHPs, or PAHPs do not cover.

(B) A total payment rate comparison, for which States must provide a comparison of the total payment rate for these services included in the State directed payment to the average commercial rate that:

(*1*) Is specific to each managed care program that the State directed payment applies to;

(*2*) Is specific to each provider class to which the State directed payment applies;

(*3*) Is projected for the rating period for which the State is seeking prior approval under paragraph (c)(2)(i) of this section;

(*4*) Uses payment data that are specific to each service included in the State directed payment; and

(*5*) Describes each of the components of the total payment rate as a percentage of the average commercial rate (demonstrated by the State as provided in paragraph (c)(2)(iii)(A) of this section) for each of these services included in the State directed payment.

(C) The ACR demonstration described in paragraph (c)(2)(iii)(A) of this section must be included with the initial documentation submitted for written prior approval of the State directed payment under paragraph (c)(2)(i) of this section, and then subsequently updated at least once every 3 years thereafter as long as the State continues to include the State directed payment that requires prior approval under paragraph (c)(2)(i) of this section in any MCO, PIHP, or PAHP contract. The total payment rate comparison described in paragraph (c)(2)(iii)(B) of this section must be included with the documentation submitted for written prior approval under paragraph (c)(2)(i) of this section and updated with each amendment and subsequent renewal.

(iv) For State directed payments for which written prior approval under paragraph (c)(2)(i) of this section is required, the State must include a written evaluation plan with its submission for written prior approval under paragraph (c)(2)(i) of this section and an updated written evaluation plan with each amendment and subsequent renewal. The evaluation plan must include the following elements:

(A) Identification of at least two metrics that will be used to measure the effectiveness of the State directed payment in advancing at least one of the goals and objectives in the quality strategy on an annual basis, which must:

(*1*) Be specific to the State directed payment, and when practicable and relevant, attributable to the performance by the providers for enrollees in all of the State's managed care program(s) to which the State directed payment applies; and

(*2*) Include at least one performance measure as defined in § 438.6(a) as part of the metrics used to measure the effectiveness of the State directed payment;

(B) Include baseline statistics on all metrics that will be used in the evaluation of the State directed payment for which the State is seeking written prior approval under paragraph (c)(2)(i) of this section;

(C) Include performance targets for all metrics to be used in the evaluation of the State directed payment for which the State is seeking written prior approval under paragraph (c)(2)(i) of this section that demonstrate either maintenance or improvement over the baseline statistics and not a decline relative to baseline. The target for at least one performance measure, as defined in § 438.6(a), must demonstrate improvement over baseline; and

(D) Include a commitment by the State to submit an evaluation report in accordance with § 438.6(c)(2)(v) if the final State directed payment cost percentage exceeds 1.5 percent.

(v) For any State directed payment for which written prior approval is required under paragraph (c)(2)(i) of this section that has a final State directed payment cost percentage greater than 1.5 percent, the State must complete and submit an evaluation report using the evaluation plan outlined during the prior approval

process under paragraph (c)(2)(iv) of this section.

(A) This evaluation report must:

(*1*) Include all of the elements in paragraph (c)(2)(iv) of this section as specified in the approved evaluation plan;

(*2*) Include three most recent and complete years of annual results for each metric as required in paragraph (c)(2)(iv)(A) of this section; and

(*3*) Be published on the public facing website as required under § 438.10(c)(3).

(B) States must submit the initial evaluation report as described in paragraph (c)(2)(v)(A) of this section to CMS no later than 2 years after the conclusion of the 3-year evaluation period. Subsequent evaluation reports must be submitted to CMS every 3 years.

(vi) Any State directed payments described in paragraph (c)(1)(i) or (ii) of this section must:

(A) Make participation in the value-based purchasing, delivery system reform, or performance improvement initiative available using the same terms of performance to a class of providers providing services under the contract related to the reform or improvement initiative;

(B) If the State directed payment for which written prior approval is required under paragraph (c)(2)(i) of this section conditions payment upon performance, the payment to providers under the State directed payment:

(*1*) Cannot be conditioned upon administrative activities, such as the reporting of data nor upon the participation in learning collaboratives or similar administrative activities.

(*2*) Must use a common set of performance measures across all of the payers and providers specified in the State directed payment;

(*3*) Must define and use a performance measurement period that must not exceed the length of the rating period and must not precede the start of the rating period in which the payment is delivered by more than 12 months, and all payments must be documented in the rate certification for the rating period in which the payment is delivered;

(*4*) Must identify baseline statistics on all metrics that will be used to measure the performance that is the basis for payment to the provider from the MCO, PIHP, or PAHP; and

(*5*) Must use measurable performance targets, which are attributable to the performance by the providers in delivering services to enrollees in each of the State's managed care program(s) to which the State directed payment applies, that demonstrate improvement over baseline data on all metrics that will be used to measure the performance that is the basis for payment to the provider from the MCO, PIHP, or PAHP.

(C) If the State directed payment is a population-based or condition-based payment, the State directed payment must:

(*1*) Be conditioned upon the delivery by the provider of one or more specified Medicaid covered service(s) during the rating period or the attribution of a covered enrollee to a provider for the rating period for treatment;

(*2*) If conditioning payment on the attribution to a provider, have an attribution methodology using data that are no older than the three most recent and complete years of data; seeks to preserve existing provider-enrollee relationships; accounts for enrollee preference in choice of provider; and describes when patient panels are attributed, how frequently they are updated, and how those updates are communicated to providers;

(*3*) Replace the negotiated rate between an MCO, PIHP, or PAHP and providers for the Medicaid covered service(s) included in the population or condition-based payment; no other payment may be made by an MCO, PIHP, or PAHP to the same provider on behalf of the same enrollee for the same services included in the population or condition-based payment; and

(*4*) Include at least one metric in the evaluation plan required under paragraph (c)(2)(iv) of this section that measures performance at the provider class level; the target for this performance measure, as defined in § 438.6(a), must be set to demonstrate improvement over baseline.

(vii) Any State directed payment described in paragraph (c)(1)(iii) of this section must:

(A) Condition payment from the MCO, PIHP, or PAHP to the provider on the utilization and delivery of services under the contract for the rating period for which the State is seeking written prior approval only; and

(B) Not condition payment from the MCO, PIHP, or PAHP to the provider on utilization and delivery of services outside of the rating period for which the State is seeking written prior approval and then require that payments be reconciled to utilization during the rating period.

(viii) A State must submit all required documentation for all State directed payments for which written prior approval is required under (c)(2)(i) of this section no later than:

(A) Ninety days before the end of the rating period for any State directed payments that begins at least 90 days before the end of the rating period.

(B) Before the end of the rating period for any State directed payment that begins less than 90 days before the end of the rating period.

(C) For any State directed payments that are approved for multiple rating periods as provided in paragraph (c)(3) of this section, the same time frames described in paragraphs (c)(2)(viii)(A) and (B) of this section apply to the first rating period for which the State is seeking written prior approval under paragraph (c)(2)(i) of this section.

(ix) States seeking to amend State directed payments after CMS has issued written prior approval under paragraph (c)(2)(i) of this section must obtain written prior approval of the amendment(s). States must submit all required documentation for written prior approval of such amendment(s):

(A) Prior to the end of the rating period to which the State directed payment applies to amend the State directed payment; and

(B) For any State directed payments that are approved for multiple rating periods as provided in paragraph (c)(3) of this section, within 120 days of the start of the rating period for amendments to the State directed payment for either the second or third rating period. States cannot amend State directed payments that are approved on a multi-year basis as defined in paragraph (c)(3) of this section for rating periods that have concluded.

(3) *Approval and renewal timeframes.* (i) Approval of a State directed payment described in paragraphs (c)(1)(i) and (ii) of this section is for one rating period unless a multi-year approval of up to three rating periods is requested and meets all of the following criteria:

(A) The State has explicitly identified and described the State directed payment in the contract as a multi-year State directed payment, including a description of the State directed payment by year and if the State directed payment varies by year.

(B) The State has developed and described its plan for implementing a multi-year State directed payment, including the State's plan for multi-year evaluation, and the impact of a multi-year State directed payment on the State's goals and objectives in the State's quality strategy in § 438.340.

(C) The State has affirmed that it will not make any changes to the State directed payment methodology, or magnitude of the payment, described in the contract for all years of the multi-year State directed payment without CMS written prior approval. If the State determines that changes to the State

directed payment methodology, or magnitude of the payment, are necessary, the State must obtain written prior approval of such changes under paragraph (c)(2) of this section.

(ii) Written prior approval of a State directed payment described in paragraph (c)(1)(iii)(C) through (E) of this section is for one rating period.

(iii) State directed payments are not automatically renewed.

(4) *Reporting requirements.* The State must submit to CMS no later than 180 days after each rating period, data to the Transformed Medicaid Statistical Information System, and in any successor format or system designated by CMS, specifying the total dollars expended by each MCO, PIHP, and PAHP for State directed payments, including amounts paid to individual providers. The initial report will be due after the rating period following the release of reporting instructions by CMS. Minimum data fields to be collected include the following:

(i) Provider identifiers.

(ii) Enrollee identifiers.

(iii) MCO, PIHP or PAHP identifiers.

(iv) Procedure and diagnosis codes.

(v) Allowed, billed, and paid amounts. Paid amounts include the amount that represents the MCO's, PIHP's or PAHP's negotiated payment amount, the amount of the State directed payment, the amount for any pass-through payments under paragraph (d) of this section, and any other amounts included in the total amount paid to the provider.

(5) *Requirements for Medicaid Managed Care contract terms for State directed payments.* State directed payments must be specifically described and documented in the MCO's, PIHP's, or PAHP's contracts. The MCO's, PIHP's or PAHP's contract must include, at a minimum, the following information for each State directed payment:

(i) The State directed payment start date and, if applicable, the end date within the applicable rating period;

(ii) A description of the provider class eligible for the State directed payment and all eligibility requirements;

(iii) A description of the State directed payment, which must include at a minimum:

(A) For State directed payments described in paragraphs (c)(1)(iii)(A), (B), and (C) of this section:

(*1*) The required fee schedule;

(*2*) The procedure and diagnosis codes to which the fee schedule applies;

(*3*) The applicable dates of service within the rating period for which the fee schedule applies;

(*4*) For State directed payments that specify State plan approved rates, the contract must also reference the State plan page, when it was approved, and a link to the currently approved State plan page when possible; and

(*5*) For State directed payments that specify a Medicare-referenced fee schedule, the contract must also include information about the Medicare fee schedule(s) that is necessary to implement the State directed payment, including identifying the specific Medicare fee schedule, the time period for which the Medicare fee schedule is in effect, and any material adjustments due to geography or provider type that need to be applied.

(B) For State directed payments described in paragraphs (c)(1)(iii)(D) of this section, the contract must include the following:

(*1*) Whether the uniform increase will be a specific dollar amount or a percentage increase of negotiated rates;

(*2*) The procedure and diagnosis codes to which the uniform dollar or percentage increase applies;

(*3*) The specific dollar amount or percentage increase that the MCO, PIHP or PAHP must apply or the methodology to establish the specific dollar amount or percentage increase;

(*4*) The applicable dates of service within the rating period for which the uniform increase applies; and

(*5*) The roles and responsibilities of the State and the MCO, PIHP, or PAHP, the timing of payments, and other significant relevant information.

(C) For State directed payments described in paragraph (c)(1)(iii)(E) of this section, the contract must include the following:

(*1*) The fee schedule the MCO, PIHP, or PAHP must ensure that payments are below;

(*2*) The procedure and diagnosis codes to which the fee schedule applies;

(*3*) The applicable dates of service within the rating period for which the fee schedule applies; and

(*4*) Details of the State's exemption process for MCOs, PIHPs, or PAHPs and providers to follow if they are under contractual obligations that result in the need to pay more than the maximum fee schedule.

(D) For State directed payments described in paragraphs (c)(1)(i) and (ii) of this section that condition payment based upon performance:

(*1*) The approved performance measures upon which payment will be conditioned;

(*2*) The approved measurement period for those measures;

(*3*) The approved baseline statistics for all measures against which performance will be measured;

(*4*) The performance targets that must be achieved on each measure for the provider to obtain the performance-based payment;

(*5*) The methodology to determine if the provider qualifies for the performance-based payment as well as the amount of the payment; and

(*6*) The roles and responsibilities of the State and the MCO, PIHP, or PAHP, the timing of payments, what to do with any unearned payments, and other significant relevant information.

(E) For State directed payments described in paragraphs (c)(1)(i) and (ii) of this section using a population-based or condition-based payment as defined in paragraph (a) of this section:

(*1*) The Medicaid covered service(s) that the population or condition-based payment is for;

(*2*) The time period that the population or condition-based payment covers;

(*3*) When the population or condition-based payment is to be made and how frequently;

(*4*) A description of the attribution methodology, if one is used, which must include at a minimum the data used, when the panels will be established, how frequently those panels will be updated, and how the attribution methodology will be communicated to providers; and

(*5*) The roles and responsibilities of the State and the MCO, PIHP, or PAHP in operationalizing the attribution methodology if an attribution methodology is used.

(iv) Any encounter reporting and separate reporting requirements necessary for auditing the State directed payment in addition to the reporting requirements in paragraph (c)(4) of this section; and

(v) If the State will be using a separate payment term as defined in paragraph (a) of this section to implement the State directed payment for which written prior approval is required under paragraph (c)(2)(i) of this section.

(vi) All State directed payments must be specifically described and documented in the MCO's, PIHP's, and PAHP's contracts no later than 120 days after the start date of the State directed payment for which the State has obtained written prior approval or 120 days after the date CMS issued written prior approval of the State directed payment under (c)(2) of this section, whichever is later.

(6) *Separate payment term requirements.* All separate payment terms must:

(i) Be reviewed and approved as part of the review of the State directed payment for which written prior approval is required under paragraph (c)(2)(i) of this section;

(ii) Not be used to implement a State directed payment described in paragraphs (c)(1)(iii)(A) and (B) of this section;

(iii) Be specific to each Medicaid managed care program and specific to the individual State directed payment for which the State has obtained written prior approval under paragraph (c)(2) of this section;

(iv) Not exceed the total amount documented in the written prior approval for each State directed payment for which the State has obtained written prior approval under paragraph (c)(2)(i) of this section and for each Medicaid managed care program; and

(v) Be documented in the State's contracts with the MCOs, PIHPs, or PAHPs no later than 120 days after the start date of the State directed payment for which the State has obtained written prior approval under paragraph (c)(2)(i) of this section or 120 days after the date CMS issued written prior approval of the State directed payment under (c)(2)(i) of this section, whichever is later.

(A) The separate payment term cannot be amended except to account for a payment methodology that is first approved by CMS as an amendment to the State directed payment for which the State has obtained written prior approval under paragraph (c)(2)(i) of this section.

(B) The documentation in the MCO's, PIHP's, or PAHP's contract must include:

(*1*) The total dollars that the State will pay to the MCOs, PIHPs, or PAHPs for the individual State directed payment for which the State has obtained written prior approval under paragraph (c)(2)(i) of this section.

(*2*) The timing and frequency of payments that will be made under the separate payment term from the State to the MCO, PIHP, or PAHP;

(*3*) A description or reference to the specific State directed payment for which the State has obtained written prior approval under paragraph (c)(2)(i) of this section for which the separate payment term is to be used; and

(*4*) Any separate reporting requirements that the State requires to ensure appropriate reporting of the separate payment term for the purposes of MLR reporting under § 438.8.

(7) *Final State directed payment cost percentage.* For each State directed payment for which written prior approval is required under paragraph (c)(2)(i) of this section, unless the State voluntarily submits the evaluation report per paragraph (c)(2)(v) of this section, the State must calculate the final State directed payment cost percentage and if the final State directed payment cost percentage is below 1.5 percent the State must provide a final State directed payment cost percentage report to CMS as follows:

(i) *State directed payment cost percentage calculation.* The final State directed payment cost percentage must be calculated on an annual basis and recalculated annually.

(ii) *State directed payment cost percentage certification.* The final State directed payment cost percentage must be certified by an actuary and developed in a reasonable and appropriate manner consistent with generally accepted actuarial principles and practices.

(iii) *Calculation of the final State directed payment cost percentage.* The final State directed payment cost percentage is the result of dividing the amount determined in paragraph (c)(7)(iii)(A) of this section by the amount determined in paragraph (c)(7)(iii)(B) of this section.

(A) The actual total amount that is paid as a separate payment term described in paragraph (c)(6) of this section and portion of the actual total capitation payments that is attributable to the State directed payment for which the State has obtained written prior approval under paragraph (c)(2)(i) of this section, for each managed care program.

(B) The actual total capitation payments, defined at § 438.2, for each managed care program, including all State directed payments in effect under § 438.6(c) and pass-through payments in effect under § 438.6(d), and the actual total amount of all State directed payments that are paid as separate payment terms as described in paragraph(c)(6).

(iv) *Annual CMS review of the final State directed payment cost percentage.* The State must submit the final State directed payment cost percentage annually to CMS for review as a separate report concurrent with the rate certification submission required in § 438.7(a) for the rating period beginning 2 years after the completion of each 12-month rating period that includes a State directed payment for which the State has obtained written prior approval under paragraph (c)(2)(i) of this section.

(8) *Applicability dates.* States must comply with:

(i) Paragraphs (a), (c)(1)(iii), (c)(2)(i), (c)(2)(ii)(A) through (C), (c)(2)(ii)(E), (c)(2)(ii)(G), (c)(2)(ii)(I) and (J), (c)(2)(vi)(A), (c)(3), (c)(6)(i) through (iv) of this section beginning on [EFFECTIVE DATE OF THE FINAL RULE].

(ii) Paragraphs (c)(2)(iii), (c)(2)(vi)(B), and (c)(2)(vi)(C)(*1*) and (*2*) of this section no later than the first rating period for contracts with MCOs, PIHPs and PAHPs beginning on or after [insert the effective date of the final rule].

(iii) Paragraphs (c)(2)(ii)(H), (c)(2)(vi)(C)(*3*) and (*4*), (c)(2)(vii), (c)(2)(viii), (c)(2)(ix) and (c)(5)(i) through (v) of this section no later than the first rating period for contracts with MCOs, PIHPs and PAHPs beginning on or after 2 years after [insert the effective date of the final rule].

(iv) Paragraphs (c)(2)(ii)(D) and (F), (c)(2)(iv), (c)(2)(v) and (c)(7) of this section no later than the first rating period for contracts with MCOs, PIHPs and PAHPs beginning on or after 3 years after [insert the effective date of the final rule].

(v) Paragraphs (c)(5)(vi) and (c)(6)(v) of this section no later than the first rating period for contracts with MCOs, PIHPs and PAHPs beginning on or after 4 years after [insert the effective date of the final rule].

(vi) Paragraph (c)(4) of this section no later than the first rating period following the release of reporting instructions by CMS.

* * * * *

(e) *Payments to MCOs and PIHPs for enrollees that are a patient in an institution for mental disease.* The State may make a monthly capitation payment to an MCO or PIHP for an enrollee aged 21–64 receiving inpatient treatment in an Institution for Mental Diseases, as defined in § 435.1010 of this chapter, so long as the facility is a hospital providing mental health or substance use disorder inpatient care or a sub-acute facility providing mental health or substance use disorder crisis residential services, and length of stay in the IMD is for a short term stay of no more than 15 days during the period of the monthly capitation payment. The provision of inpatient mental health or substance use disorder treatment in an IMD must meet the requirements for in lieu of services at § 438.3(e)(2)(i) through (iii). For purposes of rate setting, the State may use the utilization of services provided to an enrollee under this section when developing the inpatient mental health or substance use disorder component of the capitation rate, but must price utilization at the cost of the same services through providers included under the State plan.

■ 7. Amend § 438.7 by—

■ a. Revising paragraph (b)(6); and

■ b. Adding paragraphs (c)(4) through (6) and (f) and (g).

The revisions and additions read as follows:

§ 438.7 Rate certification submission.

* * * * *

(b) * * *

(6) *Special contract provisions.* A description of any of the special contract provisions related to payment in § 438.6 and ILOS in § 438.3(e)(2) that are applied in the contract.

(c) * * *

(4) The State must submit a revised rate certification for any changes in the capitation rate per rate cell, as required under paragraph (a) of this section for any special contract provisions related to payment described in § 438.6 and ILOS in § 438.3(e)(2) not already described in the rate certification, regardless of the size of the change in the capitation rate per rate cell.

(5) Retroactive adjustments to the capitation rates, as outlined in paragraph (c)(2), resulting from a State directed payment described in § 438.6(c) must be a result of adding or amending any State directed payment consistent with the requirements in § 438.6(c), or a material error in the data, assumptions or methodologies used to develop the initial capitation rate adjustment such that modifications are necessary to correct the error.

(6) The rate certification or retroactive adjustment to capitation rates resulting from any State directed payments for which the State has obtained written prior approval under § 438.6(c)(2)(i) must be submitted no later than 120 days after the start date of the State directed payment for which the State has obtained written prior approval under § 438.6(c)(2)(i) of this section or 120 days after the date CMS issued written prior approval of the State directed payment under § 438.6(c)(2)(i) of this section, whichever is later.

* * * * *

(f) *State certification.* The State, through its actuary, must certify the total dollar amount for each separate payment term included in the State's MCO, PIHP or PAHP contracts in alignment with the requirements of § 438.6(c)(6).

(1) The State may pay each MCO, PIHP or PAHP a different amount under the separate payment term that is different than the amount paid to another MCO, PIHP or PAHP, so long as the aggregate total dollars paid to all MCOs, PIHPs and PAHPs does not exceed the total dollars of the separate payment term for each respective Medicaid managed care program included in the Medicaid managed care contract.

(2) As part of the State's rate certification documentation for a separate payment term, the State, through its actuary, must provide an estimate of the impact of the separate payment term on a rate cell basis, as paid per the State directed payment approved by CMS under § 438.6(c)(2)(i).

(3) No later than 12 months following the end of the rating period, the State must submit documentation to CMS that demonstrates the impact of the separate payment term by rate cell for which the State has obtained written prior approval under § 438.6(c)(2)(i) consistent with the distribution methodology described in the State directed payment for which the State obtained written prior approval under § 438.6(c)(2)(i) in the manner and form required by CMS.

(4) Once CMS has issued written prior approval under § 438.6(c)(2)(i), the State must submit a rate certification or a rate certification amendment incorporating the separate payment term no later than 120 days after the start date of the State directed payment for which the State has obtained written prior approval under § 438.6(c)(2)(i) or 120 days after the date CMS issued written prior approval of the State directed payment under § 438.6(c)(2)(i), whichever is later.

(g) *Applicability dates.* (1) Paragraph (b)(6) of this section applies to the rating period for contracts with MCOs, PIHPs and PAHPs beginning on or after 60 days following [insert the effective date of the final rule]. Until that applicability date, States are required to continue to comply with paragraph (b)(6) of this section contained in 42 CFR, parts 430 to 481, edition most recently published prior to the final rule.

(2) Paragraphs (c)(4), (c)(5), (f)(1), (f)(2) and (f)(3) of this section applies beginning on [insert the effective date of the final rule].

(3) Paragraphs (c)(6) and (f)(4) of this section apply no later than the first rating period for contracts with MCOs, PIHPs and PAHPs beginning on or after 4 years after [insert the effective date of the final rule].

■ 8. Amend § 438.8 by—

■ a. Revising paragraph (e)(2)(iii)(A);

■ b. Adding paragraph (e)(2)(iii)(C);

■ c. Revising paragraph (e)(3)(i);

■ d. Adding paragraph (f)(2)(vii);

■ e. Revising paragraphs (h)(4) introductory text and (k)(1)(vii);

■ f. Adding paragraphs (k)(1)(xiv) through (xvi); and

■ g. Revising paragraph (m).

The revisions and additions read as follows:

§ 438.8 Medical loss ratio (MLR) standards.

* * * * *

(e) * * *

(2) * * *

(iii) * * *

(A) The amount of incentive and bonus payments made, or expected to be made, to network providers that are tied to clearly-defined, objectively measurable, and well-documented clinical or quality improvement standards that apply to providers.

* * * * *

(C) The amount of payments made under all contract arrangements that direct the MCO's, PIHP's, or PAHP's expenditures as specified in § 438.6(c)(1)(i) through (iii).

* * * * *

(3) * * *

(i) An MCO, PIHP, or PAHP activity that meets the requirements of 45 CFR 158.150(a) and (b) and is not excluded under 45 CFR 158.150(c).

* * * * *

(f) * * *

(2) * * *

(vii) Payments to the MCO, PIHP, or PAHP for expenditures approved under § 438.6(c)(1)(i) through (iii).

* * * * *

(h) * * *

(4) CMS will publish base credibility factors for MCOs, PIHPs, and PAHPs that are developed according to the following methodology:

* * * * *

(k) * * *

(1) * * *

(vii) Methodology(ies) for allocation of expenditures, which must include a detailed description of the methods used to allocate expenses, including incurred claims, quality improvement expenses, Federal and State taxes and licensing or regulatory fees, and other non-claims costs, as described in 45 CFR 158.170(b).

* * * * *

(xiv) The amount of payments made to providers under all contract arrangements that direct the MCO's, PIHP's, or PAHP's expenditures as described in § 438.6(c)(1)(i) through (iii).

(xv) Payments to the MCO, PIHP, or PAHP from the State for expenditures approved under § 438.6(c)(1)(i) through (iii).

(xvi) Paragraphs (k)(1)(xiv) and (xv) of this section apply to the rating period for contracts with MCOs. PIHPs, and PAHPs beginning on or after 60 days following [EFFECTIVE DATE OF THE FINAL RULE].

* * * * *

(m) *Recalculation of MLR.* In any instance where a State makes a retroactive change to the capitation rates for an MLR reporting year where the report has already been submitted to the State, the MCO, PIHP, or PAHP must re-

calculate the MLR for all MLR reporting years affected by the retroactive rate change and submit a new report meeting the requirements in paragraph (k) of this section.

* * * * *

■ 9. Amend § 438.10 by—

■ a. Revising paragraphs (c)(3), (d)(2), (g)(2)(ix), (h)(1) introductory text;

■ b. Adding paragraph (h)(1)(ix);

■ c. Revising paragraph (h)(2)(iv);

■ d. Adding paragraph (h)(3)(iii); and

■ e. Revising paragraph (j).

The revisions and additions read as follows:

§ 438.10 Information requirements.

* * * * *

(c) * * *

(3) The State must operate a website that provides the content, either directly or by linking to individual MCO, PIHP, PAHP, or PCCM entity web pages, specified at § 438.602(g) and elsewhere in this part. States must:

(i) Include all content, either directly or by linking to individual MCO, PIHP, PAHP, or PCCM entity websites, on one web page;

(ii) Include clear and easy to understand labels on documents and links;

(iii) Verify no less than quarterly, the accurate function of the website and the timeliness of the information presented; and

(iv) Explain that assistance in accessing the required information on the website is available at no cost and include information on the availability of oral interpretation in all languages and written translation available in each prevalent non-English language, how to request auxiliary aids and services, and a toll-free and TTY/TDY telephone number.

* * * * *

(d) * * *

(2) Make oral interpretation available in all languages and written translation available in each prevalent non-English language. Written materials that are critical to obtaining services for potential enrollees and experience surveys for enrollees must include taglines in the prevalent non-English languages in the State, explaining the availability of written translations or oral interpretation to understand the information provided, information on how to request auxiliary aids and services, and the toll-free telephone number of the entity providing choice counseling services as required by § 438.71(a). Taglines for written materials critical to obtaining services must be printed in a conspicuously-visible font size.

* * * * *

(g) * * *

(2) * * *

(ix) Enrollee rights and responsibilities, including the elements specified in § 438.100 and, if applicable, § 438.3(e)(2)(ii).

* * * * *

(h) * * *

(1) Each MCO, PIHP, PAHP, and when appropriate, the PCCM entity, must make available in paper form upon request and searchable electronic form, the following information about its network providers:

* * * * *

(ix) Whether the provider offers covered services via telehealth.

(2) * * *

(iv) Mental health and substance use disorder providers; and

* * * * *

(3) * * *

(iii) MCOs, PIHPs, or PAHPs must use the information received from the State pursuant to § 438.68(f)(1)(iii) to update provider directories no later than the timeframes specified in (h)(3)(i) and (ii).

* * * * *

(j) *Applicability.* States will not be held out of compliance with the requirements of paragraph (c)(3) of this section prior to the first rating period for contracts with MCOs, PIHPs, or PAHPs beginning on or after 2 years after [insert the effective date of the final rule], so long as they comply with the corresponding standard(s) codified in paragraph (c)(3) of this section contained in the 42 CFR, parts 430 to 481, most recently published before the final rule. States will not be held out of compliance with the requirements of paragraph (d)(2) of this section prior to the first rating period for contracts with MCOs, PIHPs, or PAHPs beginning on or after 3 years after the [insert the effective date of the final rule], so long as they comply with the corresponding standard(s) codified in paragraphs (d)(2) of this section contained in the 42 CFR, parts 430 to 481, most recently published before the final rule. States will not be held out of compliance with the requirements of paragraph (h)(1) of this section prior to July 1, 2025, so long as they comply with the corresponding standard(s) codified in paragraph (h)(1) of this section contained in the 42 CFR, parts 430 to 481, most recently published before the final rule. States will not be held out of compliance with the requirements of paragraph (h)(1)(ix) of this section prior to July 1, 2025. Paragraph (h)(3)(iii) of this section applies to the first rating period for contracts with MCOs, PIHPs and PAHPs beginning on or after 4 years after [insert the effective date of the final rule].

* * * * *

■ 10. Add § 438.16 to read as follows:

§ 438.16 In lieu of services and settings (ILOS) requirements.

(a) *Definitions.* As used in this part, the following terms have the indicated meanings:

Final ILOS cost percentage is the annual amount calculated, in accordance with paragraph (c)(3) of this section, specific to each managed care program that includes ILOS.

Projected ILOS cost percentage is the annual amount calculated, in accordance with paragraph (c)(2) of this section, specific to each managed care program that includes ILOS.

Summary report of actual MCO, PIHP, and PAHP ILOS costs is the report calculated, in accordance with paragraph (c)(4) of this section, specific to each managed care program that includes ILOS.

(b) *General rule.* An ILOS must be approvable as a service or setting through a waiver under section 1915(c) of the Act or a State plan amendment, including section 1905(a), 1915(i), or 1915(k) of the Act.

(c) *ILOS Cost Percentage and summary report of actual MCO, PIHP, and PAHP ILOS costs.*

(1) General rule. (i) The projected ILOS cost percentage calculated as required in paragraph (c)(2) of this section may not exceed 5 percent and the final ILOS cost percentage calculated as required in paragraph (c)(3) of this section may not exceed 5 percent.

(ii) The projected ILOS cost percentage, the final ILOS cost percentage, and the summary report of actual MCO, PIHP, and PAHP ILOS costs must be calculated on an annual basis and recalculated annually.

(iii) The projected ILOS cost percentage, the final ILOS cost percentage, and the summary report of actual MCO, PIHP, and PAHP ILOS costs must be certified by an actuary and developed in a reasonable and appropriate manner consistent with generally accepted actuarial principles and practices.

(2) *Calculation of the projected ILOS cost percentage.* The projected ILOS cost percentage is the result of dividing the amount determined in paragraph (c)(2)(i) of this section by the amount determined in paragraph (c)(2)(ii) of this section.

(i) The portion of the total capitation payments that is attributable to all ILOSs, excluding a short term stay in an

IMD as specified in § 438.6(e), for each managed care program.

(ii) The projected total capitation payments for each managed care program, including all State directed payments in effect under § 438.6(c) and pass-through payments in effect under § 438.6(d), and the projected total State directed payments in effect under § 438.6(c) that are paid as a separate payment term as described in § 438.6(c)(6).

(3) *Calculation of the final ILOS cost percentage.* The final ILOS cost percentage is the result of dividing the amount determined in paragraph (c)(3)(i) of this section by the amount determined in paragraph (c)(3)(ii) of this section.

(i) The portion of the total capitation payments that is attributable to all ILOSs, excluding a short term stay in an IMD as specified in § 438.6(e), for each managed care program.

(ii) The actual total capitation payments, defined at § 438.2, for each managed care program, including all State directed payments in effect under § 438.6(c) and pass-through payments in effect under § 438.6(d), and the actual total State directed payments in effect under § 438.6(c) that are paid as a separate payment term as described in § 438.6(c)(6).

(4) *Summary report of actual MCO, PIHP, and PAHP ILOS costs.* The State must submit to CMS a summary report of the actual MCO, PIHP and PAHP costs for delivering ILOSs based on the claims and encounter data provided by the MCO(s), PIHP(s) and PAHP(s).

(5) *CMS review of the projected ILOS cost percentage, the final ILOS cost percentage and the summary report of actual MCO, PIHP and PAHP ILOS costs.*

(i) The State must annually submit the projected ILOS cost percentage to CMS for review as part of the rate certification required in § 438.7(a).

(ii) The State must submit the final ILOS cost percentage and the summary report of actual MCO, PIHP, and PAHP ILOS costs annually to CMS for review as a separate report concurrent with the rate certification submission required in § 438.7(a) for the rating period beginning 2 years after the completion of each 12-month rating period that includes an ILOS.

(d) *Documentation requirements*—(1) *State requirements.* All States that include an ILOS in an MCO, PIHP, or PAHP contract are required to include, at minimum, the following:

(i) The name and definition of each ILOS;

(ii) The covered service or setting under the State plan for which each ILOS is a medically appropriate and cost-effective substitute;

(iii) The clinically defined target populations for which each ILOS is determined to be medically appropriate and cost effective;

(iv) The process by which a licensed network or MCO, PIHP, or PAHP staff provider, determines and documents in the enrollee's records that each identified ILOS is medically appropriate for the specific enrollee;

(v) The enrollee rights and protections, as defined in § 438.3(e)(2)(ii); and

(vi) A requirement that the MCO, PIHP, or PAHP will utilize specific codes established by the State that identify each ILOS in encounter data, as required under § 438.242.

(2) *Additional documentation requirements.* A State with a projected ILOS cost percentage that exceeds 1.5 percent is also required to provide the following documentation concurrent with the contract submission for review and approval by CMS under § 438.3(a).

(i) A description of the process and supporting evidence the State used to determine that each ILOS is a medically appropriate service or setting for the clinically defined target population(s), consistent with paragraph (d)(1)(iii) of this section.

(ii) A description of the process and supporting data the State used to determine that each ILOS is a cost-effective substitute for the clinically defined target population(s), consistent with paragraph (d)(1)(iii) of this section.

(3) *Provision of additional information.* At the request of CMS, the State must provide additional information, whether part of the MCO, PIHP or PAHP contract, rate certification or supplemental materials, if CMS determines that the requested information is pertinent to the review and approval of a contract that includes ILOS.

(e) *Monitoring, evaluation and oversight.* (1) *Retrospective evaluation.* A State with a final ILOS cost percentage that exceeds 1.5 percent, is required to submit at least one retrospective evaluation of ILOS to CMS. The retrospective evaluation must:

(i) Be completed separately for each managed care program that includes an ILOS.

(ii) Be completed using the 5 most recent years of accurate and validated data for the ILOS. The State must utilize these data to at least evaluate cost, utilization, access, grievances and appeals, and quality of care for each ILOS.

(iii) Evaluate at least:

(A) The impact each ILOS had on utilization of State plan approved services or settings, including any associated cost savings;

(B) Trends in MCO, PIHP, or PAHP and enrollee use of each ILOS;

(C) Whether encounter data supports the State's determination that each ILOS is a medically appropriate and cost-effective substitute for the identified covered service and setting under the State plan or a cost-effective measure to reduce or prevent the future need to utilize the covered service and setting under the State plan;

(D) The impact of each ILOS on quality of care;

(E) The final ILOS cost percentage for each year consistent with the report in paragraph (c)(5)(ii) of this section with a declaration of compliance with the allowable threshold in paragraph (c)(1)(i) of this section;

(F) Appeals, grievances, and State fair hearings data, reported separately, related to each ILOS, including volume, reason, resolution status, and trends; and

(G) The impact each ILOS had on health equity efforts undertaken by the State to mitigate health disparities.

(iv) The State must submit the retrospective evaluation to CMS no later than 2 years after the completion of the first 5 rating periods that included ILOS.

(v) CMS reserves the right to require the State to submit additional retrospective evaluations to CMS.

(2) *Oversight.* Oversight for each ILOS must include the following:

(i) *State notification requirement.* The State must notify CMS within 30 calendar days if:

(A) The State determines that an ILOS is no longer a medically appropriate or cost effective substitute for the covered service or setting under the State plan identified in the contract as required in paragraph (d)(1)(ii) of this section; or

(B) The State identifies noncompliance with requirements in this section.

(ii) *CMS oversight process.* If CMS determines that a State is out of compliance with any requirement in this part or receives a State notification in paragraph (e)(2)(i) of this section, CMS may require the State to terminate the use of an ILOS.

(iii) *Process for termination of ILOS.* When a State decides to terminate an ILOS, an MCO, PIHP or PAHP decides to cease offering an ILOS to its enrollees, or CMS makes the decision to require the State to terminate an ILOS, the State must submit an ILOS transition plan to CMS for review and approval within 15 calendar days of the

decision. The transition plan must include at least the following:

(A) A process to notify enrollees of the termination of an ILOS that they are currently receiving as expeditiously as the enrollee's health condition requires.

(B) A transition of care policy, not to exceed 12 months, to arrange for State plan services and settings to be provided timely and with minimal disruption to care to any enrollee who is currently receiving the ILOS that will be terminated. The State must make the transition of care policy publicly available.

(C) An assurance the State will submit the modification of the MCO, PIHP, or PAHP contract to remove the ILOS and submission of the modified contracts to CMS as required in § 438.3(a), and a reasonable timeline for submitting the contract amendment.

(D) An assurance the State and its actuary will submit an adjustment to the actuarially sound capitation rate, as needed, to remove utilization and cost of the ILOS from capitation rates as required in §§ 438.4, 438.7(a) and 438.7(c)(2), and a reasonable timeline for submitting the revised rate certification.

(f) *Applicability date.* Section 438.16 applies to the rating period for contracts with MCOs, PIHPs and PAHPs beginning on or after 60 days following [insert the effective date of the final rule].

■ 11. Amend § 438.66 by revising paragraphs (b)(4), (c)(5), (e)(2)(vi) and (vii), and (e)(3)(i), and (f) to read as follows:

§ 438.66 State monitoring requirements.

* * * * *

(b) * * *

(4) Enrollee materials, enrollee experience, and customer services, including the activities of the beneficiary support system.

* * * * *

(c) * * *

(5) Results from an annual enrollee experience survey conducted by the State and any provider satisfaction survey conducted by the State or MCO, PIHP, or PAHP.

* * * * *

(e) * * *

(2) * * *

(vi) Availability and accessibility of covered services, including any ILOS, within the MCO, PIHP, or PAHP contracts, including network adequacy standards.

(vii) Evaluation of MCO, PIHP, or PAHP performance on quality measures and results of an enrollee experience survey, including as applicable, consumer report card, provider surveys, or other reasonable measures of performance.

* * * * *

(3) * * *

(i) Posted on the website required under § 438.10(c)(3) within 30 calendar days of submitting it to CMS.

* * * * *

(f) With respect to applicability, States will not be held out of compliance with the requirements of paragraphs (b) through (c) of this section prior to the first rating period for contracts with MCOs, PIHPs, or PAHPs beginning on or after 3 years after [insert the effective date of the final rule], so long as they comply with the corresponding standard(s) codified in § 438.66 contained in the 42 CFR, parts 430 to 481, edition most recently published prior to the final rule.

■ 12. Amend § 438.68 by—

■ a. Revising paragraphs (b)(1) introductory text, (b)(1)(iii), (d)(1), (d)(2) and (e); and

■ b. Adding paragraphs (f) through (h).

The revisions and additions read as follows:

§ 438.68 Network adequacy standards.

* * * * *

(b) * * *

(1) *Provider types.* At a minimum, a State must develop a quantitative network adequacy standard, other than appointment wait times, for the following provider types, if covered under the contract:

* * * * *

(iii) Mental health and substance use disorder, adult and pediatric.

* * * * *

(d) * * *

(1) To the extent the State permits an exception to any of the provider-specific network standards developed under this section, the standard by which the exception will be evaluated and approved must:

(i) Be specified in the MCO, PIHP or PAHP contract.

(ii) Be based, at a minimum, on the number of providers in that specialty practicing in the MCO, PIHP, or PAHP service area.

(iii) Include consideration of the payment rates offered by the MCO, PIHP, or PAHP to the provider type for which an exception is being requested.

(2) States that grant an exception in accordance with paragraph (d)(1) of this section to an MCO, PIHP or PAHP must monitor enrollee access to that provider type on an ongoing basis and include the findings to CMS in the managed care program assessment report required under § 438.66(e).

(e) *Appointment wait time standards.* States must establish and enforce appointment wait time standards.

(1) *Routine appointments.* Standards must be established for routine appointments with the following provider types and within the specified limits:

(i) If covered in the MCO's, PIHP's, or PAHP's contract, outpatient mental health and substance use disorder, adult and pediatric, within State-established time frames but no longer than 10 business days from the date of request.

(ii) If covered in the MCO's, PIHP's, or PAHP's contract, primary care, adult and pediatric, within State-established time frames but no longer than 15 business days from the date of request.

(iii) If covered in the MCO's, PIHP's, or PAHP's contract, obstetrics and gynecological within State-established time frames but no longer than 15 business days from the date of request.

(iv) State-selected, other than those listed in paragraphs (e)(1)(i) through (iii) of this section, chosen in an evidence-based manner within State-established time frames.

(2) *Minimum compliance.* MCOs, PIHPs, and PAHPs will be deemed compliant with the standards established in paragraph (e)(1) of this section when secret shopper results, consistent with paragraph (f)(2) of this section, reflect a rate of appointment availability that meets the standards established at paragraph (e)(1)(i) through (iv) of at least 90 percent.

(3) *Selection of additional types of providers.* After consulting with States and other interested parties and providing public notice and opportunity to comment, CMS may select additional types of providers to be added to paragraph (e)(1) of this section.

(f) *Secret shopper surveys.* States must contract with an entity, independent of the State Medicaid agency and any of its contracted MCOs, PIHPs and PAHPs subject to the survey, to conduct annual secret shopper surveys of each MCO's, PIHP's, and PAHP's compliance with the provider directory requirements in § 438.10(h) as specified in paragraph (f)(1) of this section and appointment wait time requirements as specified in paragraph (f)(1) of this section.

(1) *Provider directories.* (i) A secret shopper survey must be conducted to determine the accuracy of the information specified in paragraph (f)(1)(ii) of this section in each MCO's, PIHP's, and PAHP's most current electronic provider directories, as required at § 438.10(h), for the following provider types:

(A) Primary care providers, if they are included in the MCO's, PIHP's, or PAHP's provider directory;

(B) Obstetric and gynecological providers, if they are included in the MCO's, PIHP's, or PAHP's provider directory;

(C) Outpatient mental health and substance use disorder providers, if they are included in the MCO's, PIHP's, or PAHP's provider directory; and

(D) The provider type chosen by the State in (e)(1)(iv).

(ii) A secret shopper survey must assess the accuracy of the information in each MCO's, PIHP's, and PAHP's most current electronic provider directories for at least:

(A) The active network status with the MCO, PIHP, or PAHP;

(B) The street address(es) as required at § 438.10(h)(1)(ii);

(C) The telephone number(s) as required at § 438.10(h)(1)(iii); and

(D) Whether the provider is accepting new enrollees as required at § 438.10(h)(1)(vi).

(iii) States must receive information, sufficient to facilitate correction by the MCO, PIHP, or PAHP, on errors in directory data identified in secret shopper surveys from the entity conducting the secret shopper survey no later than 3 business days from the day the error is identified by the entity conducting the secret shopper survey.

(iv) States must send information required in paragraph (f)(1)(iii) of this section to the applicable MCO, PIHP, or PAHP no later than 3 business days from receipt.

(2) *Timely appointment access.* A secret shopper survey must be used to determine each MCO's, PIHP's, and PAHP's rate of network compliance with the appointment wait time standards in paragraph (e)(1) of this section.

(i) After consulting with States and other interested parties and providing public notice and opportunity to comment, CMS may select additional types of appointments to be added to a secret shopper survey.

(ii) Appointments offered via telehealth can only be counted toward compliance with the appointment wait time standards in paragraph (e)(1) of this section if the provider being surveyed also offers in-person appointments to the MCO's, PIHP's, or PAHP's enrollees and must be identified separately from in-person appointments in survey results.

(3) *Independence.* An entity will be considered independent of the State as specified in paragraph (f)(3)(i) of this section and independent of the MCOs, PIHPs, or PAHPs subject to the surveys as specified in paragraph (f)(3)(ii) of this section.

(i) An entity will be considered independent of the State if it is not part of the State Medicaid agency.

(ii) An entity will be considered independent of an MCO, PIHP, or PAHP subject to the secret shopper surveys if the entity is not an MCO, PIHP, or PAHP, is not owned or controlled by any of the MCOs, PIHPs, or PAHPs subject to the surveys, and does not own or control any of the MCOs, PIHPs, or PAHPs subject to the surveys.

(4) *Methodological standards.* Secret shopper surveys required in this paragraph must:

(i) Use a random sample;

(ii) Include all areas of the State covered by the MCO's, PIHP's, or PAHP's contract; and

(iii) For secret shopper surveys required in paragraph (f)(2) of this section for appointment wait time standards, be completed for a statistically valid sample of providers.

(5) *Results reporting.* Results of the secret shopper surveys conducted pursuant to paragraphs (f)(1) and (2) of this section must be analyzed, summarized, and:

(i) Reported to CMS using the content, form, and submission times as specified at § 438.207(d); and

(ii) Posted on the State's website required at § 438.10(c)(3) within 30 calendar days of submission to CMS.

(g) *Publication of network adequacy standards.* States must publish the standards developed in accordance with paragraphs (b)(1) and (2), and (e) of this section on the website required by § 438.10(c)(3). Upon request, network adequacy standards must also be made available at no cost to enrollees with disabilities in alternate formats or through the provision of auxiliary aids and services.

(h) *Applicability.* States will not be held out of compliance with the requirements of paragraph (b)(1) and of this section prior to the first rating period beginning on or after 3 years after [insert the effective date of the final rule], so long as they comply with the corresponding standard(s) codified in paragraphs (b) of this section contained in the 42 CFR, parts 430 to 481, most recently published before the final rule. Paragraph (d)(1)(iii) of this section applies to the first rating period for contracts with MCOs, PIHPs and PAHPs beginning on or after 2 years after [insert the effective date of the final rule]. Paragraph (e) of this section applies to the first rating period for contracts with MCOs, PIHPs and PAHPs beginning on or after 3 years after [insert the effective date of the final rule]. Paragraph (f) of this section applies to the first rating period for contracts with MCOs, PIHPs and PAHPs beginning on or after 4 years after [insert the effective date of the final rule]. States will not be held out of compliance with the requirements of paragraph (g) of this section prior to the first rating period that begins on or after 3 years after [insert the effective date of the final rule], so long as they comply with the corresponding standard(s) codified in paragraph (g) of this section contained in the 42 CFR, parts 430 to 481, most recently published before the final rule.

■ 13. Amend § 438.74 by revising paragraph (a) to read as follows:

§ 438.74 State oversight of the minimum MLR requirement.

(a) *State reporting requirement.* (1) The State must annually submit to CMS a summary description of each report(s) received from the MCO(s), PIHP(s), and PAHP(s) under contract with the State, according to § 438.8(k), with the rate certification required in § 438.7.

(2) The summary description must be provided for each MCO, PIHP, or PAHP under contract with the State and must include, at a minimum, the amount of the numerator, the amount of the denominator, the MLR percentage achieved, the number of member months, and any remittances owed by each MCO, PIHP, or PAHP for that MLR reporting year.

(3) The summary description must also include line items for:

(i) The amount of payments made under all contract arrangements that direct the MCO's, PIHP's, or PAHP's expenditures as specified in § 438.6(c)(1)(i) through (iii); and

(ii) Payments to the MCO, PIHP, or PAHP for expenditures approved under § 438.6(c)(1)(i) through (iii).

(4) Paragraph (a)(3) of this section applies to the rating period for contracts with MCOs, PIHPs, and PAHPs beginning on or after 60 days following [insert the effective date of the final rule].

* * * * *

■ 14. Amend § 438.206 by revising paragraphs (c)(1)(i) and (d) to read as follows:

§ 438.206 Availability of services.

* * * * *

(c) * * *

(1) * * *

(i) Meet and require its network providers to meet State standards for timely access to care and services taking into account the urgency of the need for services as well as appointment wait times specified in § 438.68(e).

* * * * *

(d) *Applicability date.* States will not be held out of compliance with the requirements of paragraphs (c)(1)(i) of this section prior to the first rating period that begins on or after 4 years after [insert the effective date of the final rule], so long as they comply with the corresponding standard(s) codified in paragraph (c)(1)(i) of this section contained in the 42 CFR, parts 430 to 481, most recently published before the final rule.

* * * * *

■ 15. Amend § 438.207—

■ a. In paragraph (b)(1), by removing the ''.'' at the end of the paragraph and adding in its place '';''.

■ b. In paragraph (b)(2), by removing the ''.'' at the end of the paragraph and adding in its place ''; and'';

■ c. By adding paragraph (b)(3);

■ d. By revising paragraphs (d) and (e);

■ e. By revising paragraph (f) and adding paragraph (g).

The revisions and additions read as follows:

§ 438.207 Assurances of adequate capacity and services.

* * * * *

(b) * * *

(3) Except as specified in paragraphs (b)(3)(iii) and (iv) of this section and if covered by the MCO's, PIHP's, or PAHP's contract, provides a payment analysis using paid claims data from the immediately prior rating period that demonstrates each MCO's, PIHP's, or PAHP's level of payment as specified in paragraphs (b)(3)(i) and (ii) of this section.

(i) The payment analysis must provide the total amount paid for evaluation and management current procedural terminology codes in the paid claims data from the prior rating period for primary care, OB/GYN, mental health, and substance use disorder services, as well as the percentage that results from dividing the total published Medicare payment rate for the same services.

(A) A separate total and percentage must be reported for primary care, obstetrics and gynecology, mental health, and substance use disorder services; and

(B) If the percentage differs between adult and pediatric services, the percentages must be reported separately.

(ii) For homemaker services, home health aide services, and personal care services, the payment analysis must provide the total amount paid and the percentage that results from dividing the total amount paid by the amount the State's Medicaid FFS program would have paid for the same services.

(A) A separate total and percentage must be reported for homemaker services, home health aide services, and personal care services; and

(B) If the percentage differs between adult and pediatric services, the percentages must be reported separately.

(iii) Payments by MCOs, PIHPS, and PAHPs for the services specified in § 438.207(b)(3)(i) but for which the MCO, PIHP, or PAHP is not the primary payer are excluded from the analysis required in this paragraph.

(iv) Services furnished by a Federally-qualified health center as defined in section 1905(l)(2) and services furnished by a rural health clinic as defined in section 1905(l)(1) are excluded from the analysis required in this paragraph.

* * * * *

(d) *State review and certification to CMS.* After the State reviews the documentation submitted by the MCO, PIHP, or PAHP as specified in paragraph (b) of this section and the secret shopper evaluation results as required at § 438.68(f), the State must submit an assurance of compliance to CMS, in the format prescribed by CMS, that the MCO, PIHP, or PAHP meets the State's requirements for availability of services, as set forth in §§ 438.68 and 438.206.

(1) The submission to CMS must include documentation of an analysis that supports the assurance of the adequacy of the network for each contracted MCO, PIHP or PAHP related to its provider network.

(2) The analysis in paragraph (d)(1) of this section must include the payment analysis submitted by each MCO, PIHP, or PAHP, as required in paragraph (b)(3) of this section, and contain:

(i) The data provided by each MCO, PIHP, and PAHP in paragraph (b)(3) of this section; and

(ii) A State level payment percentage for each service type specified in paragraphs (b)(3)(i) and (ii) of this section produced by using the number of member months for the applicable rating period to weight each MCO's, PIHP's, or PAHP's reported percentages, as required in paragraph (b)(3) of this section.

(3) States must submit the assurance of compliance required in paragraph (d) of this section as specified in paragraphs (i) through (iii) of this section and post the report on the State's website required in § 438.10(c)(3) within 30 calendar days of submission to CMS.

(i) At the time it submits a completed readiness review, as specified at § 438.66(d)(1)(iii).

(ii) On an annual basis and no later than 180 calendar days after each rating period.

(iii) At any time there has been a significant change as specified in paragraph (c)(3) of this section and with the submission of the associated contract, as required at § 438.3(a).

(e) *CMS' right to inspect documentation.* The State must make available to CMS, upon request, all documentation collected by the State from the MCO, PIHP, or PAHP as well as documentation from all secret shopper surveys required at § 438.68(f).

(f) *Remedy plans to improve access.* (1) When the State, MCO, PIHP, PAHP, or CMS identifies an area in which an MCO's, PIHP's, or PAHP's access to care under the access standards in this part could be improved, including the standards at §§ 438.68 and 438.206, the State must:

(i) Submit to CMS for approval a remedy plan as specified in paragraph (f)(ii) of this section no later than 90 calendar days following the date that the State becomes aware of an MCO's, PIHP's, or PAHP's access issue;

(ii) Develop a remedy plan that addresses the identified access issue within 12 months and that identifies specific steps with timelines for implementation and completion, and responsible parties. State's and managed care plans' actions may include a variety of approaches, including, but not limited to: increasing payment rates to providers, improving outreach and problem resolution to providers, reducing barriers to provider credentialing and contracting, providing for improved or expanded use of telehealth, and improving the timeliness and accuracy of processes such as claim payment and prior authorization;

(iii) Ensure that improvements in access are measurable and sustainable; and

(iv) Submit quarterly progress updates to CMS on implementation of the remedy plan.

(2) If the remedy plan required in paragraph(f)(1) of this section does not result in addressing the MCO's, PIHP's, or PAHP's access issue by improving access within 12 months, CMS may require the State to continue the remedy plan for another 12 months and may require revision to the remedy plan required in paragraph (f)(1) of this section.

(g) *Applicability date.* Paragraphs (b)(3) and (d)(2) of this section apply to the first rating period for contracts with MCOs, PIHPs, or PAHPs beginning on or after 2 years after [insert the effective date of the final rule]. Paragraph (d)(3) of this section applies to the first rating period beginning on or after 1 year after [insert the effective date of the final rule]. States will not be held out of

compliance with the requirements of paragraph (e) of this section prior to the rating period beginning on or after 4 year after [insert the effective date of the final rule], so long as they comply with the corresponding standard(s) codified in paragraph (e) of this section contained in the 42 CFR, parts 430 to 481, most recently published before the final rule. Paragraph (f) of this section applies to the first rating period for contracts with MCOs, PIHPs, or PAHPs beginning on or after 4 years after [EFFECTIVE DATE OF THE FINAL RULE].

■ 16. Amend § 438.214 is amended by—
■ a. Revising paragraph (b)(1); and
■ b. Adding paragraph (d)(2).

The revision and addition read as follows:

§ 438.214 Provider Selection.

* * * * *

(b) * * *

(1) Each State must establish a uniform credentialing and recredentialing policy that addresses acute, primary, mental health, substance use disorders, and LTSS providers, as appropriate, and requires each MCO, PIHP and PAHP to follow those policies.

* * * * *

(d) * * *

(2) States must ensure through its contracts that MCOs, PIHPs, and PAHPs terminate any providers of services or persons terminated (as described in section 1902(kk)(8) of the Social Security Act) from participation under this title, title XVIII, or title XXI from participating as a provider in any network.

* * * * *

■ 17. Amend § 438.310 by revising paragraphs (b)(5) introductory text, (c)(2), and (d) to read as follows:

§ 438.310 Basis, scope, and applicability.

* * * * *

(b) * * *

(5) Requirements for annual external quality reviews of each contracting MCO, PIHP, PAHP including—

* * * * *

(c) * * *

(2) The provisions of § 438.330(b)(2) and (3), (c), and (e), and § 438.340 apply to States contracting with PCCM entities whose contracts with the State provide for shared savings, incentive payments or other financial reward for the PCCM entity for improved quality outcomes.

* * * * *

(d) *Applicability dates.* States will not be held out of compliance with the following requirements of this subpart prior to the dates noted below so long as they comply with the corresponding standard(s) in 42 CFR part 438 contained in the 42 CFR parts 430 to 481, edition revised as of [insert effective date of final rule]:

(1) States must comply with § 438.330(d)(4) no later than the rating period for contracts beginning after [insert the effective date of the final rule].

(2) States must comply with updates to § 438.340 no later than 1 year from [insert the effective date of the final rule].

(3) States must comply with updates to §§ 438.358 and 438.364(c)(2)(iii) no later than December 31, 2025.

(4) States must comply with § 438.364(a)(2)(iii) no later 1 year from the issuance of the associated protocol.

■ 18. Amend § 438.330 by revising paragraph (d)(4) to read as follows:

§ 438.330 Quality assessment and performance improvement program.

* * * * *

(d) * * *

(4) The State may permit an MCO, PIHP, or PAHP exclusively serving dual eligibles to substitute an MA organization chronic care improvement program conducted under § 422.152(c) of this chapter for one or more of the performance improvement projects otherwise required under this section.

* * * * *

§ 438.334 [Removed and reserved]

■ 19. Section 438.334 is removed and reserved.

■ 20. Amend § 438.340 by revising paragraphs (b)(4), (c)(1) introductory text, (c)(2)(ii), and (c)(3) to read as follows:

§ 438.340 Managed care State quality strategy.

* * * * *

(b) * * *

(4) Arrangements for annual, external independent reviews, in accordance with § 438.350, of the quality outcomes and timeliness of, and access to, the services covered under each MCO, PIHP, and PAHP contract.

* * * * *

(c) * * *

(1) Make the strategy available for public comment before submitting the strategy to CMS for review in accordance with paragraph (c)(3) of this section, including:

* * * * *

(2) * * *

(ii) The State must make the results of the review, including the evaluation conducted pursuant to paragraph (c)(2)(i) of this section, available on the website required under § 438.10(c)(3).

* * * * *

(3) Prior to adopting as final, submit to CMS the following:

(i) A copy of the initial strategy for CMS comment and feedback.

(ii) A copy of the strategy—

(A) Every 3 years following the review in paragraph (c)(2) of this section;

(B) Whenever significant changes, as defined in the State's quality strategy per paragraph (b)(10) of this section, are made to the document;

(C) Whenever significant changes occur within the State's Medicaid program.

* * * * *

§ 438.344 [Removed and reserved]

■ 21. Remove and reserve 438.344.

■ 22. Amend § 438.350 by revising the introductory text and paragraph (a) to read as follows:

§ 438.350 External quality review.

Each State that contracts with MCOs, PIHPs, or PAHPs must ensure that—

(a) Except as provided in § 438.362, a qualified EQRO performs an annual EQR for each such contracting MCO, PIHP, or PAHP.

* * * * *

■ 23. Amend § 438.354 by revising paragraph (c)(2)(iii) to read as follows:

§ 438.354 Qualifications of external quality review organizations.

* * * * *

(c) * * *

(2) * * *

(iii) Conduct, on the State's behalf, ongoing Medicaid managed care program operations related to oversight of the quality of MCO, PIHP, PAHP, or PCCM entity (described in § 438.310(c)(2)) services that it will review as an EQRO, except for the related activities specified in § 438.358;

* * * * *

■ 24. Amend § 438.358 by—
■ a. Revising paragraph (a)(1);
■ b. Adding paragraph (a)(3);
■ c. Revising paragraphs (b)(1) introductory text, (b)(1)(i), (ii), and (iv);
■ d. Removing and reserving paragraph (b)(2);
■ e. Revising paragraph (c) introductory text and (c)(6); and
■ f. Adding paragraph (c)(7).

The revisions read as follows:

§ 438.358 Activities related to external quality review.

(a) * * *

(1) The State, its agent that is not an MCO, PIHP, or PAHP or an EQRO may perform the mandatory and optional EQR-related activities in this section.

* * * * *

(3) For the EQR-related activities described in § 438.350(b)(1) and (c) of

this subpart (except § 438.350(b)(1)(iii)), the review period begins on the first day of the most recently concluded contract year or calendar year, whichever is nearest to the date of the EQR-related activity, and is 12 months in duration.

(b) * * *

(1) For each MCO, PIHP, or PAHP the following EQR-related activities must be performed in the 12 months preceding the finalization of the annual report:

(i) Validation of performance improvement projects required in accordance with § 438.330(b)(1) that were underway during the EQR review period per paragraph (a)(3) of this section.

(ii) Validation of MCO, PIHP, or PAHP performance measures required in accordance with § 438.330(b)(2) or MCO, PIHP, or PAHP performance measures calculated by the State during the EQR review period described in paragraph (a)(3) of this section.

* * * * *

(iv) Validation of MCO, PIHP, or PAHP network adequacy during the EQR review period per paragraph (a)(3) of this section to comply with requirements set forth in § 438.68 and, if the State enrolls Indians in the MCO, PIHP, or PAHP, § 438.14(b)(1).

(2) [Reserved]

(c) *Optional activities.* For each MCO, PIHP, PAHP, and PCCM entity (described in § 438.310(c)(2)), the following activities may be performed in the 12 months preceding the annual report by using information derived during the EQR review period described in paragraph (a)(3) of this section:

* * * * *

(6) Assist with the quality rating of MCOs, PIHPs, and PAHPs consistent with 42 CFR part 438, subpart G.

(7) Assist with evaluations required under §§ 438.16(e)(1), 438.340(c)(2)(i), and 438.6(c)(2)(iv) and (v) pertaining to outcomes, quality, or access to health care services

* * * * *

■ 25. Amend § 438.360 by revising paragraph (a)(1) to read as follows:

§ 438.360 Nonduplication of mandatory activities with Medicare or accreditation review.

(a) * * *

(1) The MCO, PIHP, or PAHP is in compliance with the applicable Medicare Advantage standards established by CMS, as determined by CMS or its contractor for Medicare, or has obtained accreditation from a private accrediting organization recognized by CMS;

* * * * *

■ 26. Amend § 438.362 by revising paragraph (b)(2) paragraph heading and (b)(2)(i) to read as follows:

§ 438.362 Exemption from external quality review.

* * * * *

(b) * * *

(2) *Medicare information from a private accrediting organization.* (i) If an exempted MCO has been reviewed by a private accrediting organization, the State must require the MCO to provide the State with a copy of all findings pertaining to its most recent accreditation review if that review has been used to fulfill certain requirements for Medicare external review under subpart D of part 422 of this chapter.

* * * * *

■ 27. Amend § 438.364 by revising paragraphs (a)(1), (a)(2)(iii), (a)(3) through (6), (c)(1) and (c)(2) to read as follows:

§ 438.364 External quality review results.

(a) * * *

(1) A description of the manner in which the data from all activities conducted in accordance with § 438.358 were aggregated and analyzed, and conclusions were drawn as to the quality, timeliness, and access to the care furnished by the MCO, PIHP, or PAHP.

(2) * * *

(iii) The data and a description of data obtained, including validated performance measurement, any outcomes data and results from quantitative assessments, for each activity conducted in accordance with § 438.358(b)(1)(i), (ii) and (iv) of this subpart; and

* * * * *

(3) An assessment of each MCO's, PIHP's, or PAHP's-strengths and weaknesses for the quality, timeliness, and access to health care services furnished to Medicaid beneficiaries.

(4) Recommendations for improving the quality of health care services furnished by each MCO, PIHP, or PAHP, including how the State can target goals and objectives in the quality strategy, under § 438.340, to better support improvement in the quality, timeliness, and access to health care services furnished to Medicaid beneficiaries.

(5) Methodologically appropriate, comparative information about all MCOs, PIHPs, or PAHPs, consistent with guidance included in the EQR protocols issued in accordance with § 438.352(e).

(6) An assessment of the degree to which each MCO, PIHP, or PAHP has addressed effectively the recommendations for quality improvement made by the EQRO during the previous year's EQR.

* * * * *

(c) * * *

(1) The State must contract with a qualified EQRO to produce and submit to the State an annual EQR technical report in accordance with paragraph (a) of this section. The State must finalize the annual technical report by December 31st of each year.

(2) The State must—

(i) Post the most recent copy of the annual EQR technical report on the website required-under § 438.10(c)(3) by December 31st of each year and notify CMS, in a form and manner determined by CMS, within 14 calendar days of the Web posting.

(ii) Provide printed or electronic copies of the information specified in paragraph (a) of this section, upon request, to interested parties such as participating health care providers, enrollees and potential enrollees of the MCO, PIHP, or PAHP beneficiary advocacy groups, and members of the general public.

(iii) Maintain at least the previous 5 years of EQR technical reports on the on the website required under § 438.10(c)(3).

* * * * *

■ 28. Subpart G is added to part 438 to read as follows:

Subpart G—Medicaid Managed Care Quality Rating System

Sec.

§ 438.500 Definitions.

(a) Definitions. As used in this subpart, the following terms have the indicated meanings:

Measurement period means the period for which data are collected for a measure or the performance period that a measure covers.

Measurement year means the first calendar year and each calendar year thereafter for which a full calendar year of claims and encounter data necessary to calculate a measure are available.

Medicaid managed care quality rating system framework (QRS framework) means the mandatory measure set identified by CMS in the Medicaid and CHIP managed care quality rating

system technical resource manual described in § 438.530, the methodology for calculating quality ratings described in § 438.515, and the website display described in § 438.520 of this subpart.

Medicare Advantage and Part D 5-Star Rating System (MA and Part D quality rating system) means the rating system described in subpart D of parts 422 of 423 of this chapter.

Qualified health plan rating system (QHP quality rating system) means the health plan quality rating system developed in accordance with 45 CFR 156.1120.

Quality rating means the numeric or other value of a quality measure or an assigned indicator that data for the measure is not available.

Technical resource manual means the guidance described in § 438.530.

Validation means the review of information, data, and procedures to determine the extent to which they are accurate, reliable, free from bias, and in accord with standards for data collection and analysis.

§ 438.505 General rule and applicability.

(a) *General rule.* As part of its quality assessment and improvement strategy for its managed care program, each State contracting with an applicable managed care plan, as described in paragraph (b) of this section, to furnish services to Medicaid beneficiaries must—

(1)(i) Adopt the QRS framework developed by CMS; or

(ii) Adopt an alternative managed care quality rating system in accordance with § 438.525 of this subpart.

(2) Implement such managed care quality rating system by the end of the fourth calendar year following [the effective date of the final rule published in the **Federal Register**], unless otherwise specified in this subpart.

(3) Use the State's beneficiary support system implemented under § 438.71 to provide the services identified at § 438.71(b)(1)(i) and (ii) to beneficiaries, enrollees, or both seeking assistance using the managed care quality rating system implemented by the State under this subpart.

(b) *Applicability.* The provisions of this subpart apply to States contracting with MCOs, PIHPs, and PAHPs for the delivery of services covered under Medicaid. The provisions of this subpart do not apply to States contracting with Medicare Advantage Dual Eligible Special Needs Plans for only Medicaid coverage of Medicare cost sharing.

(c) *Continued alignment.* To maintain the QRS framework, CMS aligns the mandatory measure set and methodology described in § 438.510 and § 438.515 of this subpart, to the extent appropriate, with the qualified health plan quality rating system developed in accordance with 45 CFR 156.1120, the MA and Part D quality rating system, and other similar CMS quality measurement and rating initiatives.

§ 438.510 Mandatory QRS measure set for Medicaid managed care quality rating system.

(a) *Measures required.* The quality rating system implemented by the State must include the measures in the mandatory QRS measure set identified by CMS in the Medicaid and CHIP managed care quality rating system technical resource manual, and may include other measures identified by the State as described in § 438.520(b).

(b) *Subregulatory process to update mandatory measure set.* Subject to paragraph (d) of this section, CMS will update the mandatory measure set at least every other year, including the addition, removal or updating of mandatory measures after:

(1) Engaging with States and other interested parties (such as State officials, measure experts, health plans, beneficiary advocates, tribal organizations, health plan associations, and external quality review organizations) to evaluate the current mandatory measure set and make recommendations to add, remove or update existing measures based on the criteria and standards in paragraph (c) of this section; and

(2) Providing public notice and opportunity to comment through a call letter (or similar subregulatory process using written guidance) on any planned modifications to the mandatory measure set following the engagement described in paragraph (b)(1) of this section.

(c) *Standards for adding mandatory measures.* Based on available relevant information, including the input received during the process described in paragraph (b) of this section, CMS will add a measure in the mandatory measure set when each of the following standards are met:

(1) The measure meets at least 5 of the following criteria:

(i) Is meaningful and useful for beneficiaries or their caregivers when choosing a managed care plan;

(ii) Aligns with other CMS programs described in § 438.505(c);

(iii) Measures health plan performance in at least one of the following areas: customer experience, access to services, health outcomes, quality of care, health plan administration, and health equity;

(iv) Presents an opportunity for managed care plans to influence their performance on the measure;

(v) Is based on data that are available without undue burden on States and plans such that it is feasible to report by many States and managed care plans;

(vi) Demonstrates scientific acceptability, meaning that the measure, as specified, produces consistent and credible results;

(2) The proposed measure contributes to balanced representation of beneficiary subpopulations, age groups, health conditions, services, and performance areas within a concise mandatory measure set, and

(3) The burdens associated with including the measure does not outweigh the benefits to the overall quality rating system framework of including the new measure based on the criteria listed in paragraph (c)(1).

(d) *Removing mandatory measures.* CMS may remove existing mandatory measures from the mandatory measure set if—

(1) After following the process described in paragraph (b) of this section, CMS determines that the measure no longer meets the standards described in paragraph (c) of this section;

(2) The measure steward (other than CMS) retires or stops maintaining a measure;

(3) CMS determines that the clinical guidelines associated with the specifications of the measure change such that the specifications no longer align with positive health outcomes; or

(4) CMS determines that the measure shows low statistical reliability under the standard identified in §§ 422.164(e) and 423.184(e) of this chapter.

(e) *Updating existing mandatory measures.* CMS will modify the existing mandatory measures that undergo measure technical specifications updates as follows—

(1) *Non-substantive updates.* CMS will update changes to the technical specifications for a measure made by the measure steward; such changes will be in the technical resource manual issued under paragraph (f) of this section and § 438.530. Examples of non-substantive updates include, but are not limited to, those that:

(i) Narrow the denominator or population covered by the measure.

(ii) Do not meaningfully impact the numerator or denominator of the measure.

(iii) Update the clinical codes with no change in the target population or the intent of the measure.

(iv) Provide additional clarifications such as:

(A) Adding additional tests that would meet the numerator requirements;

(B) Clarifying documentation requirements;

(C) Adding additional instructions to identify services or procedures; or

(D) Adding alternative data sources or expanding of modes of data collection to calculate a measure.

(2) *Substantive updates.* CMS may adopt substantive updates to a mandatory measure not subject to paragraph (e)(1)(i) through (iv) of this section only after following the process specified in paragraph (b) of this section.

(f) *Finalization and display of mandatory measures and updates.* CMS will finalize modifications to the mandatory measure set and the timeline for State implementation of such modifications in the technical resource manual. For new or substantively updated measures, CMS will provide each State with at least 2 calendar years from the start of the measurement year immediately following the release of the annual technical resource manual in which the modification to the mandatory measure set is finalized to display measurement results and ratings using the new or updated measure(s).

§ 438.515 Medicaid managed care quality rating system methodology.

(a) For each measurement year, the State—

(1) Must collect the data necessary to calculate quality ratings for each quality measure described in § 438.510(a) of this subpart from:

(i) The State's contracted managed care plans that have 500 or more enrollees from the State's Medicaid program on July 1 of the measurement year; and

(ii) Sources of Medicare data (including Medicare Advantage plans, Medicare providers, and CMS), the State's Medicaid fee-for-service providers, or both if all data necessary to calculate a measure cannot be provided by the managed care plans described in paragraph (a)(1) of this section and such data are available for collection by the State without undue burden.

(2) Must ensure that all data collected under paragraph (a)(1) of this section are validated.

(3) Must use the validated data described in paragraph (a)(2) of this section and the methodology described in paragraph (b) of this section to calculate for each quality measure described in § 438.510(a) of this subpart, a measure performance rate for each managed care plan whose contract includes a service or action assessed by the measure, as determined by the State.

(4) Must issue quality ratings to each managed care plan for each measure calculated for the plan under paragraph (a)(3) of this section.

(b) Subject to § 438.525, the State must ensure that the quality ratings issued under paragraph (a)(4) of this section:

(1) Include data for all enrollees who receive coverage through the managed care plan for a service or action for which data are necessary to calculate the quality rating for the managed care plan, including data for enrollees who are dually eligible for both Medicare and Medicaid, subject to the availability of data under paragraph (a)(1)(ii) of this section.

(2) Are issued to each managed care plan at the plan level, by managed care program, so that a plan participating in multiple managed care programs is issued distinct ratings for each program in which it participates resulting in quality ratings that are representative of services provided only to those beneficiaries enrolled in the plan through the rated program.

(c) After engaging with States, beneficiaries, and other interested parties, CMS will propose to implement domain-level quality ratings, including care domains for which States would be required to calculate and assign domain-level quality ratings for managed care plans, a methodology to calculate such ratings, and website display requirements for displaying such ratings on the MAC QRS website display described in § 438.520.

§ 438.520 Website display.

(a) In a manner that complies with the accessibility standards outlined in § 438.10(d) of this part and in a form and manner specified by CMS, the State must prominently display on the website required under § 438.10(c)(3):

(1) Information necessary for users to understand and navigate the contents of the QRS website display, including:

(i) A statement of the purpose of the Medicaid managed care quality rating system, relevant information on Medicaid, CHIP and Medicare and an overview of how to use the information available in the display to select a quality managed care plan;

(ii) Information on how to access the beneficiary support system described in § 438.71 to answer questions about using the State's managed care quality rating system to select a managed care plan; and

(iii) If users must input user-specific information to access or use the QRS, an explanation of why the information is requested, how it will be used, and whether it is optional or required.

(2) Information that allows beneficiaries to identify managed care plans available to them that align with their coverage needs and preferences including:

(i) All available managed care programs and plans for which a user may be eligible based on the user's age, geographic location, and dually eligible status, if applicable, as well as other demographic data identified by CMS;

(ii) A description of the drug coverage for each managed care plan, including the formulary information specified in § 438.10(i) and other similar information as specified by CMS;

(iii) Provider directory information for each managed care plan including all information required by § 438.10(h)(1) and (2) and such other provider information as specified by CMS;

(iv) Quality ratings described at § 438.515(a)(4) that are calculated by the State for each managed care plan in accordance with § 438.515 for mandatory measures identified by CMS in the technical resource manual, and

(v) The quality ratings described in § 438.520(a)(2)(iv) calculated by the State for each managed care plan in accordance with § 438.515 for mandatory measures identified by CMS, stratified by dual eligibility status, race and ethnicity, and sex.

(3) Standardized information identified by CMS that allows users to compare available managed care plans and programs, including:

(i) The name of each managed care plan;

(ii) An internet hyperlink to each managed care plan's website and each available managed care plan's toll-free customer service telephone number;

(iii) Premium and cost-sharing information including differences in premium and cost-sharing among available managed care plans within a single program;

(iv) A summary of benefits including differences in benefits among available managed care plans within a single program;

(v) Certain metrics, as specified by CMS, of managed care plan performance that States must make available to the public under subparts B and D of this part, including data most recently reported to CMS on each managed care program pursuant to § 438.66(e) of this part and the results of the secret shopper survey specified in § 438.68(f) of this part;

(vi) If a managed care plan offers an integrated Medicare-Medicaid plan or a highly or fully integrated Medicare Advantage D–SNP (as those terms are defined in § 422.2 of this chapter), an indication that an integrated plan is

available and a link to the integrated plan's most recent rating under the Medicare Advantage and Part D 5-Star Rating System.

(4) Information on quality ratings displayed in accordance with paragraph (a)(2)(iv) of this section in a manner that promotes beneficiary understanding of and trust in the ratings, including:

(i) A plain language description of the importance and impact of each quality measure assigned a quality rating;

(ii) The measurement period during which the data used to calculate the quality rating was produced; and

(iii) Information on quality ratings data validation, including a plain language description of when, how and by whom the data were validated.

(5) Information or hyperlinks directing users to resources on how and where to apply for Medicaid and enroll in a Medicaid or CHIP plan.

(6) By a date specified by CMS, which shall be no earlier than 2 years after the implementation date for the quality rating system specified in § 438.505:

(i) A search tool that enables users to identify available managed care plans that provide coverage for a drug identified by the user;

(ii) A search tool that enables users to identify available managed care plans that include a provider identified by the user in the plan's network of providers; and

(iii) The quality ratings described in § 438.520(a)(iv) calculated by the State for each managed care plan in accordance with § 438.515 for mandatory measures identified by CMS, including the display of such measures stratified by dual eligibility status, race and ethnicity, sex, age, rural/urban status, disability, language of the enrollee, or other factors specified by CMS in the annual technical resource manual.

(iv) An interactive tool that enables users to view the quality ratings described at § 438.520(a)(iv), stratified by the factors described in paragraph (a)(6)(iii) of this section.

(b) If the State chooses to display quality ratings for additional measures not included in the mandatory measures set described in § 438.510(a), the State must:

(1) Obtain input on the additional measures, prior to their use, from prospective users, including beneficiaries, caregivers, and, if the State enrolls American Indians/Alaska Natives in managed care, consult with Tribes and Tribal Organizations in accordance with the State's Tribal consultation policy; and

(2) Document the input received from prospective users required under paragraph (b)(1) of this section, including modifications made to the additional measure(s) in response to the input and rationale for input not accepted.

(c) CMS will periodically consult with States and interested parties including Medicaid managed care quality rating system users to evaluate the website display requirements described in this section for continued alignment with beneficiary preferences and values.

§ 438.525 Alternative quality rating system.

(a) A State may implement an alternative Medicaid managed care quality rating system that applies an alternative methodology from that described in § 438.510(a)(3) provided that—

(1) The alternative quality rating system includes the mandatory measures identified by CMS under § 438.510(a)(1);

(2) The ratings generated by the alternative quality rating system yield information regarding managed care plan performance which, to the extent feasible, is substantially comparable to that yielded by the methodology described in § 438.515, taking into account such factors as differences in covered populations, benefits, and stage of delivery system transformation, to enable meaningful comparison of performance across States.

(3) The State receives CMS approval prior to implementing an alternative quality rating system or modifications to an approved alternative Medicaid managed care quality rating system.

(b) Prior to submitting a request for, or modification of, an alternative Medicaid managed care quality rating system to CMS, the State must—

(1) Obtain input from the State's Medical Care Advisory Committee established under § 431.12 of this chapter; and

(2) Provide an opportunity for public comment of at least 30 days on the proposed alternative Medicaid managed care quality rating system or modification.

(c) To receive CMS approval for an alternative quality rating system, a State must:

(1) Submit a request for, or modification of, an alternative Medicaid managed care quality rating system to CMS in a form and manner and by a date determined by CMS; and

(2) Include the following in the State's request for or modification of an alternative quality rating system:

(i) The alternative methodology to be used in generating plan ratings;

(ii) Documentation of the public comment process specified in paragraph (b)(1) and (2) this section, including discussion of the issues raised by the Medical Care Advisory Committee and any policy revisions or modifications made in response to the comments and rationale for comments not accepted;

(iii) Other information or documentation specified by CMS to demonstrate compliance with paragraph (a) of this section; and

(iv) Other supporting documents and evidence that the State believes demonstrates compliance with the requirements of (a)(2) of this section.

§ 438.530 Annual technical resource manual.

(a) No later than August 1, 2025, CMS will publish a Medicaid managed care quality rating system technical resource manual, and update it annually thereafter. The technical resource manual must include all of the following:

(1) Identification of all Medicaid managed care quality rating system measures, including:

(i) A list of the mandatory measures; and

(ii) Any measures newly added or removed from the prior year's mandatory measure set.

(iii) The subset of mandatory measures that must be displayed and stratified by factors such as race and ethnicity, sex, age, rural/urban status, disability, language, or such other factors as may be specified by the CMS in accordance with §§ 438.520(a)(2)(iv) and 438.520(a)(6)(iii).

(2) Guidance on the application of the methodology used to calculate and issue quality ratings as described in § 438.515.

(3) Measure steward technical specifications for mandatory measures.

(4) A summary of interested party engagement and public comments received during the public notice and comment process described in § 438.510(b) using the process identified in § 438.510(c) for the most recent modifications to the mandatory measure set including:

(i) Discussion of the feedback and recommendations received on potential modifications to mandatory measures;

(ii) The final modifications and the timeline by which such modifications must be implemented; and

(iii) The rationale for not accepting or implementing specific recommendations or feedback submitted during the consultation process.

(b) In developing and issuing the manual content described in paragraphs (a)(1) and (2) of this section, CMS will take into account whether stratification is currently required by the measure steward or other CMS programs and by

which factors when issuing guidance that identifies which measures, and by which factors, States must stratify mandatory measures.

§ 438.535 Reporting.

(a) Upon CMS' request, but no more frequently than annually, the State must submit a Medicaid managed care quality rating system report in a form and manner determined by CMS. Such report must include:

(1) A list of all mandatory measures displayed as required under § 438.520(a)(1)(i) and any additional measures the State chooses to include in the Medicaid managed care quality rating system as permitted under § 438.510(a).

(2) An attestation that all displayed quality ratings for mandatory measures were calculated and issued in compliance with § 438.515, and a description of the methodology used to calculate ratings for any additional measures, if such methodology deviates from the methodology in § 438.515.

(3) The documentation required under § 438.520(b)(2), if including additional measures in the State's Medicaid managed care quality rating system in accordance with § 438.520(c)(3).

(4) The date on which the State publishes or updates the quality ratings for the State's managed care plans.

(5) A link to the State's website for their Medicaid managed care quality rating system.

(6) The application of any technical specification adjustments used to calculate and issue quality ratings described in § 438.515(a)(3) and (4), at the plan- or State-level, that are outside a measure steward's allowable adjustments for a mandatory measure but that the measure steward has approved for use by the State.

(7) A summary of each alternative QRS approved by CMS, including the effective dates for each approved alternative QRS.

(b) States will be given no less than 90 days to submit such a report to CMS on their Medicaid managed care quality rating system.

■ 29. Amend § 438.602 by adding paragraphs (g)(5) through (13) and (j) to read as follows:

§ 438.602 State responsibilities.

* * * * *

(g) * * *

(5) Enrollee handbooks, provider directories, and formularies required at § 438.10(g), (h), and (i).

(6) The information on rate ranges required at § 438.4(c)(2)(iv), if applicable.

(7) The reports required at § 438.66(e) and § 438.207(d).

(8) The network adequacy standards required at § 438.68(b)(1) through (2) and (e).

(9) The results of secret shopper surveys required at § 438.68(f).

(10) State directed payment evaluation reports required in § 438.6(c)(2)(v)(C).

(11) Information on all required Application Programming Interfaces including as specified in § 431.60(d) and (f).

(12) Quality related information as required in §§ 438.332(c)(1), 438.340(d), 438.362(c) and 438.364(c)(2)(i).

(13) Documentation of compliance with requirements in Subpart K—Parity in Mental Health and Substance Use Disorder Benefits.

* * * * *

(j) *Applicability.* Paragraphs (g)(5) through (13) apply to the first rating period for contracts with MCOs, PIHPs and PAHPs beginning on or after 2 years after [EFFECTIVE DATE OF THE FINAL RULE].

■ 30. Amend § 438.608 by revising paragraphs (a)(2) and (d)(3) and adding paragraph (e) to read as follows:

§ 438.608 Program integrity requirements under the contract.

(a) * * *

(2) Provision for reporting within 10 business days all overpayments identified or recovered, specifying the overpayments due to potential fraud, to the State.

* * * * *

(d) * * *

(3) Each MCO, PIHP, or PAHP must report annually to the State on all overpayments identified or recovered.

* * * * *

(e) *Standards for provider incentive or bonus arrangements.* The State, through its contract with the MCO, PIHP or PAHP, must require that incentive payment contracts between managed care plans and network providers meet the requirements as specified in §§ 438.3(i)(3) and (4).

PART 457—ALLOTMENTS AND GRANTS TO STATES

■ 31. The authority citation for part 457 continues to read as follows:

Authority: 42 U.S.C. 1302.

■ 32. Amend § 457.10 by adding the definition of ''In lieu of service or setting (ILOS)'' in alphabetical order to read as follows:

§ 457.10 Definitions and use of terms.

* * * * *

In lieu of service or setting (ILOS) is defined as provided in § 438.2 of this chapter.

* * * * *

■ 33. Amend § 457.1200 by adding paragraph (d) to read as follows:

§ 457.1200 Basis, scope, and applicability.

* * * * *

(d) *Applicability dates.* States must comply with the requirements of this subpart by the dates established at §§ 438.3(v), 438.16(f), 438.68(h), 438.206(d) and 438.310(d) of this chapter.

■ 34. Amend § 457.1201 by revising paragraphs (c), (e), and (n)(2) to read as follows:

§ 457.1201 Standard contract requirements.

* * * * *

(c) *Payment.* The final capitation rates for all MCO, PIHP or PAHP contracts must be identified and developed, and payment must be made in accordance with §§ 438.3(c) and 438.16(c)(1) through (3) of this chapter, except that the requirement for preapproval of contracts, certifications by an actuary, annual cost reports, contract arrangements described in § 438.6(c), and references to pass through payments do not apply, and contract rates must be submitted to CMS upon request of the Secretary.

* * * * *

(e*) Services that may be covered by an MCO, PIHP, or PAHP.* An MCO, PIHP, or PAHP may cover, for enrollees, services that are not covered under the State plan in accordance with §§ 438.3(e) and 438.16(b), (d), and (e) of this chapter, except that references to § 438.7, IMDs, and rate certifications do not apply and that references to enrollee rights and protections under part 438 should be read to refer to the rights and protections under subparts K and L of this part.

* * * * *

(n) * * *

(2) Contracts with PCCMs must comply with the requirements of paragraph (o) of this section; § 457.1207; § 457.1240(b) (cross-referencing § 438.330(b)(2), (b)(3), (c), and (e) of this chapter); § 457.1240(e) (cross-referencing § 438.340 of this chapter).

* * * * *

■ 35. Amend § 457.1203 by revising paragraphs (e) and (f) to read as follows:

§ 457.1203 Rate development standards and medical loss ratio.

* * * * *

(e) The State must comply with the requirements related to medical loss ratios in accordance with the terms of

§ 438.74 of this chapter, except contract arrangements described in § 438.6(c) do not apply and the description of the reports received from the MCOs, PIHPs and PAHPs under § 438.8(k) of this chapter will be submitted independently, and not with the rate certification described in § 438.7 of this chapter.

(f) The State must ensure, through its contracts, that each MCO, PIHP, and PAHP complies with the requirements in § 438.8 of this chapter, except that contract arrangements described in § 438.6(c) do not apply.

■ 36. Revise § 457.1207 to read as follows:

§ 457.1207 Information requirements.

The State must provide, or ensure its contracted MCO, PAHP, PIHP, PCCM, and PCCM entities provide, all enrollment notices, informational materials, and instructional materials related to enrollees and potential enrollees in accordance with the terms of § 438.10 of this chapter, except that the terms of § 438.10(c)(2), (g)(2)(xi)(E), and (g)(2)(xii) of this chapter do not apply and that references to enrollee rights and protections under part 438 should be read to refer to the rights and protections under subparts K and L of this part. The State must annually post comparative summary results of enrollee experience surveys by managed care plan on the State's website as described at § 438.10(c)(3) of this chapter.

■ 37. Amend § 457.1230 by revising paragraph (b) to read as follows:

§ 457.1230 Access standards.

* * * * *

(b) *Assurances of adequate capacity and services.* The State must ensure, through its contracts, that each MCO, PIHP and PAHP has adequate capacity to serve the expected enrollment in accordance with the terms of § 438.207 of this chapter, except that the reporting requirements in § 438.207(d)(3)(i) of this chapter do not apply. The State must evaluate the most recent annual enrollee experience survey results as required at section 2108(e)(4) of the Act as part of the State's analysis of network adequacy as described at § 438.207(d) of this chapter.

* * * * *

■ 38. Amend § 457.1240 by revising paragraphs (d) and (f) to read as follows:

§ 457.1240 Quality measurement and improvement.

* * * * *

(d) *Managed care quality rating system.* The State must determine a quality rating or ratings for each MCO, PIHP, and PAHP in accordance with the requirements set forth subpart G of part 438 of this chapter, except that references to dually eligible beneficiaries, a beneficiary support system, and the terms of § 438.525(b)(1) and (c)(2)(ii) of this chapter related to consultation with the Medical Care Advisory Committee do not apply.

* * * * *

(f) *Applicability to PCCM entities.* For purposes of paragraphs (b) and (e) of this section, a PCCM entity described in this paragraph is a PCCM entity whose contract with the State provides for shared savings, incentive payments or other financial reward for improved quality outcomes.

■ 39. Amend § 457.1250 by revising paragraph (a) to read as follows:

§ 457.1250 External quality review.

(a) Each State that contracts with MCOs, PIHPs, or PAHPs must follow all applicable external quality review requirements as set forth in §§ 438.350 (except for references to § 438.362), 438.352, 438.354, 438.356, 438.358 (except for references to § 438.6), 438.360 (only with respect to nonduplication of EQR activities with private accreditation) and 438.364 of this chapter.

* * * * *

■ 40. Revise § 457.1285 to read as follows:

§ 457.1285 Program integrity safeguards.

The State must comply with the program integrity safeguards in accordance with the terms of subpart H of part 438 of this chapter, except that the terms of §§ 438.66(e), 438.362(c), 438.602(g)(6) and (10), 438.604(a)(2), 438.608(d)(4) and references to LTSS of this chapter do not apply and that references to subpart K under part 438 should be read to refer to parity requirements at § 457.496.

Dated: April 24, 2023.

Xavier Becerra,

Secretary, Department of Health and Human Services.

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Part IV

United States Sentencing Commission

Sentencing Guidelines for United States Courts; Notice

UNITED STATES SENTENCING COMMISSION

Sentencing Guidelines for United States Courts

AGENCY: United States Sentencing Commission.

ACTION: Notice of submission to Congress of amendments to the sentencing guidelines effective November 1, 2023, and request for comment.

SUMMARY: The United States Sentencing Commission hereby gives notice that the Commission has promulgated amendments to the sentencing guidelines, policy statements, commentary, and statutory index; and the Commission requests comment regarding whether Parts A and B of Amendment 8, relating to ''status points'' and certain offenders with zero criminal history points, should be included in the *Guidelines Manual* as an amendment that may be applied retroactively to previously sentenced defendants. This notice sets forth the text of the amendments and the reason for each amendment, and the request for comment regarding Parts A and B of Amendment 8.

DATES: *Effective Date of Amendments.* The Commission has specified an effective date of November 1, 2023, for the amendments set forth in this notice.

Written Public Comment. Written public comment regarding retroactive application of Parts A and B of Amendment 8, should be received by the Commission not later than June 23, 2023. Any public comment received after the close of the comment period may not be considered.

ADDRESSES: There are two methods for submitting public comment.

Electronic Submission of Comments. Comments may be submitted electronically via the Commission's Public Comment Submission Portal at *https://comment.ussc.gov.* Follow the online instructions for submitting comments.

Submission of Comments by Mail. Comments may be submitted by mail to the following address: United States Sentencing Commission, One Columbus Circle, NE, Suite 2–500, Washington, DC 20002–8002, Attention: Public Affairs—Issue for Comment on Retroactivity.

FOR FURTHER INFORMATION CONTACT: Jennifer Dukes, Senior Public Affairs Specialist, (202) 502–4597.

SUPPLEMENTARY INFORMATION: The United States Sentencing Commission is an independent agency in the judicial branch of the United States Government. The Commission promulgates sentencing guidelines and policy statements for federal courts pursuant to 28 U.S.C. 994(a). The Commission also periodically reviews and revises previously promulgated guidelines pursuant to 28 U.S.C. 994(o) and submits guideline amendments to the Congress not later than the first day of May each year pursuant to 28 U.S.C. 994(p). Absent action of the Congress to the contrary, submitted amendments become effective by operation of law on the date specified by the Commission (generally November 1 of the year in which the amendments are submitted to Congress).

(1) Amendments to the Sentencing Guidelines, Policy Statements, Official Commentary, and Statutory Index

Pursuant to its authority under 28 U.S.C. 994(p), the Commission has promulgated amendments to the sentencing guidelines, policy statements, commentary, and statutory index. Notice of the proposed amendment was published in the **Federal Register** on February 2, 2023 (*see* 88 FR 7180). The Commission held public hearings on the proposed amendments in Washington, DC, on February 23–24 and March 7–8, 2023. On April 27, 2023, the Commission submitted the promulgated amendments to the Congress and specified an effective date of November 1, 2023.

The text of the amendments to the sentencing guidelines, policy statements, commentary, and statutory index, and the reason for each amendment, is set forth below. Additional information pertaining to the amendments described in this notice may be accessed through the Commission's website at *www.ussc.gov.*

(2) Request for Comment on Parts A and B of Amendment 8, Relating to ''Status Points'' and Certain ''Zero-Point'' Offenders

This notice sets forth a request for comment regarding whether Parts A and B of Amendment 8, relating to the impact of ''status points'' at § 4A1.1 ((Criminal History Category) and offenders with zero criminal history points at new § 4C1.1 (Adjustment for Certain Zero-Point Offenders), should be included in subsection (d) of § 1B1.10 (Reduction in Term of Imprisonment as a Result of Amended Guideline Range (Policy Statement)) as an amendment that may be applied retroactively to previously sentenced defendants.

The Background Commentary to § 1B1.10 lists the purpose of the amendment, the magnitude of the change in the guideline range made by the amendment, and the difficulty of applying the amendment retroactively to determine an amended guideline range under § 1B1.10(b) as among the factors the Commission considers in selecting the amendments included in § 1B1.10(d). To the extent practicable, public comment should address each of these factors.

Authority: 28 U.S.C. 994(a), (o), (p), and (u); USSC Rules of Practice and Procedure 2.2, 4.1, and 4.1A.

Carlton W. Reeves,

Chair.

(1) Amendments to the Sentencing Guidelines, Policy Statements, Official Commentary, and Statutory Index

1. Amendment: Section 1B1.13 is amended—

by inserting at the beginning the following new heading: ''(a) *In General.*—'';

by striking ''Bureau of Prisons under'' and inserting ''Bureau of Prisons or the defendant pursuant to'';

and by inserting at the end the following:

''(b) *Extraordinary and Compelling Reasons.*—Extraordinary and compelling reasons exist under any of the following circumstances or a combination thereof:

(1) *Medical Circumstances of the Defendant.*—

(A) The defendant is suffering from a terminal illness (*i.e.,* a serious and advanced illness with an end-of-life trajectory). A specific prognosis of life expectancy (*i.e.,* a probability of death within a specific time period) is not required. Examples include metastatic solid-tumor cancer, amyotrophic lateral sclerosis (ALS), end-stage organ disease, and advanced dementia.

(B) The defendant is—

(i) suffering from a serious physical or medical condition,

(ii) suffering from a serious functional or cognitive impairment, or

(iii) experiencing deteriorating physical or mental health because of the aging process,

that substantially diminishes the ability of the defendant to provide self-care within the environment of a correctional facility and from which he or she is not expected to recover.

(C) The defendant is suffering from a medical condition that requires long-term or specialized medical care that is not being provided and without which the defendant is at risk of serious deterioration in health or death.

(D) The defendant presents the following circumstances—

(i) the defendant is housed at a correctional facility affected or at

imminent risk of being affected by (I) an ongoing outbreak of infectious disease, or (II) an ongoing public health emergency declared by the appropriate federal, state, or local authority;

(ii) due to personal health risk factors and custodial status, the defendant is at increased risk of suffering severe medical complications or death as a result of exposure to the ongoing outbreak of infectious disease or the ongoing public health emergency described in clause (i); and

(iii) such risk cannot be adequately mitigated in a timely manner.

(2) *Age of the Defendant.*—The defendant (A) is at least 65 years old; (B) is experiencing a serious deterioration in physical or mental health because of the aging process; and (C) has served at least 10 years or 75 percent of his or her term of imprisonment, whichever is less.

(3) *Family Circumstances of the Defendant.*—

(A) The death or incapacitation of the caregiver of the defendant's minor child or the defendant's child who is 18 years of age or older and incapable of self-care because of a mental or physical disability or a medical condition.

(B) The incapacitation of the defendant's spouse or registered partner when the defendant would be the only available caregiver for the spouse or registered partner.

(C) The incapacitation of the defendant's parent when the defendant would be the only available caregiver for the parent.

(D) The defendant establishes that circumstances similar to those listed in paragraphs (3)(A) through (3)(C) exist involving any other immediate family member or an individual whose relationship with the defendant is similar in kind to that of an immediate family member, when the defendant would be the only available caregiver for such family member or individual. For purposes of this provision, 'immediate family member' refers to any of the individuals listed in paragraphs (3)(A) through (3)(C) as well as a grandchild, grandparent, or sibling of the defendant.

(4) *Victim of Abuse.*—The defendant, while in custody serving the term of imprisonment sought to be reduced, was a victim of:

(A) sexual abuse involving a 'sexual act,' as defined in 18 U.S.C. 2246(2) (including the conduct described in 18 U.S.C. 2246(2)(D) regardless of the age of the victim); or

(B) physical abuse resulting in 'serious bodily injury,' as defined in the Commentary to § 1B1.1 (Application Instructions);

that was committed by, or at the direction of, a correctional officer, an employee or contractor of the Bureau of Prisons, or any other individual who had custody or control over the defendant.

For purposes of this provision, the misconduct must be established by a conviction in a criminal case, a finding or admission of liability in a civil case, or a finding in an administrative proceeding, unless such proceedings are unduly delayed or the defendant is in imminent danger.

(5) *Other Reasons.*—The defendant presents any other circumstance or combination of circumstances that, when considered by themselves or together with any of the reasons described in paragraphs (1) through (4), are similar in gravity to those described in paragraphs (1) through (4).

(6) *Unusually Long Sentence.*—If a defendant received an unusually long sentence and has served at least 10 years of the term of imprisonment, a change in the law (other than an amendment to the Guidelines Manual that has not been made retroactive) may be considered in determining whether the defendant presents an extraordinary and compelling reason, but only where such change would produce a gross disparity between the sentence being served and the sentence likely to be imposed at the time the motion is filed, and after full consideration of the defendant's individualized circumstances.

(c) *Limitation on Changes in Law.*—Except as provided in subsection (b)(6), a change in the law (including an amendment to the Guidelines Manual that has not been made retroactive) shall not be considered for purposes of determining whether an extraordinary and compelling reason exists under this policy statement. However, if a defendant otherwise establishes that extraordinary and compelling reasons warrant a sentence reduction under this policy statement, a change in the law (including an amendment to the Guidelines Manual that has not been made retroactive) may be considered for purposes of determining the extent of any such reduction.

(d) *Rehabilitation of the Defendant.*—Pursuant to 28 U.S.C. 994(t), rehabilitation of the defendant is not, by itself, an extraordinary and compelling reason for purposes of this policy statement. However, rehabilitation of the defendant while serving the sentence may be considered in combination with other circumstances in determining whether and to what extent a reduction in the defendant's term of imprisonment is warranted.

(e) *Foreseeability of Extraordinary and Compelling Reasons.*—For purposes of this policy statement, an extraordinary and compelling reason need not have been unforeseen at the time of sentencing in order to warrant a reduction in the term of imprisonment. Therefore, the fact that an extraordinary and compelling reason reasonably could have been known or anticipated by the sentencing court does not preclude consideration for a reduction under this policy statement.''.

The Commentary to § 1B1.13 captioned ''Application Notes'' is amended—

by striking Notes 1 through 5 as follows:

''1. *Extraordinary and Compelling Reasons.*—Provided the defendant meets the requirements of subdivision (2), extraordinary and compelling reasons exist under any of the circumstances set forth below:

(A) *Medical Condition of the Defendant.*—

(i) The defendant is suffering from a terminal illness (*i.e.,* a serious and advanced illness with an end of life trajectory). A specific prognosis of life expectancy (*i.e.,* a probability of death within a specific time period) is not required. Examples include metastatic solid-tumor cancer, amyotrophic lateral sclerosis (ALS), end-stage organ disease, and advanced dementia.

(ii) The defendant is—

(I) suffering from a serious physical or medical condition,

(II) suffering from a serious functional or cognitive impairment, or

(III) experiencing deteriorating physical or mental health because of the aging process,

that substantially diminishes the ability of the defendant to provide self-care within the environment of a correctional facility and from which he or she is not expected to recover.

(B) *Age of the Defendant.*—The defendant (i) is at least 65 years old; (ii) is experiencing a serious deterioration in physical or mental health because of the aging process; and (iii) has served at least 10 years or 75 percent of his or her term of imprisonment, whichever is less.

(C) *Family Circumstances.*—

(i) The death or incapacitation of the caregiver of the defendant's minor child or minor children.

(ii) The incapacitation of the defendant's spouse or registered partner when the defendant would be the only available caregiver for the spouse or registered partner.

(D) *Other Reasons.*—As determined by the Director of the Bureau of Prisons, there exists in the defendant's case an

extraordinary and compelling reason other than, or in combination with, the reasons described in subdivisions (A) through (C).

2. *Foreseeability of Extraordinary and Compelling Reasons.*—For purposes of this policy statement, an extraordinary and compelling reason need not have been unforeseen at the time of sentencing in order to warrant a reduction in the term of imprisonment. Therefore, the fact that an extraordinary and compelling reason reasonably could have been known or anticipated by the sentencing court does not preclude consideration for a reduction under this policy statement.

3. *Rehabilitation of the Defendant.*—Pursuant to 28 U.S.C. 994(t), rehabilitation of the defendant is not, by itself, an extraordinary and compelling reason for purposes of this policy statement.

4. *Motion by the Director of the Bureau of Prisons.*—A reduction under this policy statement may be granted only upon motion by the Director of the Bureau of Prisons pursuant to 18 U.S.C. 3582(c)(1)(A). The Commission encourages the Director of the Bureau of Prisons to file such a motion if the defendant meets any of the circumstances set forth in Application Note 1. The court is in a unique position to determine whether the circumstances warrant a reduction (and, if so, the amount of reduction), after considering the factors set forth in 18 U.S.C. 3553(a) and the criteria set forth in this policy statement, such as the defendant's medical condition, the defendant's family circumstances, and whether the defendant is a danger to the safety of any other person or to the community.

This policy statement shall not be construed to confer upon the defendant any right not otherwise recognized in law.

5. *Application of Subdivision (3).*—Any reduction made pursuant to a motion by the Director of the Bureau of Prisons for the reasons set forth in subdivisions (1) and (2) is consistent with this policy statement.'';

and by inserting the following new Notes 1 and 2:

''1. *Interaction with Temporary Release from Custody Under 18 U.S.C. 3622 ('Furlough').*—A reduction of a defendant's term of imprisonment under this policy statement is not appropriate when releasing the defendant under 18 U.S.C. 3622 for a limited time adequately addresses the defendant's circumstances.

2. *Notification of Victims.*—Before granting a motion pursuant to 18 U.S.C. 3582(c)(1)(A), the Commission encourages the court to make its best effort to ensure that any victim of the offense is reasonably, accurately, and timely notified, and provided, to the extent practicable, with an opportunity to be reasonably heard, unless any such victim previously requested not to be notified.''.

The Commentary to § 1B1.13 captioned ''Background'' is amended by striking ''the Commission is authorized'' and inserting ''the Commission is required''.

Reason for Amendment: This amendment responds to, among other things, the First Step Act of 2018 (''First Step Act''), Public Law 115–391, 603(b), 132 Stat. 5194, 5239, which amended 18 U.S.C. 3582(c)(1)(A) to authorize courts to grant a motion for a sentence reduction upon a defendant's own motion. Previously, a court was authorized to do so only upon the motion of the Director of the Bureau of Prisons (''BOP''). Congress amended the law for the express purpose, set forth on the face of the enactment, of ''increasing the use'' of sentence reduction motions under section 3582(c)(1)(A). First Step Act § 603(b).

Section 3582(c)(1)(A) authorizes a court to reduce a defendant's term of imprisonment if ''extraordinary and compelling reasons'' warrant a reduction and ''such a reduction is consistent with applicable policy statements issued by the Sentencing Commission.'' Congress directed the Commission to ''describe what should be considered extraordinary and compelling reasons for sentence reduction, including the criteria to be applied and a list of specific examples.'' Sentencing Reform Act of 1984 (''SRA''), Public Law 98–473, 98 Stat. 1987, 2023 (codified at 28 U.S.C. 994(t)). Congress also directed the Commission to promulgate general policy statements regarding the appropriate use of section 3582(c). 28 U.S.C. 994(a)(2)(C).

For more than 30 years, reductions pursuant to section 3582(c)(1)(A) could be granted only upon the motion of the BOP. BOP filed such motions extremely rarely—the number of defendants receiving relief averaged two dozen per year—and for the most part limited its motions to cases involving inmates who were expected to die within a year or were profoundly and irremediably incapacitated. U.S. Dep't of Just., Off. of the Inspector Gen., The Federal Bureau of Prisons' Compassionate Release Program, I–2013–006 1 & n.9 (2013).

Sentence reductions under section 3582(c)(1)(A) thus came to be known as ''compassionate release,'' though that phrase appears nowhere in the SRA and sentence reductions that do not result in immediate release are authorized by the law. BOP's sparing use of its authority persisted despite guidance from the Commission in 2007 that ''extraordinary and compelling reasons'' can be based on (a) the medical condition of the defendant, (b) the age of the defendant, (c) the defendant's family circumstances, and (d) reasons other than, or in combination with, those three specified ones. USSG App. C, amend. 698 (effective Nov. 1, 2007).

In 2018, the First Step Act put an end to BOP's gatekeeping function and allowed individuals to file motions for sentence reductions under the statute. Because the Commission lost its quorum in early 2019 and did not regain it until 2022, it was unable to amend § 1B1.13 during the more than four-year period since defendants were first permitted to file such motions. During those years, courts have found extraordinary and compelling reasons warranting sentence reductions based on all of the factors the Commission identified in 2007, *i.e.,* the three specified bases of medical condition, age, and family circumstances, and the ''other reasons'' catchall. Commission data indicate courts have hewed to the ''extraordinary and compelling'' requirement, *see* U.S. Sent'g Comm'n, Compassionate Release Data Report (Dec. 2022), at tbls. 10, 12, & 14, and while they have found such circumstances to be present in more cases than BOP had before the First Step Act, they have been judicious in granting relief.

Among other things, the amendment extends the applicability of the policy statement to defendant-filed motions; expands the list of specified extraordinary and compelling reasons that can warrant sentence reductions; retains the existing ''other reasons'' catchall; provides specific guidance with regard to the permissible consideration of changes in the law; and responds to case law that developed after the enactment of the First Step Act.

The amendment is informed by Commission data, including its analysis of the factors identified by courts in granting sentence reduction motions in the years since the First Step Act was signed into law. It is also informed by extensive public comment, including from the Department of Justice, the Federal Public and Community Defenders, the Commission's advisory groups, law professors, currently and formerly incarcerated individuals, and other stakeholders in the federal criminal justice system.

Applicability to Defendant-Filed Motions and Structural Revisions

The amendment revises § 1B1.13(a) to reflect that a defendant is now

authorized to file a motion under 18 U.S.C. 3582(c)(1)(A), making the policy statement applicable to both defendant-filed and BOP-filed motions.

The amendment also makes two structural changes to § 1B1.13. First, it moves the description of the permissible bases for a reduction from the Commentary to the policy statement itself.

Second, the amendment moves Application Notes 2 and 3 into the body of the policy statement as new subsections (e) and (d). Application Note 3 previously provided that, pursuant to 28 U.S.C. 994(t), rehabilitation of a defendant is not, by itself, an extraordinary and compelling reason for purposes of § 1B1.13. New subsection (d) adopts this same language but adds, consistent with the plain language of section 994(t) and courts' interpretations of it, that rehabilitation of the defendant while incarcerated may be considered *in combination* with other circumstances in determining whether extraordinary and compelling reasons warrant a sentence reduction. *See* U.S. Sent'g Comm'n, Compassionate Release Data Report (Dec. 2022), tbls. 10, 12 & 14 (showing that courts have frequently considered rehabilitation in connection with other factors when granting sentence reduction motions). Application Note 2 provided that ''an extraordinary and compelling reason need not have been unforeseen at the time of sentencing in order to warrant a reduction in the term of imprisonment.'' New subsection (e) retains this instruction without change.

Revisions to ''Extraordinary and Compelling Reasons''

The amendment expands the list of specified extraordinary and compelling reasons and retains the ''other reasons'' basis for a sentence reduction to better account for and reflect the plain language of section 3582(c)(1)(A), its legislative history, and decisions by courts made in the absence of a binding policy statement.

The list of specified ''extraordinary and compelling reasons'' is expanded by: (a) adding two new subcategories to the ''Medical Circumstances of the Defendant'' ground for relief; (b) making three modifications to the ''Family Circumstances'' ground; (c) adding a new ground called ''Victim of Abuse''; and (d) adding a new ground called ''Unusually Long Sentence,'' which permits a judge to consider a non-retroactive change in sentencing law as an extraordinary and compelling reason in specified circumstances.

The first of the two new subcategories under ''Medical Circumstances of the Defendant'' applies when a defendant is ''suffering from a medical condition that requires long-term or specialized medical care that is not being provided'' and who, without that care, ''is at risk of serious deterioration in health or death.'' The second applies when a defendant, due to personal health risk factors and custodial status, is at increased risk of suffering severe medical complications or death as a result of exposure to an ongoing outbreak of infectious disease or public health emergency. The amendment incorporates several factors courts considered during the COVID–19 pandemic related to the defendant's individual health circumstances, the level of risk at the defendant's facility, and the ability to adequately mitigate the defendant's individualized risk. The public health emergency prong requires that the emergency be declared by the appropriate governmental authority. These new subcategories reflect the medical circumstances not expressly identified in § 1B1.13 that were most often cited by courts in granting sentence reduction motions during the pandemic. *See* U.S. Sent'g Comm'n, Compassionate Release Data Report (Dec. 2022) tbls. 10, 12 & 14.

The second modification to the list of specified extraordinary and compelling reasons revises the ''Family Circumstances'' ground in three ways. First, it expands the existing provision relating to the death or incapacitation of the caregiver of a defendant's minor child to include a child who is 18 years of age or older and incapable of self-care because of a mental or physical disability or a medical condition. This expansion reflects the Commission's determination that providing care for a non-minor child with severe caretaking needs presents a circumstance similar to providing care for a minor child, as some courts have recognized. *See, e.g., United States* v. *Barnes,* No. 3:17-cr-00011, 2021 WL 1269783, at *4 (S.D. Ind. Jan. 29, 2021) (granting a sentence reduction to a defendant whose 21-year-old son had numerous physical and mental disabilities that required 24-hour care, finding these circumstances ''to be analogous to a minor child''). Second, the amendment adds a new provision for cases in which a defendant's parent is incapacitated and the defendant would be the only available caregiver. Other than the relationships specified in the current policy statement, a parent has been the family member most often identified as needing care by courts granting sentence reductions under § 3582(c)(1)(A). *See* U.S. Sent'g Comm'n, Compassionate Release: The Impact of the First Step Act and COVID–19 Pandemic (2022), at 32; *see also United States* v. *Bucci,* 409 F. Supp. 3d 1, 2 (D. Mass. 2019) (concluding that there is ''no reason to discount'' a defendant's caregiving role ''simply because the incapacitated family member is a parent and not a spouse,'' registered partner, or minor child). The third modification to the family circumstances ground for relief adds a provision that applies when the defendant establishes that similar circumstances exist with respect to a person whose relationship with the defendant is similar in kind to that of an immediate family member, and the defendant would be the only available caregiver. This provision recognizes the diversity of family structures in America, and that caretaking needs within all of those family structures may give rise to equally extraordinary and compelling circumstances. The amendment accords with decisions by courts after the First Step Act. *See, e.g., United States* v. *Griffin,* No. 1:95–cr–00751, 2020 WL 7295765, at *2–3 (S.D. Fla. Dec. 8, 2020) (granting release because the defendant was ''the only viable, adequate caregiver for his sister'' who had significant cognitive impairment due to vascular dementia and stroke); *United States* v. *Reyes,* No. 04–cr–970, 2020 WL 1663129, at *3 (N.D. Ill. Apr. 3, 2020) (granting defendant relief to assist in caring for his aunt with stage four cancer, recognizing ''non-traditional family arrangements and the need for others in the family to contribute when a relative is sick''). Relief is available under this subsection only if the defendant establishes both the qualifying relationship and that the defendant is the only available caregiver.

The third modification to the list of specified extraordinary and compelling reasons adds a ground for relief at new subsection (b)(4) (''Victim of Abuse''), which applies if a defendant has suffered sexual or physical abuse that was committed by or at the direction of a correctional officer, an employee or contractor of the BOP, or any other individual having custody or control over the defendant. This provision responds to the Department of Justice's (''DOJ'') suggestion that a sentence reduction may be appropriate where an individual in BOP custody has been determined to have been the victim of sexual assault perpetrated by BOP personnel. Principal Assoc. Deputy Att'y Gen. Working Grp. of DOJ Components, Dep't of Just., Report and

Recommendations Concerning the Department of Justice's Response to Sexual Misconduct by Employees of the Bureau of Prisons 22 (2022); *see also* Staff of Permanent S. Subcomm. on Investigations, 117th Cong., Rep. on Sexual Abuse of Female Inmates in Federal Prisons (Comm. Print 2022) (summarizing results of investigation into sexual abuse of federal prisoners in BOP custody). New subsection (b)(4) is limited to instances in which the defendant was a victim of either (a) sexual abuse involving a ''sexual act,'' as defined in 18 U.S.C. 2246(2) (including the conduct described in 18 U.S.C. 2246(2)(D) regardless of the age of the victim); or (b) physical abuse resulting in ''serious bodily injury,'' as defined at § 1B1.1, while in custody serving the term of imprisonment sought to be reduced. New subsection (b)(4) provides that the misconduct must be established by a conviction in a criminal case, a finding or admission of liability in a civil case, or a finding in an administrative proceeding, unless the defendant establishes that such proceedings are unduly delayed or the defendant is in imminent danger.

Apart from the specified extraordinary and compelling reasons, the amendment retains the ''Other Reasons'' catchall ground currently found in Application Note 1(D). It also makes clear that extraordinary and compelling reasons exist if the defendant presents any other circumstance or combination of circumstances that, considered by themselves or together with any of the reasons specified in paragraphs (1) through (4), are similar in gravity to those described in paragraphs (1) through (4). The Commission considered but specifically rejected a requirement that ''other reasons'' be similar in nature and consequence to the specified reasons. Rather, they need be similar only in gravity, a requirement that inheres in the statutory requirement that they present extraordinary and compelling reasons for a sentence reduction. *See* 18 U.S.C. 3582(c)(1)(A).

The Commission recognized that during the period between the enactment of the First Step Act in 2018 and this amendment, district courts around the country based sentence reductions on dozens of reasons and combinations of reasons. Based on a careful review of those cases, the Commission continues to believe what is stated in Application Note 4 to the current policy statement, *i.e.,* that judges are ''in a unique position to determine whether the circumstances warrant a reduction.'' Guidance beyond that provided in the amended policy statement regarding what circumstances or combination of circumstances are sufficiently extraordinary and compelling to warrant a reduction in sentence is best provided by reviewing courts, rather than through an effort by the Commission to predict and specify in advance all of the grounds on which relief may be appropriate.

The fifth modification to the list of specified extraordinary and compelling reasons appears in new subsection (b)(6) (''Unusually Long Sentence'') and permits non-retroactive changes in law (other than non-retroactive amendments to the Guidelines Manual) to be considered extraordinary and compelling reasons warranting a sentence reduction, but only in narrowly circumscribed circumstances. Specifically, where (a) the defendant is serving an unusually long sentence; (b) the defendant has served at least ten years of the sentence; and (c) an intervening change in the law has produced a gross disparity between the sentence being served and the sentence likely to be imposed at the time the motion is filed, the change in law can qualify as an extraordinary and compelling reason after the court has fully considered the defendant's individualized circumstances.

One of the expressed purposes of section 3582(c)(1)(A) when it was enacted in 1984 was to provide a narrow avenue for judicial relief from unusually long sentences. S. Rep. No. 98–225 (1983). Having abolished parole in the interest of certainty in sentencing, Congress recognized the need for such judicial authority. In effect, it replaced opaque Parole Commission review of every federal sentence with a transparent, judicial authority to consider reducing only a narrow subset of sentences—those presenting ''extraordinary and compelling'' reasons for a reduction.

Subsections (b)(6) and (c) operate together to respond to a circuit split concerning when, if ever, non-retroactive changes in law may be considered as extraordinary and compelling reasons within the meaning of section 3582(c)(1)(A). *Compare United States* v. *Ruvalcaba,* 26 F.4th 14, 16, 26–28 (1st Cir. 2022) (holding that non-retroactive changes in sentencing law may be considered in light of a defendant's particular circumstances), *United States* v. *McCoy,* 981 F.3d 271, 286–88 (4th Cir. 2020) (same), *United States* v. *Chen,* 48 F.4th 1092, 1098 (9th Cir. 2022) (same), *and United States* v. *McGee,* 992 F.3d 1035, 1047–48 (10th Cir. 2021) (same), *with United States* v. *Andrews,* 12 F.4th 255, 260–62 (3d Cir. 2021), *cert. denied,* 142 S. Ct. 1446 (2022) (holding that non-retroactive changes in law are not permissible considerations), *United States* v. *McMaryion,* 64 F.4th 257, 259–60 (5th Cir. 2023) (same), *United States* v. *McCall,* 56 F.4th 1048, 1061 (6th Cir. 2022) (en banc) (same), *United States* v. *King,* 40 F.4th 594, 595 (7th Cir. 2022) (same), *United States* v. *Crandall,* 25 F.4th 582, 585–86 (8th Cir. 2022) (same), *and United States* v. *Jenkins,* 50 F.4th 1185, 1198, 1198 (DC Cir. 2022) (same).

The Commission considered whether the foregoing split among the circuit courts of appeals was properly addressed by the Commission, which typically resolves such disagreements when they relate to its guidelines or policy statements, *see Braxton* v. *United States,* 500 U.S. 344 (1991), or by the Supreme Court. In making that determination, the Commission was influenced by the fact that on several occasions the Department of Justice successfully opposed Supreme Court review of the issue on the ground that it should be addressed first by the Commission. *See, e.g.,* Brief For the United States in Opposition to Grant of Certiorari, *Jarvis* v. *United States,* No. 21–568, 2021 WL 5864543 (U.S. Dec. 8, 2021); Memorandum For the United States in Opposition to Grant of Certiorari, *Watford* v. *United States,* No. 21–551, 2021 WL 5983234 (U.S. Dec. 15, 2021); Memorandum For the United States in Opposition to Grant of Certiorari, *Williams* v. *United States,* No. 21–767, 2022 WL 217947 (U.S. Jan. 24, 2022); Memorandum For the United States in Opposition to Grant of Certiorari, *Thacker* v. *United States,* No. 21–877, 2022 WL 467984 (U.S. Feb. 14, 2022).

The amendment agrees with the circuits that authorize a district court to consider non-retroactive changes in the law as extraordinary and compelling circumstances warranting a sentence reduction but adopts a tailored approach that narrowly limits that principle in multiple ways. First, it permits the consideration of such changes only in cases involving ''unusually long sentences,'' which the legislative history to the SRA expressly identified as a context in which sentence reduction authority is needed. *See* S. Rep. No. 98–225, at 55 (1983), *reprinted in* 1984 U.S.C.C.A.N. 3182, 3238–39. (''The Committee believes that there may be unusual cases in which the eventual reduction in the length of a term of imprisonment is justified by changed circumstances. These would include cases of severe illness, cases in which other extraordinary and compelling circumstances justify a reduction of an unusually long

sentence, and some cases in which the sentencing guidelines for the offense of which the defender [sic] was convicted have been later amended to prove a shorter term of imprisonment.''). Second, the change in law itself may be considered an extraordinary and compelling reason only where it would produce a gross disparity between the length of the sentence being served and the sentence likely to be imposed at the time the motion is filed. Finally, to address administrative concerns raised by some commenters, the amendment limits the application of this provision to individuals who have served at least 10 years of the sentence the motion seeks to reduce. Commission data show that between fiscal year 2013 and fiscal year 2022, fewer than 12 percent (11.5%) of all offenders were sentenced to a term of imprisonment of ten years or longer.

Subsection (b)(6) excludes from consideration as extraordinary and compelling reasons warranting a reduction in sentence changes to the Guidelines Manual that the Commission has not made retroactive. Public comment requested that the Commission clarify the interaction between § 1B1.13 and § 1B1.10, and the Commission determined that excluding non-retroactive changes to the guidelines from consideration as extraordinary and compelling reasons was consistent with § 1B1.10 and the Supreme Court's decision in *Dillon* v. *United States,* 560 U.S. 817 (2010).

To more fully address the proper role of changes in law in this context, the amendment also adds a new subsection (c) to the policy statement. Whereas subsection (b)(6) narrowly limits the circumstances in which a non-retroactive change in the law can constitute an extraordinary and compelling reason that itself can warrant a reduction in sentence, subsection (c) of the amended policy statement governs the use of changes in the law in cases where a defendant ''otherwise establishes that extraordinary and compelling reasons warrant a sentence reduction.'' In those circumstances, *all* changes in law, including non-retroactive amendments to the Guidelines Manual, may properly be considered in determining the extent of a sentencing reduction. For example, a defendant's motion may present the following circumstances: (a) commendable rehabilitation while incarcerated; (b) the offense conduct occurred when the defendant was in his late teens or early twenties; and (c) pursuant to intervening legislation or intervening Guidelines amendments, the sentence likely to be imposed at the time of the motion would be lower than the sentence being served, but not grossly so. In those circumstances, the change in law could not properly be considered an extraordinary and compelling reason warranting a reduction in sentence. However, if the court determines that the combination of the other two factors constitutes an extraordinary and compelling reason, the change in law is among the broad array of factors that may properly be considered in determining the extent of any such reduction. This aspect of the amendment is fully consistent with *Concepcion* v. *United States,* 142 S. Ct. 2389 (2022).

Finally, the requirements in subsection (b)(6) that the defendant be serving an unusually long sentence and have served at least ten years of such sentence are not applicable to cases not covered by that subsection. Those requirements apply only when a defendant seeks to have a non-retroactive change in law itself be considered an extraordinary and compelling reason warranting a reduction in sentence.

New Application Notes Regarding Interaction With 18 U.S.C. 3622 and Notification of Victims

The amendment also adds two new application notes to the Commentary to § 1B1.13. New Application Note 1 provides that a reduction under this policy statement is not appropriate when temporary release under 18 U.S.C. 3622 (a furlough granted by the Bureau of Prisons) ''adequately addresses'' the defendant's circumstances. This new application note responds to public comment, including comment from the Criminal Law Committee for the Judicial Conference of the United States, urging the Commission to clarify that this policy statement is not intended to address temporary medical or family circumstances that a BOP-granted furlough adequately addresses.

New Application Note 2 ''encourages the court to make its best effort to ensure that any victim of the offense is reasonably, accurately, and timely notified, and provided, to the extent practicable, with an opportunity to be reasonably heard, unless any such victim previously requested not to be notified.'' Although § 3582(c)(1)(A) does not require a court to conduct a public court proceeding before resolving a motion, and in many cases the passage of time can make victim identification and notification difficult, the Commission encourages the court to make its best effort to notify any victims and, to the extent public court proceedings are held, afford them an opportunity to be heard, unless the victim previously requested not to be notified.

Conforming Changes

Finally, as conforming changes, the amendment deletes Application Notes 4 and 5 and makes a minor technical change to the Background Commentary. Application Note 4 reflected that only the Bureau of Prisons could file a motion under 18 U.S.C. 3582(c)(1)(A) before the First Step Act and, as such, ''encourage[d] the Director of the Bureau of Prisons to file such a motion.'' Application Note 5 provided that ''[a]ny reduction made pursuant to a motion by the Director of the Bureau of Prisons for the reasons set forth in subdivisions (1) and (2) is consistent with this policy statement.'' These two application notes were deleted because a motion by the Director of the Bureau of Prisons is no longer required after the enactment of the First Step Act. The Background Commentary is also amended to reflect that the Commission is ''required,'' as opposed to ''authorized,'' to ''describe what should be considered extraordinary and compelling reasons for sentence reduction.''

2. Amendment: The Commentary to § 2A2.4 captioned ''Statutory Provisions'' is amended by striking ''18 U.S.C. §§ 111'' and inserting ''18 U.S.C. §§ 40A, 111''.

Section 2A5.2 is amended in the heading by striking ''Vehicle'' and inserting ''Vehicle; Unsafe Operation of Unmanned Aircraft''.

The Commentary to § 2A5.2 captioned ''Statutory Provisions'' is amended by striking ''18 U.S.C. § 1992(a)(1)'' and inserting ''18 U.S.C. § 39B, 1992(a)(1)''.

The Commentary to § 2B1.1 captioned ''Statutory Provisions'' is amended by striking ''7 U.S.C. § 6, 6b, 6c, 6h, 6o, 13, 23; 15 U.S.C. § 50, 77e, 77q, 77x, 78j, 78ff, 80b–6, 1644, 6821; 18 U.S.C. § 38, 225, 285–289, 471–473, 500, 510, 553(a)(1), 641, 656, 657, 659, 662, 664, 1001–1008, 1010–1014, 1016–1022, 1025, 1026, 1028, 1029, 1030(a)(4)–(5), 1031, 1037, 1040, 1341–1344, 1348, 1350, 1361, 1363, 1369, 1702, 1703 (if vandalism or malicious mischief, including destruction of mail, is involved), 1708, 1831, 1832, 1992(a)(1), (a)(5), 2113(b), 2282A, 2282B, 2291, 2312–2317, 2332b(a)(1), 2701; 19 U.S.C. § 2401f; 29 U.S.C. § 501(c); 42 U.S.C. § 1011; 49 U.S.C. 14915, 30170, 46317(a), 60123(b)'', and inserting ''5 U.S.C. §§ 8345a, 8466a; 7 U.S.C. § 6, 6b, 6c, 6h, 6o, 13, 23; 15 U.S.C. §§ 50, 77e, 77q, 77x, 78j, 78ff, 80b–6, 1644, 6821; 18 U.S.C. § 38, 220, 225, 285–289, 471–473, 500, 510, 553(a)(1), 641, 656, 657, 659, 662, 664, 1001–1008, 1010–1014,

1016–1022, 1025, 1026, 1028, 1029, 1030(a)(4)–(5), 1031, 1037, 1040, 1341–1344, 1348, 1350, 1361, 1363, 1369, 1702, 1703 (if vandalism or malicious mischief, including destruction of mail, is involved), 1708, 1831, 1832, 1992(a)(1), (a)(5), 2113(b), 2282A, 2282B, 2291, 2312–2317, 2332b(a)(1), 2701; 19 U.S.C. § 2401f; 20 U.S.C. 1097(a), (b), (d), (e); 29 U.S.C. 501(c); 42 U.S.C. §1011; 49 U.S.C. § 14915, 30170, 46317(a), 60123(b)''.

The Commentary to § 2B4.1 captioned ''Statutory Provisions'' is amended by striking ''18 U.S.C. § 215'' and inserting ''18 U.S.C. § 215, 220''.

Section 2G1.1(b)(1)(B) is amended by striking ''the offense involved fraud or coercion'' and inserting ''(i) the offense involved fraud or coercion; or (ii) the offense of conviction is 18 U.S.C. §§ 2421A(b)(2)''.

The Commentary to § 2G1.1 captioned ''Statutory Provisions'' is amended by striking ''2422(a) (only if the offense involved a victim other than a minor)'' and inserting ''2421A (only if the offense involved a victim other than a minor), 2422(a) (only if the offense involved a victim other than a minor). For additional statutory provision(s), *see* Appendix A (Statutory Index)''.

Section 2G1.3(b) is amended—

in paragraph (3) by striking ''increase by 2 levels'' and inserting ''increase by 2 levels. *Provided,* however, that subsection (b)(3)(B) shall not apply if the offense of conviction is 18 U.S.C. § 2421A'';

and in paragraph (4) by striking ''If (A) the offense involved the commission of a sex act or sexual contact; or (B) subsection (a)(3) or (a)(4) applies and the offense involved a commercial sex act, increase by 2 levels.'', and inserting the following:

''(Apply the greater):

(A) If (i) the offense involved the commission of a sex act or sexual contact; or (ii) subsection (a)(3) or (a)(4) applies and the offense involved a commercial sex act, increase by 2 levels.

(B) If (i) subsection (a)(4) applies; and (ii) the offense of conviction is 18 U.S.C. §§ 2421A(b)(2), increase by 4 levels.''.

The Commentary to § 2G1.3 captioned ''Statutory Provisions'' is amended by striking ''2422 (only if the offense involved a minor), 2423, 2425'' and inserting ''2421A (only if the offense involved a minor), 2422 (only if the offense involved a minor), 2423, 2425. For additional statutory provision(s), *see* Appendix A (Statutory Index)''.

The Commentary to § 2H3.1 captioned ''Statutory Provisions'' is amended by striking ''47 U.S.C. § 605'' and inserting ''44 U.S.C. § 3572; 47 U.S.C. § 605''.

The Commentary to § 2N1.1 captioned ''Statutory Provisions'' is amended by striking ''18 U.S.C. § 1365(a), (e)'' and inserting ''18 U.S.C. § 1365(a), (e); 21 U.S.C. 333(b)(7). For additional statutory provision(s), *see* Appendix A (Statutory Index)''.

The Commentary to § 2N2.1 captioned ''Statutory Provisions'' is amended by striking ''333(a)(1), (a)(2), (b)'' and inserting ''333(a)(1), (a)(2), (b)(1)–(6), (b)(8)''.

The Commentary to § 2S1.3 captioned ''Statutory Provisions'' is amended by striking ''5332'' and inserting ''5332, 5335, 5336''.

The Commentary to § 2X5.2 captioned ''Statutory Provisions'' is amended by striking ''18 U.S.C. § 1365(f), 1801; 34 U.S.C. § 12593; 49 U.S.C. § 31310.'' and inserting ''10 U.S.C. § 2733a(g)(2); 18 U.S.C. § 39B, 1365(f), 1801, 2259(d)(4); 34 U.S.C. § 12593; 49 U.S.C. § 31310. For additional statutory provision(s), *see* Appendix A (Statutory Index).''.

Appendix A (Statutory Index) is amended—

by inserting before the line referenced to 7 U.S.C. 6 the following new line references:

''5 U.S.C. § 8345a 2B1.1
5 U.S.C. § 8466a 2B1.1'';

by inserting before the line referenced to 12 U.S.C. § 631 the following new line reference:

''10 U.S.C. § 2733a(g)(2) 2X5.2'';

by inserting before the line referenced to 18 U.S.C. § 43 the following new line references:

''18 U.S.C. § 39B 2A5.2, 2X5.2
18 U.S.C. § 40A 2A2.4'';

by inserting before the line referenced to 18 U.S.C. § 224 the following new line reference:

''18 U.S.C. § 220 2B1.1, 2B4.1'';

by inserting before the line referenced to 18 U.S.C. § 2260(a) the following new line reference:

''18 U.S.C. § 2259(d)(4) 2X5.2'';

by inserting before the line referenced to 18 U.S.C. § 2320 the following new line reference:

''18 U.S.C. § 2319C 2B5.3'';

by inserting before the line referenced to 18 U.S.C. § 2422 the following new line reference:

''18 U.S.C. § 2421A 2G1.1, 2G1.3'';

by inserting before the line referenced to 21 U.S.C. § 101 the following new line reference:

''20 U.S.C. § 1097(e) 2B1.1'';

by inserting before the line referenced to 21 U.S.C. § 458 the following new line reference:

''21 U.S.C. § 333(b)(8) 2N2.1'';

by inserting before the line referenced to 31 U.S.C. § 5363 the following new line references:

''31 U.S.C. § 5335 2S1.3
31 U.S.C. § 5336 2S1.3'';

and by inserting before the line referenced to 45 U.S.C. § 359(a) the following new line reference:

''44 U.S.C. § 3572 2H3.1''.

Reason for Amendment: This multi-part amendment responds to recently enacted legislation.

FDA Reauthorization Act of 2017

First, the amendment amends Appendix A (Statutory Index) to reference a new offense for counterfeit drugs at 21 U.S.C. 333(b)(8) (Penalties [for violations of the Federal Food, Drug, and Cosmetic Act (FDCA)]) to § 2N2.1 (Violations of Statutes and Regulations Dealing With Any Food, Drug, Biological Product, Device, Cosmetic, Agricultural Product, or Consumer Product) in response to the FDA Reauthorization Act of 2017, Public Law 115–52 (Aug. 18, 2017). The Act added subsection 333(b)(8), which provides that the statutory maximum term of imprisonment is ten years for a violation of 21 U.S.C. 331(i)(3) (Prohibited acts [under the FDCA]). Subsection 331(i)(3) prohibits causing a drug to be counterfeited, or making, selling, dispensing, or holding for sale or dispensing, a counterfeit drug. The Commission determined that § 2N2.1 is the most appropriate guideline to which to reference this offense because § 2N2.1 covers similar penalty provisions at section 333.

Allow States and Victims To Fight Online Sex Trafficking Act

Second, the amendment amends §§ 2G1.1 (Promoting a Commercial Sex Act or Prohibiting Sexual Conduct with an Individual Other than a Minor) and 2G1.3 (Promoting a Commercial Sex Act or Prohibited Sexual Conduct with a Minor; Transportation of Minors to Engage in a Commercial Sex Act or Prohibited Sexual Conduct; Travel to Engage in Commercial Sex Act or Prohibited Sexual Conduct with a Minor; Sex Trafficking of Children; Use of Interstate Facilities to Transport Information about a Minor) in response to the Allow States and Victims to Fight Online Sex Trafficking Act of 2017, Public Law 115–164 (Apr. 11, 2017). The Act added a new offense at 18 U.S.C. 2421A(a) (Promotion or facilitation of prostitution and reckless disregard of sex trafficking) which prohibits owning, managing, or operating an interactive computer service with the intent to promote or

facilitate prostitution. Section 2421A has a statutory maximum term of imprisonment of ten years. The Act included an aggravated offense at subsection 2421A(b)(2) if the offender commits an offense under subsection 2421A(a) while acting in reckless disregard of the fact that such conduct contributed to sex trafficking in violation of 18 U.S.C. 1591(a) (Sex trafficking of children or by force, fraud, or coercion). Offenses under section 1591(a) that involve force, fraud, coercion, or minors have statutory mandatory minimum terms of imprisonment of at least ten years and statutory maximum terms of imprisonment of life. Offenses under subsection 2421A(b)(2) have a 25-year statutory maximum term of imprisonment to reflect the serious nature of the sex trafficking conduct in violation of section 1591(a). To reflect the statutory maximum term of imprisonment at subsection 2421A(b)(2), the amendment amends the 4-level enhancement at § 2G1.1(b)(1)(B) and adds a new 4-level enhancement at § 2G1.3(b)(4)(B) that apply if the offense of conviction is 18 U.S.C. 2421A(b)(2). The amendment also amends § 2G1.3(b)(3) to provide that § 2G1.3(b)(3)(B) shall not apply if the offense of conviction is 18 U.S.C. 2421A because the use of a computer is already accounted for in the base offense level.

FAA Reauthorization Act of 2018

Third, the amendment amends Appendix A to reference new offenses in the FAA Reauthorization Act of 2018, Public Law 115–254 (Oct. 5, 2018). The new offense at 18 U.S.C. 39B (Unsafe operation of unmanned aircraft) is referenced to § 2A5.2 (Interference with Flight Crew Member or Flight Attendant; Interference with Dispatch, Navigation, Operation, or Maintenance of Mass Transportation Vehicle) and § 2X5.2 (Class A Misdemeanors (Not Covered by Another Specific Offense Guideline)). Section 39B prohibits the knowing or reckless unsafe operation of drones that interfere with the safe operation of an aircraft carrying one or more persons or operated in close proximity to an airport runway. Section 39B has a statutory maximum term of imprisonment of one year. The statutory maximum term of imprisonment for reckless violations that cause serious bodily injury or death is ten years, and for knowing violations that cause serious bodily injury or death is any term of years or life. The Commission determined that § 2A5.2 is the most appropriate guideline to which to reference felony violations of section 39B because it covers conduct interfering with the operation of aircraft. Additionally, providing a reference to § 2X5.2 is consistent with Commission practice relating to new misdemeanor offenses.

The FAA Reauthorization Act also added a new offense at 18 U.S.C. 40A (Operation of unauthorized unmanned aircraft over wildfires) which is referenced in Appendix A to § 2A2.4 (Obstructing or Impeding Officers). Section 40A prohibits operating a drone in a manner that interferes with wildfire suppression or with law enforcement or emergency response efforts related to wildfire suppression. Section 40A has a statutory maximum term of imprisonment of two years. The Commission determined that § 2A2.4 is the most appropriate guideline to which to reference this offense because it covers conduct involving interfering with and obstructing or impeding officers.

SUPPORT for Patients and Communities Act

Fourth, the amendment amends Appendix A to reference a new offense at 18 U.S.C. 220 (Illegal remunerations for referrals to recovery homes, clinical treatment facilities, and laboratories) to §§ 2B1.1 (Theft, Property Destruction, and Fraud) and 2B4.1 (Bribery in Procurement of Bank Loan and Other Commercial Bribery) in response to the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (''the SUPPORT for Patients and Communities Act''), Public Law 115–271 (Oct. 24, 2018). Section 220 prohibits soliciting, receiving, paying, or offering any remuneration, including kickbacks, bribes, or rebates, for referring patients to a facility covered by a health care benefit program. Section 220 has a statutory maximum term of imprisonment of ten years. The Commission determined that §§ 2B1.1 and 2B4.1 are the most appropriate guidelines to which to reference this offense because both guidelines cover conduct involving kickbacks and bribery.

Amy, Vicky, and Andy Child Pornography Victim Assistance Act

Fifth, the amendment amends Appendix A to reference a new offense at 18 U.S.C. 2259(d) (Mandatory restitution [for child pornography victims]) to § 2X5.2 in response to the Amy, Vicky, and Andy Child Pornography Victim Assistance Act, Public Law 115–299 (Dec. 7, 2018). Subsection 2259(d) prohibits attorneys from charging fees in excess of 15 percent when representing a child pornography victim who receives ''defined monetary assistance'' from the Child Pornography Victims Reserve and provides for a statutory maximum term of imprisonment of one year. Providing a reference to § 2X5.2 is consistent with Commission practice relating to new misdemeanor offenses.

Foundations for Evidence-Based Policymaking Act

Sixth, the amendment amends Appendix A to reference a new offense at 44 U.S.C. 3572 (Confidential information protection) to § 2H3.1 (Interception of Communications; Eavesdropping; Disclosure of Certain Private or Protected Information) in response to the Confidential Information Protection and Statistical Efficiency Act, part of the Foundations for Evidence-Based Policymaking Act of 2018, Public Law 115–435 (Jan. 14, 2019).

Section 3572 prohibits the unauthorized disclosure of information collected by an agency under a pledge of confidentiality for exclusively statistical purposes or using the information for other than statistical purposes. Section 3572 has a statutory maximum term of imprisonment of five years. The Commission determined that § 2H3.1 is the most appropriate guideline to which to reference this offense because it covers conduct involving the unauthorized disclosure of information.

National Defense Authorization Act for Fiscal Year 2020

Seventh, the amendment amends Appendix A to reference a new offense at 10 U.S.C. 2733a (Armed Forces; Medical malpractice claims by members of the uniformed services) to § 2X5.2 in response to the National Defense Authorization Act for Fiscal Year 2020, Public Law 116–92 (Dec. 20, 2019). Section 2733a prohibits attorneys from charging fees in excess of 20 percent when representing a member of the uniformed services who receives a payment under section 2733a for medical malpractice caused by a health care provider of the Department of Defense. Section 2733a has a statutory maximum term of imprisonment of one year. Providing a reference to § 2X5.2 is consistent with Commission practice relating to new misdemeanor offenses.

Representative Payee Fraud Prevention Act

Eighth, the amendment amends Appendix A to reference two new offenses at 5 U.S.C. 8345a (Government Organization and Employees; Embezzlement or conversion of

payments) and 8466a (Embezzlement or conversion of payments) to § 2B1.1 in response to the Representative Payee Fraud Prevention Act of 2019, Public Law 116–126 (Mar. 18, 2020). Sections 8345a and 8466a prohibit representative payees of minors or other individuals under a legal disability from embezzling or converting retirement payments under the Civil Service Retirement System or the Federal Employees' Retirement System. The statutory maximum term of imprisonment for both sections is five years. The Commission determined that § 2B1.1 is the most appropriate guideline to which to reference these offenses because it covers conduct involving similar financial fraud.

Stop Student Debt Relief Scams Act

Ninth, the amendment amends Appendix A to reference a new offense at 20 U.S.C. 1097(e) (Education; Student Assistance Programs; Criminal penalties) to § 2B1.1 in response to the Stop Student Debt Relief Scams Act of 2019, Public Law 116–251 (Dec. 22, 2020). Subsection 1097(e) prohibits the unauthorized use of an access device relating to student assistance programs issued to another or obtained by fraud to access the information technology systems of the Department of Education for commercial advantage or private financial gain. Subsection 1097(e) has a statutory maximum term of imprisonment of five years. The Commission determined that § 2B1.1 is the most appropriate guideline to which to reference this offense because § 2B1.1 covers other section 1097 offenses prohibiting embezzlement, fraud and false statements involved in student assistance programs.

Protecting Lawful Streaming Act

Tenth, the amendment amends Appendix A to reference a new offense at 18 U.S.C. 2319C (Illicit digital transmission services) to § 2B5.3 (Criminal Infringement of Copyright or Trademark) in response to the Protecting Lawful Streaming Act, part of the 2021 Consolidated Appropriations Act, Public Law 116–260 (Dec. 27, 2020). Section 2319C prohibits publicly offering or providing digital transmission services designed to provide the unauthorized transmission of copyrighted works, including pre-release works being prepared for commercial public performance, and provides for a statutory maximum term of imprisonment of three years. The statutory maximum term of imprisonment is five years if the offense involved one or more pre-release works, and for a second or subsequent violation of section 2319C, the statutory maximum term of imprisonment is ten years. The Commission determined that § 2B5.3 is the most appropriate guideline to which to reference this offense because it covers conduct involving criminal copyright infringement including pre-release works.

William M. (Mac) Thornberry National Defense Authorization Act for Fiscal Year 2021

Eleventh, the amendment amends Appendix A to reference multiple new offenses at 31 U.S.C. 5335 (Money and Finance; Concealment of source of assets in monetary transactions) and 5336 (Beneficial ownership information reporting requirements) to § 2S1.3 (Structuring Transactions to Evade Reporting Requirement; Failure to Report Cash or Monetary Transactions; Failure to File Currency and Monetary Instruments Report) in response to the William M. (Mac) Thornberry National Defense Authorization Act for Fiscal Year 2021, Public Law 116–283 (Jan. 1, 2021).

Subsection 5335(b) prohibits concealing, falsifying, or misrepresenting a material fact from a financial institution about the ownership or control of certain assets over $1,000,000 if the person or entity controlling the assets is a certain foreign figure or associate. Subsection 5335(c) prohibits concealing, falsifying, or misrepresenting a material fact, to or from a financial institution, about the source of funds in monetary transactions involving ''primary money laundering concerns'' and that violate the prohibitions prescribed in section 5318A(b)(5). Both subsections 5335(b) and 5335(c) have a statutory maximum term of imprisonment of ten years.

Subsection 5336(h)(1) prohibits willfully providing false or fraudulent beneficial ownership information to the Department of the Treasury's Financial Crimes Enforcement Network (''FinCEN'') in accordance with the reporting requirements in subsection 5336(b). Subsection 5336(h)(1) has a statutory maximum term of imprisonment of two years. Subsection 5336(c)(4) prohibits employees and officers of any requesting agency from violating the protocols established by the Secretary of the Treasury or the unauthorized disclosure or use of the beneficial ownership information submitted to FinCEN. Subsection 5336(h)(2) prohibits any person from knowingly disclosing or using beneficial ownership information obtained through a report submitted to, or through a disclosure made by, FinCEN, without authorization. Both subsections 5336(c)(4) and 5336(h)(2) have a statutory maximum term of imprisonment of five years. The statutory maximum term of imprisonment for a violation of subsection 5336(c)(4) or 5336(h)(2) is ten years if the offense was committed while violating another law of the United States or as part of a pattern of certain unlawful activities.

The Commission determined that § 2S1.3 is the most appropriate guideline to which to reference these new offenses because it covers similar conduct involving structuring financial transactions and requiring the filing of a Currency Transaction Report regarding payment, receipt, or transfer of United States coins or currency.

3. Amendment: Section 2A3.3 is amended—

in the heading by striking ''Acts'' and inserting ''Acts; Criminal Sexual Abuse of an Individual in Federal Custody''.

in subsection (a) by striking ''14'' and inserting ''18'';

and by inserting at the end the following new subsection (c):

''(c) Cross Reference

(1) If the offense involved criminal sexual abuse or attempt to commit criminal sexual abuse (as defined in 18 U.S.C. § 2241 or § 2242), apply § 2A3.1 (Criminal Sexual Abuse; Attempt to Commit Criminal Sexual Abuse). If the victim had not attained the age of 12 years, § 2A3.1 shall apply, regardless of the 'consent' of the victim.''.

The Commentary to § 2A3.3 captioned ''Statutory Provision'' is amended by striking ''§ 2243(b)'' and inserting ''§§ 2243(b), 2243(c)''.

The Commentary to § 2H1.1 captioned ''Statutory Provisions'' is amended by striking ''246, 247, 248, 249'' and inserting ''246–250''.

Appendix A (Statutory Index) is amended—

by inserting before the line referenced to 18 U.S.C. 281 the following new line reference:

''18 U.S.C. § 250 2H1.1'';

and by inserting before the line referenced to 18 U.S.C. 2244 the following new line reference:

''18 U.S.C. § 2243(c) 2A3.3''.

Reason for Amendment: This multi-part amendment responds to statutory changes provided in division W, title XII, of the Violence Against Women Act Reauthorization Act, Public Law 117–103 (Nov. 9, 2022) and separately addresses concerns regarding cases involving sexual abuse committed by law enforcement or correctional personnel against victims in their custody, care, or supervision.

First, the amendment amends Appendix A (Statutory Appendix) to reference the new offense created at 18 U.S.C. 250 (Penalties for civil rights offenses involving sexual misconduct) to § 2H1.1 (Offenses Involving Individual Rights). New section 250 criminalizes engaging in or causing another to engage in sexual misconduct while committing any civil rights offense under chapter 13 (Civil Rights) of title 18, U.S. Code, or 42 U.S.C. 3631 (Fair Housing [violations]). Section 250 delineates different degrees of prohibited sexual misconduct, including aggravated sexual abuse as defined in 18 U.S.C. 2241 (Aggravated sexual abuse), sexual abuse as defined in 18 U.S.C. 2242 (Sexual abuse), a sexual act not amounting to aggravated sexual abuse or sexual abuse, and sexual contact, as defined in 18 U.S.C. 2244 (Abusive sexual contact). The statutory maximum term of imprisonment for a violation of section 250 ranges from two years to any term of years or life, depending on the sexual conduct involved in the offense.

The Commission determined that § 2H1.1 is the most appropriate guideline to which to reference this new offense. Other similar offenses are referenced to this guideline. In addition, the Commission concluded that the alternative base offense levels provided in § 2H1.1 effectively address both the broad array of conduct criminalized under this new statute and the varying statutory maximum terms of imprisonment applicable to such conduct.

Second, the amendment amends Appendix A to reference new subsection (c) at 18 U.S.C. 2243 (Sexual abuse of a minor, a ward, or an individual in Federal custody) to § 2A3.3 and makes a conforming change to § 2A3.3's title. The new subsection at 18 U.S.C. 2243 prohibits law enforcement officers from knowingly engaging in a sexual act with an individual under arrest or supervision, in detention, or in federal custody. The Commission determined § 2A3.3 is the most appropriate guideline to which to reference the new offense because it covers a similar offense at 18 U.S.C. 2243(b) prohibiting anyone in a federal prison, institution, or facility from knowingly engaging in a sexual act with a ward, defined as an inmate or other person in official detention and under the custodial, supervisory, or disciplinary authority of the person engaging in the act. Subsection 2243(b) also has the same 15-year statutory maximum term of imprisonment, and a reference to this guideline will result in similar penalties for both subsections of section 2243.

Finally, the amendment increases the base offense level at § 2A3.3 for offenses involving the sexual abuse of a ward or an individual in federal custody from 14 to 18. The Commission determined that the increased base offense level will more appropriately reflect the 15-year statutory maximum penalty for offenses referenced to this guideline and punish the serious sexual conduct involved in these offenses. In promulgating the amendment, the Commission was informed by both the rate and extent of above-range sentences in these cases. While the average guideline minimum in fiscal years 2018 through 2022 was 17 months (median 12 months), the average sentence imposed was more than double, at 35 months (median 15 months).

The Commission also concluded that an increased guideline range for § 2A3.3 offenses would be more proportional to the guideline range at § 2A3.2 (Criminal Sexual Abuse of a Minor Under the Age of Sixteen Years (Statutory Rape) or Attempt to Commit Such Acts) for the sexual abuse of minors over the age of 12 and under the age of 16 years, conduct prohibited by 18 U.S.C. 2243(a) with the same 15-year statutory maximum term of imprisonment as subsections 2243(b) and 2243(c). Section 2A3.2 has a base offense level 18 and a 4-level enhancement if the victim is in the care, custody, or supervisory control of the defendant.

Consistent with this approach, the amendment also amends § 2A3.3 to include the same cross reference currently provided for in § 2A3.2 in order to ensure proportional guideline ranges for all section 2243 offenses when the offense involved aggravating sexual conduct. The new cross reference sends cases to § 2A3.1 (Criminal Sexual Abuse; Attempt to Commit Criminal Sexual Abuse) if the offense involved criminal sexual abuse or attempt to commit criminal sexual abuse (as defined in 18 U.S.C. 2241 or § 2242), and further directs that § 2A3.1 shall apply if the victim had not attained the age of 12 years, regardless of the ''consent'' of the victim.

4. Amendment: Section 2D1.1(a) is amended—

in paragraph (1) by striking the following:

''43, if the defendant is convicted under 21 U.S.C. 841(b)(1)(A), (b)(1)(B), or (b)(1)(C), or 21 U.S.C. 960(b)(1), (b)(2), or (b)(3), and the offense of conviction establishes that death or serious bodily injury resulted from the use of the substance and that the defendant committed the offense after one or more prior convictions for a similar offense; or'',

and inserting the following:

''43, if—

(A) the defendant is convicted under 21 U.S.C. 841(b)(1)(A) or (b)(1)(B), or 21 U.S.C. 960(b)(1) or (b)(2), and the offense of conviction establishes that death or serious bodily injury resulted from the use of the substance and that the defendant committed the offense after one or more prior convictions for a serious drug felony or serious violent felony; or

(B) the defendant is convicted under 21 U.S.C. 841(b)(1)(C) or 21 U.S.C. 960(b)(3) and the offense of conviction establishes that death or serious bodily injury resulted from the use of the substance and that the defendant committed the offense after one or more prior convictions for a felony drug offense; or'';

and in paragraph (3) by striking ''similar offense'' and inserting ''felony drug offense''.

Section 2D1.1(b)(18) is amended by striking ''subdivisions'' and inserting ''paragraphs''.

The Commentary to § 2D1.1 captioned ''Application Notes'' is amended—

by striking Note 2 as follows:

''2. *'Plant'.*—For purposes of the guidelines, a 'plant' is an organism having leaves and a readily observable root formation (*e.g.,* a marihuana cutting having roots, a rootball, or root hairs is a marihuana plant).'';

by redesignating Note 1 as Note 2;

by inserting before Note 2 (as so redesignated) the following new Note 1:

''1. *Definitions.*—

For purposes of the guidelines, a 'plant' is an organism having leaves and a readily observable root formation (*e.g.,* a marihuana cutting having roots, a rootball, or root hairs is a marihuana plant).

For purposes of subsection (a), 'serious drug felony,' 'serious violent felony,' and 'felony drug offense' have the meaning given those terms in 21 U.S.C. 802.'';

and in Note 21 by striking ''a minimum offense level of level 17'' and inserting ''that the applicable guideline range shall not be less than 24 to 30 months of imprisonment''.

Section 2D1.11(b)(6) is amended by striking ''subdivisions'' and inserting ''paragraphs''.

The Commentary to § 2D1.11 captioned ''Application Notes'' is amended in Note 7 by striking ''a minimum offense level of level 17'' and inserting ''an applicable guideline range of not less than 24 to 30 months of imprisonment''.

Section 4A1.3(b)(3)(B) is amended—

in the heading by striking ''*to Category I*'';

by striking ''whose criminal history category is Category I after receipt of'' and inserting ''who receives'';

by striking ''criterion'' and inserting ''criminal history requirement'';

and by striking ''if, before receipt of the downward departure, the defendant had more than one criminal history point under § 4A1.1 (Criminal History Category)'' and inserting ''if the defendant did not otherwise meet such requirement before receipt of the downward departure''.

Section 5C1.2(a) is amended—

by inserting after ''§ 963,'' the following: ''or 46 U.S.C. 70503 or § 70506,'';

by striking ''set forth below'' and inserting ''as follows'';

and by striking paragraph (1) as follows:

''(1) the defendant does not have more than 1 criminal history point, as determined under the sentencing guidelines before application of subsection (b) of § 4A1.3 (Departures Based on Inadequacy of Criminal History Category);'',

and inserting the following new paragraph (1):

''(1) the defendant does not have—

(A) more than 4 criminal history points, excluding any criminal history points resulting from a 1-point offense, as determined under the sentencing guidelines;

(B) a prior 3-point offense, as determined under the sentencing guidelines; and

(C) a prior 2-point violent offense, as determined under the sentencing guidelines;''.

Section 5C1.2(b) is amended by striking ''the offense level applicable from Chapters Two (Offense Conduct) and Three (Adjustments) shall not be less than 17'' and inserting ''the applicable guideline range shall not be less than 24 to 30 months of imprisonment''.

The Commentary to § 5C1.2 captioned ''Application Notes'' is amended—

by striking Notes 1, 2, and 3 as follows:

''1. 'More than 1 criminal history point, as determined under the sentencing guidelines,' as used in subsection (a)(1), means more than one criminal history point as determined under § 4A1.1 (Criminal History Category) before application of subsection (b) of § 4A1.3 (Departures Based on Inadequacy of Criminal History Category).

2. 'Dangerous weapon' and 'firearm,' as used in subsection (a)(2), and 'serious bodily injury,' as used in subsection (a)(3), are defined in the Commentary to § 1B1.1 (Application Instructions).

3. 'Offense,' as used in subsection (a)(2)–(4), and 'offense or offenses that were part of the same course of conduct or of a common scheme or plan,' as used in subsection (a)(5), mean the offense of conviction and all relevant conduct.'';

by inserting the following new Note 1:

''1. *Definitions.*—

(A) The term 'violent offense' means a 'crime of violence,' as defined in 18 U.S.C. 16, that is punishable by imprisonment.

(B) 'Dangerous weapon' and 'firearm,' as used in subsection (a)(2), and 'serious bodily injury,' as used in subsection (a)(3), are defined in the Commentary to § 1B1.1 (Application Instructions).

(C) 'Offense,' as used in subsection (a)(2)–(4), and 'offense or offenses that were part of the same course of conduct or of a common scheme or plan,' as used in subsection (a)(5), mean the offense of conviction and all relevant conduct.'';

by redesignating Note 4 as Note 2;

in Note 2 (as so redesignated) by inserting at the beginning the following new heading: ''*Application of subsection (a)(2).*—'';

by striking Notes 5, 6, and 7 as follows:

''5. 'Organizer, leader, manager, or supervisor of others in the offense, as determined under the sentencing guidelines,' as used in subsection (a)(4), means a defendant who receives an adjustment for an aggravating role under § 3B1.1 (Aggravating Role).

6. 'Engaged in a continuing criminal enterprise,' as used in subsection (a)(4), is defined in 21 U.S.C. 848(c). As a practical matter, it should not be necessary to apply this prong of subsection (a)(4) because (i) this section does not apply to a conviction under 21 U.S.C. 848, and (ii) any defendant who 'engaged in a continuing criminal enterprise' but is convicted of an offense to which this section applies will be an 'organizer, leader, manager, or supervisor of others in the offense.'

7. Information disclosed by the defendant with respect to subsection (a)(5) may be considered in determining the applicable guideline range, except where the use of such information is restricted under the provisions of § 1B1.8 (Use of Certain Information). That is, subsection (a)(5) does not provide an independent basis for restricting the use of information disclosed by the defendant.'';

by inserting the following new Notes 3 and 4:

''3. *Application of Subsection (a)(4).*—

(A) *'Organizer, leader, manager, or supervisor of others in the offense'.*—The first prong of subsection (a)(4) requires that the defendant was not subject to an adjustment for an aggravating role under § 3B1.1 (Aggravating Role).

(B) *'Engaged in a continuing criminal enterprise'.*—'Engaged in a continuing criminal enterprise,' as used in subsection (a)(4), is defined in 21 U.S.C. 848(c). As a practical matter, it should not be necessary to apply this prong of subsection (a)(4) because (i) this section does not apply to a conviction under 21 U.S.C. 848, and (ii) any defendant who 'engaged in a continuing criminal enterprise' but is convicted of an offense to which this section applies will be an 'organizer, leader, manager, or supervisor of others in the offense.'

4. *Use of Information Disclosed under Subsection (a).*—Information disclosed by a defendant under subsection (a) may not be used to enhance the sentence of the defendant unless the information relates to a violent offense, as defined in Application Note 1(A).'';

by redesignating Notes 8 and 9 as Notes 5 and 6, respectively;

in Note 5 (as so redesignated) by inserting at the beginning the following new heading: ''*Government's Opportunity to Make Recommendation.*—'';

and in Note 6 (as so redesignated) by inserting at the beginning the following new heading: ''*Exemption from Otherwise Applicable Statutory Minimum Sentences.*—''.

The Commentary to § 5C1.2 captioned ''Background'' is amended by inserting after ''Violent Crime Control and Law Enforcement Act of 1994'' the following: ''and subsequently amended''.

Reason for Amendment: This two-part amendment revises § 5C1.2 (Limitation on Applicability of Statutory Minimum Sentences in Certain Cases) and subsections (a)(1) and (a)(3) of § 2D1.1 (Unlawful Manufacturing, Importing, Exporting, or Trafficking (Including Possession with Intent to Commit These Offenses); Attempt or Conspiracy) in response to the First Step Act of 2018, Public Law 115–391 (Dec. 21, 2018) (''First Step Act''). The First Step Act amended the eligibility criteria of the ''safety valve'' provision at 18 U.S.C. 3553(f) and the enhanced penalty provisions for certain drug trafficking defendants at 21 U.S.C. 841(b) and 960(b). The amendment primarily revises § 5C1.2 to conform it to the statutory safety valve, as amended by the First Step Act. In addition, the amendment revises subsections (a)(1) and (a)(3) of § 2D1.1 to make the guideline's reference to the type of prior offenses that trigger enhanced mandatory minimum penalties

consistent with the amended statutory provisions.

First, the amendment makes three changes to § 5C1.2 and its corresponding commentary to reflect the statutory changes to section 3553(f) made by the First Step Act. The First Step Act expanded the safety valve provision at section 3553(f) by extending its applicability to defendants convicted of maritime offenses (46 U.S.C. 70503 and 70506) and broadening the criminal history eligibility criteria to include defendants who do not have: (1) ''more than 4 criminal history points, excluding any criminal history points resulting from a 1-point offense, as determined under the sentencing guidelines''; (2) a ''prior 3-point offense, as determined under the sentencing guidelines''; and (3) a ''prior 2-point violent offense, as determined under the sentencing guidelines.'' The amendment revises § 5C1.2(a) to include maritime offenses and the expanded statutory criminal history criteria. Next, it revises Application Note 1 to incorporate the statutory definition for the term ''violent offense.'' Finally, it revises Application Note 7 to reflect the new statutory limitation that information disclosed by a defendant pursuant to 18 U.S.C. 3553(f) ''may not be used to enhance the defendant's sentence unless the information relates to a violent offense.''

Second, the amendment revises § 5C1.2(b) to account for the expanded class of defendants who qualify for safety valve relief. Section 5C1.2(b) implemented Congress's directive requiring that the guideline minimum be at least 24 months for defendants whose statutorily required minimum sentence was at least five years by providing a minimum offense level of 17 for such offenders. *See* Violent Crime Control and Law Enforcement Act of 1994, Public Law 103–222, 80001(b), 108 Stat. 1796, 1985 (1994) (''In the case of a defendant for whom the statutorily required minimum sentence is 5 years, such guidelines and amendments to guidelines . . . shall call for a guideline range in which the lowest term of imprisonment is at least 24 months.''); *see also* USSG App. C, amend. 624 (effective Nov. 1, 2001) (adding § 5C1.2(b) ''in order to comply more strictly with the directive''). Before the First Step Act, only defendants in Criminal History Category (CHC) I (with no more than one criminal history point) could qualify for safety valve relief, and a base offense level of 17 therefore correlated with a guideline range of 24 to 30 months for all safety-valve-eligible defendants. After the First Step Act, a safety-valve-eligible defendant can be in any CHC, and an offense level of 17 correlates with the following guideline ranges at each category: I (24–30 months); II (27–33); III (30–37); IV (37–46); V (46–57); and VI (51–63). Because Congress's directive is tied to the existence of a 5-year mandatory minimum penalty and not to the defendant's CHC, the amendment replaces the offense-level floor with a guideline-range floor. The Commission determined that the proportionality concerns raised in public comment and testimony are addressed by the operation of the Sentencing Table, irrespective of the offense-level floor.

Third, the amendment makes conforming changes to § 4A1.3 (Departures Based on Inadequacy of Criminal History Category (Policy Statement)), which references the number of criminal history points permitted under § 5C1.2(a)(1).

Fourth, the amendment makes only non-substantive changes to § 2D1.1(b)(18) and § 2D1.11(b)(6), the 2-level reductions that are tethered to the eligibility criteria of paragraphs (1)–(5) of § 5C1.2(a). The 2-level reductions in § 2D1.1 and § 2D1.11 apply to any defendant who meets the revised criteria of § 5C1.2.

Finally, the amendment revises subsections (a)(1) and (a)(3) of § 2D1.1 to replace the term ''similar offense'' with the appropriate terms set forth in the relevant statutory provisions, as amended by the First Step Act.

The penalty provisions at 21 U.S.C. 841(b) and 960(b) provide enhanced mandatory minimum penalties for defendants (1) whose instant offense resulted in death or serious bodily injury or (2) who have prior convictions for certain specified offenses. Penalties are further increased if death or serious bodily injury occurred as a result of the instant offense *and* the defendant has a qualifying prior conviction. Prior to the First Step Act, all of the recidivist penalty provisions within sections 841(b) and 960(b) provided for an enhanced mandatory minimum penalty if a defendant had one or more convictions for a prior ''felony drug offense,'' as defined in 21 U.S.C. 802(44). The First Step Act both narrowed and expanded the type of prior offenses that trigger enhanced mandatory minimum penalties under 21 U.S.C. 841(b)(1)(A), 841(b)(1)(B), 960(b)(1), and 960(b)(2) by replacing the term ''felony drug offense'' with ''serious drug felony,'' as defined in 21 U.S.C. 802(57), and adding ''serious violent felony'' offenses, as defined in 21 U.S.C. 802(58). The First Step Act did not amend 21 U.S.C. 841(b)(1)(C), 841(b)(1)(E), 960(b)(3), or 960(b)(5), which still provide for enhanced mandatory minimum penalties if a defendant was convicted of a prior ''felony drug offense.''

The enhanced statutory penalty structure is accounted for through heightened alternative base offense levels (BOL) at § 2D1.1(a)(1)–(a)(4). Prior to the amendment, § 2D1.1(a)(1) provided for a BOL of 43 ''if the defendant is convicted under [any of six enumerated subsections], and the offense of conviction establishes that death or serious bodily injury resulted from the use of the substance and that the defendant committed the offense after one or more prior convictions *for a similar offense*.'' Subsection 2D1.1(a)(3) is identical to § 2D1.1(a)(1), except that it provides a BOL of 30 and applies if the defendant is convicted of an offense involving a Schedule III controlled substance under 21 U.S.C. 841(b)(1)(E) or 21 U.S.C. 960(b)(5).

The First Step Act amended four of the six penalty provisions referenced in § 2D1.1(a)(1) and, for those amended provisions, the term ''similar offense'' is over-inclusive, because it includes drug offenses that do not meet the definition of ''serious drug felony,'' and under-inclusive, because it fails to account for a prior ''serious violent felony.'' The amendment divides § 2D1.1(a)(1) into two subparagraphs, (A) and (B). Subparagraph (A), which references the four statutory provisions amended by the First Step Act, replaces the term ''similar offense'' with ''serious drug felony or serious violent felony.'' Subparagraph (B), which references the two provisions that were not amended, replaces the term ''similar offense'' with ''felony drug offense.'' The amendment also amends § 2D1.1(a)(3), by replacing the term ''similar offense'' with ''felony drug offense,'' for consistency with the terminology used in § 2D1.1(a)(1).

5. Amendment: Section 2D1.1(b)(13) is amended—

by inserting after ''defendant'' the following: ''(A)'';

and by inserting after ''4 levels'' the following: ''; or (B) represented or marketed as a legitimately manufactured drug another mixture or substance containing fentanyl (N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl] propanamide) or a fentanyl analogue, and acted with willful blindness or conscious avoidance of knowledge that such mixture or substance was not the legitimately manufactured drug, increase by 2 levels. The term 'drug,' as used in subsection (b)(13)(B), has the meaning given that term in 21 U.S.C. 321(g)(1)''.

Reason for Amendment: This amendment revises subsection (b)(13) of

§ 2D1.1 (Unlawful Manufacturing, Importing, Exporting, or Trafficking (Including Possession with Intent to Commit These Offenses); Attempt or Conspiracy) to add a new subparagraph (B) with an alternative 2-level enhancement for offenses where the defendant represented or marketed as a legitimately manufactured drug another mixture or substance containing fentanyl or a fentanyl analogue, and acted with willful blindness or conscious avoidance of knowledge that such mixture or substance was not the legitimately manufactured drug. The new subparagraph (B) refers to 21 U.S.C. 321(g)(1) to define the term ''drug.''

Since § 2D1.1(b)(13)'s initial promulgation in 2018, the distribution of fentanyl and fentanyl analogues has dramatically increased. The Drug Enforcement Administration reported a substantial increase in the seizure of fake prescription pills, seizing over 50.6 million in calendar year 2022, with 70 percent containing fentanyl. Of those seized pills containing fentanyl, six out of ten contained a potentially lethal dose of the substance, according to lab testing. Additionally, the Centers for Disease Control and Prevention (CDC) estimates there were 107,622 drug overdose deaths in the United States in 2021, an increase of nearly 15 percent from the 93,655 deaths estimated in 2020. The CDC attributes 80,816 of the drug overdose deaths in 2021 to synthetic opioids, primarily fentanyl.

Commission data also indicates an increase in fentanyl and fentanyl analogue offenses, with fentanyl supplanting other drug types, such as crack cocaine and heroin, to become the third most prevalent primary drug (12.6%) among federal drug offenses in fiscal year 2022. In fiscal year 2017, 166 offenders were held accountable for fentanyl or fentanyl analogues. By fiscal year 2022, the number of offenders increased to 2,511 offenders.

The new alternative 2-level enhancement reflects the increased culpability of an individual who acted with willful blindness or conscious avoidance of knowledge that the substance the individual represented or marketed as a legitimately manufactured drug contained fentanyl or a fentanyl analogue. The Commission determined that the ''willful blindness'' and ''conscious avoidance'' doctrines are ''well established in criminal law,'' as recognized by the Supreme Court. *See Glob.-Tech Appliances, Inc.* v. *SEB S.A.,* 563 U.S. 754, 766 (2011). While appellate courts articulate the ''willful blindness'' or ''conscious avoidance'' doctrines slightly differently, the requirement makes clear that the government bears the burden to prove by a preponderance of the evidence that the enhancement applies based on the subjective belief and deliberate action of the defendant committing the offense.

6. Amendment: Section 2K2.1(a)(4)(B) is amended by inserting after ''18 U.S.C. 922(d)'' the following: '', § 932, or § 933''.

Section 2K2.1(a)(6)(B) is amended by inserting after ''18 U.S.C. 922(d)'' the following: '', § 932, or § 933''.

Section 2K2.1(b) is amended—

in paragraph (4) by striking ''If any firearm (A) was stolen, increase by 2 levels; or (B) had an altered or obliterated serial number, increase by 4 levels'' and inserting ''If (A) any firearm was stolen, increase by 2 levels; or (B)(i) any firearm had an altered or obliterated serial number; or (ii) the defendant knew that any firearm involved in the offense was not otherwise marked with a serial number (other than a firearm manufactured prior to the effective date of the Gun Control Act of 1968) or was willfully blind to or consciously avoided knowledge of such fact, increase by 4 levels'';

in paragraph (5) by striking ''If the defendant engaged in the trafficking of firearms, increase by 4 levels.'' and inserting the following:

''(Apply the Greatest) If the defendant—

(A) was convicted under 18 U.S.C. 933(a)(2) or (a)(3), increase by 2 levels;

(B) (i) transported, transferred, sold, or otherwise disposed of, or purchased or received with intent to transport, transfer, sell, or otherwise dispose of, a firearm or any ammunition knowing or having reason to believe that such conduct would result in the receipt of the firearm or ammunition by an individual who (I) was a prohibited person; or (II) intended to use or dispose of the firearm or ammunition unlawfully; (ii) attempted or conspired to commit the conduct described in clause (i); or (iii) received a firearm or any ammunition as a result of inducing the conduct described in clause (i), increase by 2 levels; or

(C) (i) transported, transferred, sold, or otherwise disposed of, or purchased or received with intent to transport, transfer, sell, or otherwise dispose of, two or more firearms knowing or having reason to believe that such conduct would result in the receipt of the firearms by an individual who (I) had a prior conviction for a crime of violence, controlled substance offense, or misdemeanor crime of domestic violence; (II) was under a criminal justice sentence at the time of the offense; or (III) intended to use or dispose of the firearms unlawfully; (ii) attempted or conspired to commit the conduct described in clause (i); or (iii) received two or more firearms as a result of inducing the conduct described in clause (i), increase by 5 levels.

Provided, however, that subsection (b)(5)(C)(i)(I) shall not apply based upon the receipt or intended receipt of the firearms by an individual with a prior conviction for a misdemeanor crime of domestic violence against a person in a dating relationship if, at the time of the instant offense, such individual met the criteria set forth in the proviso of 18 U.S.C. 921(a)(33)(C).'';

and by inserting at the end the following new paragraphs (8) and (9):

''(8) If the defendant—

(A) receives an enhancement under subsection (b)(5); and

(B) committed the offense in connection with the defendant's participation in a group, club, organization, or association of five or more persons, knowing or acting with willful blindness or conscious avoidance of knowledge that the group, club, organization, or association had as one of its primary purposes the commission of criminal offenses;

increase by 2 levels.

(9) If the defendant—

(A) receives an enhancement under subsection (b)(5);

(B) does not have more than 1 criminal history point, as determined under § 4A1.1 (Criminal History Category) and § 4A1.2 (Definitions and Instructions for Computing Criminal History), read together, before application of subsection (b) of § 4A1.3 (Departures Based on Inadequacy of Criminal History Category); and

(C) (i) was motivated by an intimate or familial relationship or by threats or fear to commit the offense and was otherwise unlikely to commit such an offense; or (ii) was unusually vulnerable to being persuaded or induced to commit the offense due to a physical or mental condition;

decrease by 2 levels.''.

The Commentary to § 2K2.1 captioned ''Statutory Provisions'' is amended by inserting after ''(k)–(o),'' the following: ''932, 933,''.

The Commentary to § 2K2.1 captioned ''Application Notes'' is amended—

in Note 3 by striking ''subsections (a)(4)(B) and (a)(6)'' and inserting ''subsections (a)(4)(B), (a)(6), and (b)(5)'';

in Note 8(A)—

in the first paragraph by striking ''However, if the offense involved a firearm with an altered or obliterated serial number, apply subsection (b)(4)(B)'' and inserting ''However, if the offense involved a firearm with an altered or obliterated serial number, or

if the defendant knew that any firearm involved in the offense was not otherwise marked with a serial number (other than a firearm manufactured prior to the effective date of the Gun Control Act of 1968) or was willfully blind to or consciously avoided knowledge of such fact, apply subsection (b)(4)(B)(i) or (ii)'';

and by striking the second paragraph as follows:

''Similarly, if the offense to which § 2K2.1 applies is 18 U.S.C. §§ 922(k) or 26 U.S.C. §§ 5861(g) or (h) (offenses involving an altered or obliterated serial number) and the base offense level is determined under subsection (a)(7), do not apply the enhancement in subsection (b)(4)(B). This is because the base offense level takes into account that the firearm had an altered or obliterated serial number. However, if the offense involved a stolen firearm or stolen ammunition, apply subsection (b)(4)(A).'',

and inserting the following paragraph:

''Similarly, if the offense to which § 2K2.1 applies is 18 U.S.C. §§ 922(k) or 26 U.S.C. §§ 5861(g) or (h) (offenses involving an altered or obliterated serial number) and the base offense level is determined under subsection (a)(7), do not apply the enhancement in subsection (b)(4)(B)(i). This is because the base offense level takes into account that the firearm had an altered or obliterated serial number. However, if the offense involved a stolen firearm or stolen ammunition, or if the defendant knew that any firearm involved in the offense was not otherwise marked with a serial number (other than a firearm manufactured prior to the effective date of the Gun Control Act of 1968) or was willfully blind to or consciously avoided knowledge of such fact, apply subsection (b)(4)(A) or (B)(ii).'';

in Note 8(B) by striking the following:

''*Knowledge or Reason to Believe.*—Subsection (b)(4) applies regardless of whether the defendant knew or had reason to believe that the firearm was stolen or had an altered or obliterated serial number.'',

and inserting the following:

''*Defendant's State of Mind.*—Subsection (b)(4)(A) or (B)(i) applies regardless of whether the defendant knew or had reason to believe that the firearm was stolen or had an altered or obliterated serial number. However, subsection (b)(4)(B)(ii) only applies if the defendant knew that any firearm involved in the offense was not otherwise marked with a serial number (other than a firearm manufactured prior to the effective date of the Gun Control Act of 1968) or was willfully blind to or consciously avoided knowledge of such fact.'';

in Note 10 by striking ''subsection (a)(1) and (a)(2)'' and inserting ''subsections (a)(1) and (a)(2)'';

in Note 13—

by striking paragraph (A) as follows:

''(A) *In General.*—Subsection (b)(5) applies, regardless of whether anything of value was exchanged, if the defendant—

(i) transported, transferred, or otherwise disposed of two or more firearms to another individual, or received two or more firearms with the intent to transport, transfer, or otherwise dispose of firearms to another individual; and

(ii) knew or had reason to believe that such conduct would result in the transport, transfer, or disposal of a firearm to an individual—

(I) whose possession or receipt of the firearm would be unlawful; or

(II) who intended to use or dispose of the firearm unlawfully.'';

by redesignating paragraphs (B), (C), and (D) as paragraphs (A), (B), and (C), respectively;

in paragraph (A) (as so redesignated) by striking the following paragraphs:

'' 'Individual whose possession or receipt of the firearm would be unlawful' means an individual who (i) has a prior conviction for a crime of violence, a controlled substance offense, or a misdemeanor crime of domestic violence; or (ii) at the time of the offense was under a criminal justice sentence, including probation, parole, supervised release, imprisonment, work release, or escape status. 'Crime of violence' and 'controlled substance offense' have the meaning given those terms in § 4B1.2 (Definitions of Terms Used in Section 4B1.1). 'Misdemeanor crime of domestic violence' has the meaning given that term in 18 U.S.C. §§ 921(a)(33)(A).

The term 'defendant', consistent with § 1B1.3 (Relevant Conduct), limits the accountability of the defendant to the defendant's own conduct and conduct that the defendant aided or abetted, counseled, commanded, induced, procured, or willfully caused.'',

and inserting the following paragraphs:

'' 'Crime of violence' and 'controlled substance offense' have the meaning given those terms in § 4B1.2 (Definitions of Terms Used in Section 4B1.1).

'Misdemeanor crime of domestic violence' has the meaning given that term in 18 U.S.C. §§ 921(a)(33)(A).

The term 'criminal justice sentence' includes probation, parole, supervised release, imprisonment, work release, or escape status.

The term 'defendant,' consistent with § 1B1.3 (Relevant Conduct), limits the accountability of the defendant to the defendant's own conduct and conduct that the defendant aided or abetted, counseled, commanded, induced, procured, or willfully caused.'';

and in paragraph (B) (as so redesignated) by striking ''If the defendant trafficked substantially more than 25 firearms'' and inserting ''If the defendant transported, transferred, sold, or otherwise disposed of, or purchased or received with intent to transport, transfer, sell, or otherwise dispose of, substantially more than 25 firearms'';

and by striking Note 15 as follows:

''15. *Certain Convictions Under 18 U.S.C. §§ 922(a)(6), 922(d), and 924(a)(1)(A).*—In a case in which the defendant is convicted under 18 U.S.C. §§ 922(a)(6), 922(d), or 924(a)(1)(A), a downward departure may be warranted if (A) none of the enhancements in subsection (b) apply, (B) the defendant was motivated by an intimate or familial relationship or by threats or fear to commit the offense and was otherwise unlikely to commit such an offense, and (C) the defendant received no monetary compensation from the offense.''.

Appendix A (Statutory Index) is amended by inserting before the line referenced to 18 U.S.C. 956 the following new line references:

''18 U.S.C. §§ 932 2K2.1
18 U.S.C. §§ 933 2K2.1''.

Reason for Amendment: This multi-part amendment responds to the directive in section 12004(a)(5) of the Bipartisan Safer Communities Act, Public Law 117–159 (the ''Act''), addresses new offenses and other changes in law made by the Act, and revises the primary firearms guideline, § 2K2.1 (Unlawful Receipt, Possession, or Transportation of Firearms or Ammunition; Prohibited Transactions Involving Firearms or Ammunition), to account for firearms that are not marked with a serial number. In the Act, Congress directed that the Commission:

shall review and amend its guidelines and policy statements to ensure that persons convicted of an offense under section 932 or 933 of title 18, United States Code, and other offenses applicable to the straw purchases and trafficking of firearms are subject to increased penalties in comparison to those currently provided by the guidelines and policy statements for such straw purchasing and trafficking of firearms offenses. In its review, the Commission shall consider, in particular, an appropriate amendment to reflect the intent of Congress that straw purchasers without significant criminal histories receive sentences that are sufficient to deter participation in such

activities and reflect the defendant's role and culpability, and any coercion, domestic violence survivor history, or other mitigating factors. The Commission shall also review and amend its guidelines and policy statements to reflect the intent of Congress that a person convicted of an offense under section 932 or 933 of title 18, United States Code, who is affiliated with a gang, cartel, organized crime ring, or other such enterprise should be subject to higher penalties than an otherwise unaffiliated individual.

Public Law 117–159, 12004(a)(5), 136 Stat. 1313, 1328 (2022).

New Straw Purchase and Firearms Trafficking Offenses

The amendment makes two changes to account for the new offenses at 18 U.S.C. 932 and 933 established by the Act. First, the amendment amends Appendix A (Statutory Index) to reference the new offenses to § 2K2.1. Section 12004(a)(1) of the Act makes it unlawful to engage in straw purchasing of firearms (18 U.S.C. 932) or trafficking in firearms (18 U.S.C. 933). Sections 932 and 933 both carry statutory maximum sentences of 15 years of imprisonment. 18 U.S.C. 932(c)(1), 933(b). The statutory maximum in section 932 increases to 25 years where the defendant has reasonable cause to believe the firearm would be used to commit a felony or certain other offenses. 18 U.S.C. 932(c)(2). As both offenses address conduct that is analogous to other firearms offenses, the Commission determined that the most appropriate guideline is § 2K2.1.

Second, the amendment revises § 2K2.1 to set the base offense level for defendants convicted of these crimes at level 14, or level 20 if the offense involved either a semiautomatic firearm that is capable of accepting a large capacity magazine or a firearm described in 26 U.S.C. 5845(a). The Commission set these base offense levels to the same levels applicable to defendants convicted under a third statute used to prosecute straw purchasers and traffickers with the same 15-year statutory maximum, 18 U.S.C. 922(d), to ensure proportionality.

Increase Penalties for Straw Purchasing and Trafficking Offenses

The amendment next revises § 2K2.1 to respond to section 12004(a)(5) of the Act, which directs the Commission to provide increased penalties for defendants convicted under 18 U.S.C. 932, 18 U.S.C. 933, or ''other offenses applicable to the straw purchases and trafficking of firearms.'' Specifically, the amendment revises the existing ''trafficking'' specific offense characteristic at § 2K2.1(b)(5).

Prior to the amendment, subsection (b)(5) provided an enhancement of four levels ''[i]f the defendant engaged in the trafficking of firearms.'' Application Note 13(A) provided that this enhancement applied if the defendant transported, transferred, or otherwise disposed of two or more firearms to another individual, or received two or more firearms with the intent to transport, transfer, or otherwise dispose of firearms to another individual, whose possession or receipt would be unlawful or who intended to use or dispose of the firearm unlawfully. Application Note 13(B) defined a person whose possession or receipt would be unlawful as an individual who (i) had a prior conviction for a crime of violence, a controlled substance offense, or a misdemeanor crime of domestic violence; or (ii) at the time of the offense was under a criminal justice sentence, including probation, parole, supervised release, imprisonment, work release, or escape status.

The amendment revises subsection (b)(5) in three ways to comply with Congress's directive to include an increase for all defendants convicted under 18 U.S.C. 932, 18 U.S.C. 933, or other offenses involving straw purchasing or trafficking of firearms.

First, the amendment creates a new subsection, § 2K2.1(b)(5)(A), which provides a 2-level enhancement for defendants convicted of illegally receiving a firearm under 18 U.S.C. 933(a)(2) (the trafficking receipt provision) or § 933(a)(3) (attempting/conspiring to violate section 933). This ensures that receipt-only defendants convicted under section 933 receive the requisite increase.

Second, the amendment creates a new subsection, § 2K2.1(b)(5)(B), which provides a 2-level enhancement for any defendant engaged in straw purchasing or trafficking. This provision incorporates the elements of the straw purchasing and firearms trafficking statutes, including 18 U.S.C. 922(d), § 932, and § 933(a)(1), to provide an increase for defendants who attempted, conspired, or engaged in conduct involving the illicit transfer of a firearm or ammunition but who would not have received the trafficking enhancement prior to the amendment because of the limiting criteria in the existing Application Note 13. Those criteria included trafficking two or more firearms and that the recipient have criminal convictions for specified crimes.

Third, the amendment revises the criteria previously set forth in Application Notes 13(A) and (B) and incorporates the criteria into subsection (b)(5)(C). New subsection (b)(5)(C) provides an increase for defendants who attempted, conspired, or engaged in conduct involving the illicit transfer of two or more firearms to a person who (i) had a prior conviction of a crime of violence, controlled substance offense, or misdemeanor crime of domestic violence; (ii) was under a criminal justice sentence at the time of the offense; or (iii) intended to use or dispose of the firearms unlawfully. The new subsection (b)(5)(C) increases the enhancement from four levels to five levels to ensure straw purchasers and firearms traffickers meeting these criteria receive increased penalties as required by the directive.

The Commission determined that the expanded specific offense characteristic at subsection (b)(5) fully implements the directive by ensuring that defendants who illegally transfer a firearm receive an increased penalty under the guidelines. Specifically, the enhancement is tailored to apply to the most culpable defendants who engage in (a) straw purchasing, including those defendants who induce straw purchasing, and (b) firearms trafficking, including those defendants whose conduct was ''upstream'' in the gun trafficking pipeline. Consistent with the legislative history of the Act, public comment, and witness testimony, the Commission determined that such an increase is appropriate to reflect Congress's view that such conduct contributes to the illegal flow of firearms and that such defendants are currently under-punished as compared to felons in possession of the trafficked weapons. At the same time, by incorporating the elements of the core straw purchasing and firearms trafficking statutes, including the new offenses (sections 932 and 933), the new enhancement narrowly targets such defendants without also impacting other firearms defendants who were not intended to receive an increase.

The amendment also makes two conforming changes. First, to conform with statutory changes in 18 U.S.C. 921(a)(33), the amended subsection (b)(5)(C) includes a proviso that the enhancement does not apply by reason of the transferee's prior misdemeanor crime of domestic violence where the transferee's rights were restored. Second, the amendment amends the upward departure provision in Application Note 13(B) to conform the language with the revised subsection (b)(5).

Increase Penalties for Organized Crime

The amendment next amends § 2K2.1 to respond to section 12004(a)(5) of the Act, which directs the Commission to increase penalties for defendants convicted under 18 U.S.C. 932 or § 933 who are affiliated with organized crime. The amendment implements this portion of the directive by creating a new specific offense characteristic providing for a 2-level enhancement under § 2K2.1(b)(8). Section 2K2.1(b)(8) applies to those defendants who receive an increase at subsection (b)(5) and who committed the offense in connection with the defendant's participation in an organization of five or more persons, knowing, or acting with willful blindness or conscious avoidance of knowledge, that the organization has as one of its primary purposes the commission of criminal offenses.

To ensure that a defendant would not receive the enhancement based solely on evidence unrelated to the criminal act or mere inclusion in gang databases, the enhancement requires that the defendant committed the offense ''in connection with'' the defendant's ''participation'' in a criminal organization, and that the defendant knew or consciously avoided knowledge of the criminal nature of the organization's activities. As with other amendments this year, the Commission determined that the doctrines of ''willful blindness'' and ''conscious avoidance'' are ''well established in criminal law.'' *See Glob.-Tech Appliances, Inc.* v. *SEB S.A.,* 563 U.S. 754, 766, 769 (2011) (noting that, while the Courts of Appeals articulate the ''willful blindness'' or ''conscious avoidance'' doctrines slightly differently, ''[the Courts of Appeals] all appear to agree on two basic requirements: (1) The defendant must subjectively believe that there is a high probability that a fact exists and (2) the defendant must take deliberate actions to avoid learning of that fact.'').

Finally, the Commission determined that a 2-level increase for defendants receiving this enhancement is appropriate because specific offense characteristics accounting for other aggravating factors, such as the number of firearms and the use or possession of any firearm or ammunition in connection with another felony offense, may also apply to gang-affiliated defendants in addition to the new enhancement at subsection (b)(8). Accordingly, the Commission determined that an incremental 2-level enhancement appropriately and adequately differentiates straw purchasing and firearms trafficking defendants affiliated with organized crime from those who are unaffiliated.

Reduction for Mitigating Circumstances

The amendment amends § 2K2.1 to respond to section 12004(a)(5) of the Act, which directs the Commission to consider an amendment accounting for straw purchasers with mitigating circumstances. The amendment implements this portion of the directive by creating a new specific offense characteristic at § 2K2.1(b)(9) providing a 2-level reduction available to defendants who receive an increase at subsection (b)(5) and satisfy other eligibility criteria. The amendment also deletes Application Note 15, which provided for a downward departure for certain straw purchasers, because subsection (b)(9) provides a reduction with broader criteria.

Consistent with congressional intent that the reduction apply to straw purchasers without significant criminal histories, a defendant must have no more than 1 criminal history point to qualify for the specific offense characteristic. Also consistent with congressional intent that the Commission account for mitigating circumstances, the adjustment applies to a defendant motivated by an intimate or familial relationship or by threats or fear who was otherwise unlikely to commit such an offense, or to a defendant who was unusually vulnerable due to physical or mental conditions. The Commission determined that such qualifiers appropriately ensure that the reduction is not so broad as to include highly culpable defendants, while also ensuring it is not so narrow as to exclude the less culpable defendants.

Similarly, the Commission determined that a 2-level reduction is appropriate to ensure that the magnitude of the reduction matches the magnitude of the increase provided in subsections (b)(5)(A) and (B) so that qualifying defendants do not receive increased penalties as a result of the amendment taken as a whole.

Firearms Not Marked With a Serial Number

Finally, the amendment amends § 2K2.1 to account for privately made firearms not marked with a serial number, commonly referred to as ''ghost guns.'' The amendment provides a 4-level enhancement if the defendant knew that the offense involved a firearm not marked with a serial number, or the defendant was willfully blind or consciously avoided knowing this fact.

In adding the enhancement, the Commission concluded that there is no meaningful distinction between a firearm with an obliterated serial number, which has long-triggered a 4-level enhancement under § 2K2.1(b)(4), and a firearm that is not marked with a serial number. The Commission also concluded that firearms not marked with a serial number share the traits that led the Commission to implement a 4-level enhancement for firearms with altered or obliterated serial numbers: ''difficulty in tracing firearms with altered or obliterated serial numbers, and the increased market for these types of weapons.'' USSG App. C, amend. 691 (effective Nov. 1, 2006). Specifically, the Commission shared concerns raised by the Department of Justice regarding the proliferation of ghost guns, the increased frequency with which ghost guns are used in connection with criminal activity, and the difficulty in tracing these firearms. Therefore, the Commission concluded that the same 4-level enhancement applied in offenses involving an altered or obliterated serial number is also appropriate for firearms not marked with a serial number.

The Commission determined that the enhancement should apply only to those defendants who knew or consciously avoided knowing that the firearm was not marked with a serial number. The amendment also specifically excepts firearms manufactured before the effective date of the Gun Control Act of 1968, which imposed the requirement that federal firearms licensees serialize newly manufactured or imported firearms.

The amendment also makes conforming changes to Application Note 8.

7. Amendment: Section 3E1.1(b) is amended by inserting after ''1 additional level.'' the following: ''The term 'preparing for trial' means substantive preparations taken to present the government's case against the defendant to a jury (or judge, in the case of a bench trial) at trial. 'Preparing for trial' is ordinarily indicated by actions taken close to trial, such as preparing witnesses for trial, in limine motions, proposed voir dire questions and jury instructions, and witness and exhibit lists. Preparations for pretrial proceedings (such as litigation related to a charging document, discovery motions, and suppression motions) ordinarily are not considered 'preparing for trial' under this subsection. Post-conviction matters (such as sentencing objections, appeal waivers, and related issues) are not considered 'preparing for trial.' ''.

The Commentary to § 3E1.1 captioned ''Application Notes'' is amended in Note 6 by striking ''The government

should not withhold such a motion based on interests not identified in § 3E1.1, such as whether the defendant agrees to waive his or her right to appeal.''.

Reason for Amendment: This amendment responds to circuit conflicts over whether a reduction under subsection (b) of § 3E1.1 (Acceptance of Responsibility), which requires a motion from the government, may be withheld or denied if a defendant moves to suppress evidence or raises sentencing challenges. The amendment addresses the circuit conflicts by providing a definition of the term ''preparing for trial,'' which appears in § 3E1.1(b) and Application Note 6 to § 3E1.1. The amendment also deletes hortatory language that the Commission previously added to Application Note 6 providing that the ''government should not withhold such a motion based on interests not identified in § 3E1.1, such as whether the defendant agrees to waive his or her right to appeal.'' *See* USSG App. C, amend. 775 (effective Nov. 1, 2013).

The amendment defines ''preparing for trial'' as ''substantive preparations taken to present the government's case against the defendant to a jury (or judge, in the case of a bench trial) at trial.'' The amendment further provides examples of actions that ordinarily indicate preparing for trial (such as preparing witnesses for trial, in limine motions, proposed voir dire questions and jury instructions, and witnesses and exhibit lists). The amendment further provides that preparations for pretrial proceedings (such as litigation related to a charging document, discovery motions, and suppression motions) ordinarily are not considered preparing for trial, and that post-conviction matters (such as sentencing objections, appeal waivers, and related issues) are not considered preparing for trial.

As Justices Sotomayor and Gorsuch observed in 2021, the conflict as to whether a suppression hearing is a valid basis for denying a § 3E1.1(b) reduction is both longstanding and has a potentially significant impact on defendants. *See Longoria* v. *United States,* 141 S. Ct. 978, 979 (2021) (statement of Sotomayor, J., with whom Gorsuch, J. joins, respecting the denial of certiorari, ''emphasiz[ing] the need for clarification from the Commission'' on this ''important and longstanding split among the Courts of Appeals over the proper interpretation of § 3E1.1(b)''). Three circuits (the Third, Fifth, and Sixth Circuits) have permitted the government to withhold a § 3E1.1(b) motion based on a suppression motion, while five circuits (the First, Second, Ninth, Tenth, and D.C. Circuits) have held that a reduction may not be denied based on a suppression motion. *Compare United States* v. *Longoria,* 958 F.3d 372 (5th Cir. 2020), *cert. denied,* 141 S. Ct. 978 (2021), *United States* v. *Collins,* 683 F.3d 697 (6th Cir. 2012), and *United States* v. *Drennon,* 516 F.3d 160 (3d Cir. 2008), *with United States* v. *Vargas,* 961 F.3d 566 (2d Cir. 2020), *United States* v. *Price,* 409 F.3d 436 (D.C. Cir. 2005), *United States* v. *Marquez,* 337 F.3d 1203 (10th Cir. 2003), *United States* v. *Marroquin,* 136 F.3d 220 (1st Cir. 1998), and *United States* v. *Kimple,* 27 F.3d 1409 (9th Cir. 1994).

Similarly, the First, Third, Seventh, and Eighth Circuits have held that the government may withhold a § 3E1.1(b) motion based on sentencing challenges, while the Second and Fifth Circuits have held that it may not. *Compare United States* v. *Adair,* 38 F.4th 341 (3d Cir. 2022), *United States* v. *Jordan,* 877 F.3d 391 (8th Cir. 2017), *United States* v. *Sainz-Preciado,* 566 F.3d 708 (7th Cir. 2009), and *United States* v. *Beatty,* 538 F.3d 8 (1st Cir. 2008), *with United States* v. *Castillo,* 779 F.3d 318 (5th Cir. 2015), and *United States* v. *Lee,* 653 F.3d 170 (2d Cir. 2011).

These conflicts have resulted in variation in § 3E1.1(b) motion practice across—and even within—judicial districts. In some jurisdictions, defendants receive the additional reduction as a matter of course, even if they assert pre-trial or post-conviction challenges. In others, the § 3E1.1(b) motion has been withheld based on motions to suppress, sentencing challenges, or other grounds. Because the sentencing impact of losing one additional level under § 3E1.1(b) can be significant, the practice in the latter districts has had a chilling effect, deterring defendants from pursuing certain evidentiary and sentencing challenges.

The Commission promulgated this amendment to decrease variation between jurisdictions in applying § 3E1.1(b). The amendment also aims to minimize any deterrent effect on defendants' ability to exercise their constitutional rights. *See also* § 3E1.1, comment. (n.2) (allowing consideration for the adjustment where a defendant exercises constitutional rights to trial to raise a constitutional challenge to a statute or challenge the applicability of a statute to the defendant's conduct).

In promulgating this amendment, the Commission recognizes that these circuit conflicts involve guideline and commentary provisions that Congress directly amended, and that Congress also directed the Commission not to ''alter or repeal'' the congressional amendments. *See* Prosecutorial Remedies and Other Tools to end the Exploitation of Children Today Act of 2003, Public Law 108–21, 401(g), (j)(4), 117 Stat. 650. In recognition of this limitation, the amendment defines a term that the congressional amendments did not define—''preparing for trial''—without altering or repealing the amendments that Congress made.

8. Amendment:

Part A (Status Points Under § 4A1.1)

The Commentary to § 2P1.1 captioned ''Application Notes'' is amended in Note 5 by striking ''§ 4A1.1(d)'' and inserting ''§ 4A1.1(e)''.

Section 4A1.1 is amended—

by striking subsection (d) as follows:

''(d) Add 2 points if the defendant committed the instant offense while under any criminal justice sentence, including probation, parole, supervised release, imprisonment, work release, or escape status.'';

by redesignating subsection (e) as subsection (d);

and by inserting at the end the following new subsection (e):

''(e) Add 1 point if the defendant (1) receives 7 or more points under subsections (a) through (d), and (2) committed the instant offense while under any criminal justice sentence, including probation, parole, supervised release, imprisonment, work release, or escape status.''.

The Commentary to § 4A1.1 captioned ''Application Notes'' is amended—

by striking Note 4 as follows:

''4. *§ 4A1.1(d).* Two points are added if the defendant committed any part of the instant offense (*i.e.,* any relevant conduct) while under any criminal justice sentence, including probation, parole, supervised release, imprisonment, work release, or escape status. Failure to report for service of a sentence of imprisonment is to be treated as an escape from such sentence. *See* § 4A1.2(n). For the purposes of this subsection, a 'criminal justice sentence' means a sentence countable under § 4A1.2 (Definitions and Instructions for Computing Criminal History) having a custodial or supervisory component, although active supervision is not required for this subsection to apply. For example, a term of unsupervised probation would be included; but a sentence to pay a fine, by itself, would not be included. A defendant who commits the instant offense while a violation warrant from a prior sentence is outstanding (*e.g.,* a probation, parole, or supervised release violation warrant) shall be deemed to be under a criminal justice sentence for the purposes of this

provision if that sentence is otherwise countable, even if that sentence would have expired absent such warrant. *See* § 4A1.2(m).'';

by redesignating Note 5 as Note 4;

in Note 4 (as so redesignated) by striking ''§ 4A1.1(e)'' each place such term appears and inserting ''§ 4A1.1(d)'';

and by inserting at the end the following new note 5:

''5. *§ 4A1.1(e).* One point is added if the defendant (1) receives 7 or more points under § 4A1.1(a) through (d), and (2) committed any part of the instant offense (*i.e.,* any relevant conduct) while under any criminal justice sentence, including probation, parole, supervised release, imprisonment, work release, or escape status. Failure to report for service of a sentence of imprisonment is to be treated as an escape from such sentence. *See* § 4A1.2(n). For the purposes of this subsection, a 'criminal justice sentence' means a sentence countable under § 4A1.2 (Definitions and Instructions for Computing Criminal History) having a custodial or supervisory component, although active supervision is not required for this subsection to apply. For example, a term of unsupervised probation would be included; but a sentence to pay a fine, by itself, would not be included. A defendant who commits the instant offense while a violation warrant from a prior sentence is outstanding (*e.g.,* a probation, parole, or supervised release violation warrant) shall be deemed to be under a criminal justice sentence for the purposes of this provision if that sentence is otherwise countable, even if that sentence would have expired absent such warrant. *See* § 4A1.2(m).''.

The Commentary to § 4A1.1 captioned ''Background'' is amended in the last paragraph by striking ''Section 4A1.1(d) adds two points if the defendant was under a criminal justice sentence during any part of the instant offense'' and inserting ''Section 4A1.1(e) adds one point if the defendant receives 7 or more points under § 4A1.1(a) through (d) and was under a criminal justice sentence during any part of the instant offense''.

Section 4A1.2 is amended—

in subsection (a)(2) by striking ''§ 4A1.1(e)'' and inserting ''§ 4A1.1(d)'';

in subsection (m) by striking ''§ 4A1.1(d)'' and inserting ''§ 4A1.1(e)'';

in subsection (n) by striking ''§ 4A1.1(d)'' and inserting ''§ 4A1.1(e)'';

and in subsection (p) by striking ''§ 4A1.1(e)'' and inserting ''§ 4A1.1(d)''.

Part B (Zero-Point Offenders)

Subpart 1 (Adjustment for Certain Zero-Point Offenders)

Chapter Four is amended by inserting at the end the following new Part C:

''PART C—ADJUSTMENT FOR CERTAIN ZERO-POINT OFFENDERS

§ 4C1.1. *Adjustment for Certain Zero-Point Offenders*

(a) *Adjustment.*—If the defendant meets all of the following criteria:

(1) the defendant did not receive any criminal history points from Chapter Four, Part A;

(2) the defendant did not receive an adjustment under § 3A1.4 (Terrorism);

(3) the defendant did not use violence or credible threats of violence in connection with the offense;

(4) the offense did not result in death or serious bodily injury;

(5) the instant offense of conviction is not a sex offense;

(6) the defendant did not personally cause substantial financial hardship;

(7) the defendant did not possess, receive, purchase, transport, transfer, sell, or otherwise dispose of a firearm or other dangerous weapon (or induce another participant to do so) in connection with the offense;

(8) the instant offense of conviction is not covered by § 2H1.1 (Offenses Involving Individual Rights);

(9) the defendant did not receive an adjustment under § 3A1.1 (Hate Crime Motivation or Vulnerable Victim) or § 3A1.5 (Serious Human Rights Offense); and

(10) the defendant did not receive an adjustment under § 3B1.1 (Aggravating Role) and was not engaged in a continuing criminal enterprise, as defined in 21 U.S.C. 848;

decrease the offense level determined under Chapters Two and Three by 2 levels.

(b) *Definitions and Additional Considerations.*—

(1) 'Dangerous weapon,' 'firearm,' 'offense,' and 'serious bodily injury' have the meaning given those terms in the Commentary to § 1B1.1 (Application Instructions).

(2) 'Sex offense' means (A) an offense, perpetrated against a minor, under (i) chapter 109A of title 18, United States Code; (ii) chapter 110 of title 18, not including a recordkeeping offense; (iii) chapter 117 of title 18, not including transmitting information about a minor or filing a factual statement about an alien individual; or (iv) 18 U.S.C. 1591; or (B) an attempt or a conspiracy to commit any offense described in subparagraphs (A)(i) through (iv) of this definition.

(3) In determining whether the defendant's acts or omissions resulted in 'substantial financial hardship' to a victim, the court shall consider, among other things, the non-exhaustive list of factors provided in Application Note 4(F) of the Commentary to § 2B1.1 (Theft, Property Destruction, and Fraud).

Commentary

Application Notes:

1. *Application of Subsection (a)(6).*—The application of subsection (a)(6) is to be determined independently of the application of subsection (b)(2) of § 2B1.1 (Theft, Property Destruction, and Fraud).

2. *Upward Departure.*—An upward departure may be warranted if an adjustment under this guideline substantially underrepresents the seriousness of the defendant's criminal history. For example, an upward departure may be warranted if the defendant has a prior conviction or other comparable judicial disposition for an offense that involved violence or credible threats of violence.''.

Subpart 2 (Implementation of 28 U.S.C. 994(j))

The Commentary to § 5C1.1 captioned ''Application Notes'' is amended—

by inserting at the beginning of Note 1 the following new heading: ''*Application of Subsection (a).*—'';

by inserting at the beginning of Note 2 the following new heading: ''*Application of Subsection (b).*—'';

by inserting at the beginning of Note 3 the following new heading: ''*Application of Subsection (c).*—'';

by striking Note 4 as follows:

''If the defendant is a nonviolent first offender and the applicable guideline range is in Zone A or B of the Sentencing Table, the court should consider imposing a sentence other than a sentence of imprisonment, in accordance with subsection (b) or (c)(3). *See* 28 U.S.C. 994(j). For purposes of this application note, a 'nonviolent first offender' is a defendant who has no prior convictions or other comparable judicial dispositions of any kind and who did not use violence or credible threats of violence or possess a firearm or other dangerous weapon in connection with the offense of conviction. The phrase 'comparable judicial dispositions of any kind' includes diversionary or deferred dispositions resulting from a finding or admission of guilt or a plea of *nolo contendere* and juvenile adjudications.'';

by redesignating Notes 5 through 10 as Notes 4 through 9, respectively;

by inserting at the beginning of Note 4 (as so redesignated) the following new

heading: ''*Application of Subsection (d).*—'';

by inserting at the beginning of Note 5 (as so redesignated) the following new heading: ''*Application of Subsection (e).*—'';

by inserting at the beginning of Note 6 (as so redesignated) the following new heading: ''*Departures Based on Specific Treatment Purpose.*—'';

by inserting at the beginning of Note 7 (as so redesignated) the following new heading: ''*Use of Substitutes for Imprisonment.*—'';

by inserting at the beginning of Note 8 (as so redesignated) the following new heading: ''*Residential Treatment Program.*—'';

by inserting at the beginning of Note 9 (as so redesignated) the following new heading: ''*Application of Subsection (f).*—'';

and by inserting at the end the following new Note 10:

''10. *Zero-Point Offenders.*—

(A) *Zero-Point Offenders in Zones A and B of the Sentencing Table.*—If the defendant received an adjustment under § 4C1.1 (Adjustment for Certain Zero-Point Offenders) and the defendant's applicable guideline range is in Zone A or B of the Sentencing Table, a sentence other than a sentence of imprisonment, in accordance with subsection (b) or (c)(3), is generally appropriate. *See* 28 U.S.C. 994(j).

(B) *Departure for Cases Where the Applicable Guideline Range Overstates the Gravity of the Offense.*—A departure, including a departure to a sentence other than a sentence of imprisonment, may be appropriate if the defendant received an adjustment under § 4C1.1 (Adjustment for Certain Zero-Point Offenders) and the defendant's applicable guideline range overstates the gravity of the offense because the offense of conviction is not a crime of violence or an otherwise serious offense. *See* 28 U.S.C. 994(j).''.

Subpart 3 (Additional Changes)

Chapter One, Part A is amended in Subpart 1(4)(d) (Probation and Split Sentences)—

by adding an asterisk after ''community confinement or home detention.'';

by adding a second asterisk after ''through departures.*'';

and by striking the following Note:

''*Note: Although the Commission had not addressed 'single acts of aberrant behavior' at the time the Introduction to the Guidelines Manual originally was written, it subsequently addressed the issue in Amendment 603, effective November 1, 2000. (*See* USSG App. C, amendment 603.)'',

and inserting the following Notes:

''*Note: The Commission expanded Zones B and C of the Sentencing Table in 2010 to provide a greater range of sentencing options to courts with respect to certain offenders. (*See* USSG App. C, amendment 738.) In 2018, the Commission added a new application note to the Commentary to § 5C1.1 (Imposition of a Term of Imprisonment), stating that if a defendant is a 'nonviolent first offender and the applicable guideline range is in Zone A or B of the Sentencing Table, the court should consider imposing a sentence other than a sentence of imprisonment.' (*See* USSG App. C, amendment 801.) In 2023, the Commission added a new Chapter Four guideline, at § 4C1.1 (Adjustment for Certain Zero-Point Offenders), providing a decrease of 2 levels from the offense level determined under Chapters Two and Three for 'zero-point' offenders who meet certain criteria. In addition, the Commission further amended the Commentary to § 5C1.1 to address the alternatives to incarceration available to 'zero-point' offenders by revising the application note in § 5C1.1 that addressed 'nonviolent first offenders' to focus on 'zero-point' offenders. (*See* USSG App. C, amendment 821.)

**Note: Although the Commission had not addressed 'single acts of aberrant behavior' at the time the Introduction to the Guidelines Manual originally was written, it subsequently addressed the issue in Amendment 603, effective November 1, 2000. (*See* USSG App. C, amendment 603.)''.

Section 4A1.3(b)(2)(A) is amended by striking ''A departure'' and inserting ''Unless otherwise specified, a departure''.

The Commentary to § 4A1.3 captioned ''Application Notes'' is amended in Note 3 by striking ''due to the fact that the lower limit of the guideline range for Criminal History Category I is set for a first offender with the lowest risk of recidivism'' and inserting ''unless otherwise specified''.

Part C (Impact of Simple Possession of Marihuana Offenses)

The Commentary to § 4A1.3 captioned ''Application Notes'', as amended by Part B, Subpart 3 of this amendment, is further amended in Note 3 by striking the following:

''*Downward Departures.*—A downward departure from the defendant's criminal history category may be warranted if, for example, the defendant had two minor misdemeanor convictions close to ten years prior to the instant offense and no other evidence of prior criminal behavior in the intervening period. A departure below the lower limit of the applicable guideline range for Criminal History Category I is prohibited under subsection (b)(2)(A), unless otherwise specified.'',

and inserting the following:

''*Downward Departures.*—

(A) *Examples.*—A downward departure from the defendant's criminal history category may be warranted based on any of the following circumstances:

(i) The defendant had two minor misdemeanor convictions close to ten years prior to the instant offense and no other evidence of prior criminal behavior in the intervening period.

(ii) The defendant received criminal history points from a sentence for possession of marihuana for personal use, without an intent to sell or distribute it to another person.

(B) *Downward Departures from Criminal History Category I.*—A departure below the lower limit of the applicable guideline range for Criminal History Category I is prohibited under subsection (b)(2)(A), unless otherwise specified.''.

Reason for Amendment: This amendment is the result of several Commission studies regarding the nature of the criminal history of federal offenders, including analyses of the number and types of prior convictions included as criminal history and the ability of the criminal history rules to predict an offender's likelihood of rearrest. While these studies continue to recognize the close association between an offender's criminal history calculation under the guidelines and the likelihood of future recidivism, the amendment makes targeted changes to reduce the impact of providing additional criminal history points for offenders under a criminal justice sentence (commonly known as ''status points''), to reduce recommended guideline ranges for offenders with zero criminal history points under the guidelines (''zero-point offenders''), and to recognize the changing legal landscape as it pertains to simple possession of marihuana offenses. These targeted amendments balance the Commission's mission of implementing data-driven sentencing policies with its duty to craft penalties that reflect the statutory purposes of sentencing.

Part A—Status Points

Part A of the amendment addresses ''status points'' for offenders, namely the additional criminal history points given to offenders for the fact of having committed the instant offense while under a criminal justice sentence,

including probation, parole, supervised release, imprisonment, work release, or escape status. The amendment redesignates current subsection (d) of § 4A1.1, which addresses ''status points,'' as subsection (e) and redesignates current subsection (e), which addresses multiple crimes of violence treated as a single sentence, as subsection (d). This redesignation is made for ease of application.

Under the previous ''status points'' provision, two criminal history points were added under § 4A1.1(d) if the defendant committed the instant offense ''while under any criminal justice sentence, including probation, parole, supervised release, imprisonment, work release, or escape status.'' The amendment limits the overall criminal history impact of ''status points'' in two ways. First, as revised, the ''status points'' provision under redesignated subsection (e) applies only to offenders with more serious criminal histories under the guidelines by requiring that an offender have seven or more criminal history points under subsections (a) through (d) in addition to having been under a criminal justice sentence at the time of the instant offense. Offenders with six or fewer criminal history points under subsections (a) through (d) will no longer receive ''status points.'' Second, the amendment also reduces from two points to one point the ''status points'' assessed for offenders to whom the revised provision applies. Part A of the amendment also makes conforming changes to the Commentary to § 4A1.1, § 2P1.1 (Escape, Instigating or Assisting Escape), and § 4A1.2 (Definitions and Instructions for Computing Criminal History).

As part of its study of criminal history, the Commission found that ''status points'' are relatively common in cases with at least one criminal history point, having been applied in 37.5 percent of cases with criminal history points over the last five fiscal years. Of the offenders who received ''status points,'' 61.5 percent had a higher Criminal History Category as a result of the addition of the ''status points.'' The Commission also recently published a series of research reports regarding the recidivism rates of federal offenders. *See, e.g.,* U.S. Sent'g Comm'n, Recidivism of Federal Offenders Released in 2010 (2021), available at *https://www.ussc.gov/research/research-reports/recidivism-federal-offenders-released-2010.* These reports again concluded that an offender's criminal history calculation under the guidelines is strongly associated with the likelihood of future recidivism by the defendant. In a related publication, the Commission also found, however, that status points add little to the overall predictive value associated with the criminal history score. *See* U.S. Sent'g Comm'n, Revisiting Status Points (2022), available at *https://www.ussc.gov/research/research-reports/revisiting-status-points.*

The Commission's action to limit the impact of ''status points'' builds upon its tradition of data-driven evolution of the guidelines. As described in the Introduction to Chapter Four, the original Commission envisioned status points as ''consistent with the extant empirical research assessing correlates of recidivism and patterns of career criminal behavior'' and therefore envisioned ''status points'' as being reflective of, among other sentencing goals, the increased likelihood of future recidivism. *See* USSG Ch.4, Pt.A, intro. comment. The original Commission also explained, however, that it would ''review additional data insofar as they become available in the future.'' The Commission's recent research suggests that ''status points'' improve the predictive value of the criminal history score less than the original Commission may have expected, suggesting that the treatment of ''status points'' under Chapter Four should be refined.

Accordingly, the Commission determined that it was appropriate to address several concerns regarding the scope and impact of status points. In taking these steps, the Commission observed that the operation of the *Guidelines Manual* separately accounts for consecutive punishment imposed upon revocations of supervised release, a likely occurrence if an offender was under a criminal justice sentence during the commission of another offense. The Commission further recognized that it is also possible that an offender's criminal history score would be independently increased as the result of additional time imposed as the result of a revocation of probation or supervised release for the offense that also results in the addition of status points.

At the same time, by retaining ''status points'' for those offenders in higher criminal history categories, the Commission continues to recognize that ''status points,'' like the other criminal history provisions in Chapter Four, reflect and serve multiple purposes of sentencing, including the offender's perceived lack of respect for the law, as reflected both in the offender's overall criminal history and the fact that the offender has reoffended while under a criminal justice sentence ordered by a court. *See* 18 U.S.C. 3553(a)(2)(A)–(C).

The Commission concluded that accounting for status on a more limited basis continues to serve the broader purposes of sentencing while also addressing other concerns raised regarding the impact of status points.

Part B—Zero-Point Offenders

Part B of the amendment includes three subparts making changes pertaining to offenders who did not receive any criminal history points from Chapter Four, Part A. Subpart 1 provides for an adjustment for certain offenders with zero criminal history points. Subpart 2 revises § 5C1.1 (Imposition of a Term of Imprisonment) to implement the congressional directive at 28 U.S.C. 994(j). Finally, Subpart 3 makes other conforming changes.

Subpart 1—Adjustment for Certain Zero-Point Offenders

Subpart 1 of Part B of the amendment creates a new Chapter Four guideline at § 4C1.1 (Adjustment for Certain Zero-Point Offenders). New § 4C1.1 provides a decrease of two levels from the offense level determined under Chapters Two and Three for offenders who did not receive any criminal history points under Chapter Four, Part A and whose instant offense did not involve specified aggravating factors. In establishing new § 4C1.1, the Commission was informed by its studies of recidivism among federal offenders, as well as other extensive data analyses of offenders with no criminal history points, and public comment. The Sentencing Table in Chapter Five, Part A is divided into six criminal history categories, from I (lowest) to VI (highest). Criminal History Category I includes offenders with zero criminal history points and those with one criminal history point. Recidivism data analyzed by the Commission shows, however, that offenders with zero criminal history points have considerably lower recidivism rates than other offenders, including offenders with one criminal history point. *See* U.S. Sent'g Comm'n, Recidivism of Federal Offenders Released in 2010 (2021), available at *https://www.ussc.gov/research/research-reports/recidivism-federal-offenders-released-2010.* Among other findings, the report concluded that ''zero-point offenders'' were less likely to be rearrested than ''one point'' offenders (26.8% compared to 42.3%), the largest variation of any comparison of offenders within the same Criminal History Category.

In promulgating this change, the Commission also considered the rates of departures and variances in cases involving offenders with no criminal history points. The Commission has

long viewed the rates and extents of departures and variances from the applicable guideline ranges as a feedback mechanism from the courts that a particular area of the guidelines may warrant further review and possible amendment. In fiscal year 2021, 39.2 percent of offenders with zero criminal history points received a sentence within the guidelines range; by comparison, 47.4 percent of offenders with one criminal history point were sentenced within the guideline range. The Commission determined that the departure and variance rates for zero-point offenders, coupled with its recidivism data, warranted action.

The amendment applies to offenders with no criminal history points, including (1) offenders with no prior convictions; (2) offenders who have prior convictions that are not counted because those convictions were not within the time limits set forth in subsection (d) and (e) of § 4A1.2 (Definitions and Instructions for Computing Criminal History); and (3) offenders who have prior convictions that are not used in computing the criminal history category for reasons other than their ''staleness'' (*e.g.,* sentences resulting from foreign or tribal court convictions, minor misdemeanor convictions, or infractions). In adopting this definition of ''zero-point offenders,'' the Commission opted to hew to the long-standing and carefully crafted criminal history rules set forth in Chapter Four, regarding which prior convictions count for criminal history purposes and which do not. The Commission also observed that attempts to exclude offenders with certain prior convictions could lead to increased complexity and litigation and require the additional practical step of investigating prior unscorable offenses for which records may not be readily available.

While determining that a reduction is appropriate for some offenders with zero criminal history points, the Commission also identified circumstances in which zero-point offenders are appropriately excluded from eligibility in light of the seriousness of the instant offense of conviction or the existence of aggravating factors in the instant offense (*e.g.,* where the offender used violence or credible threats of violence in connection with the offense or where the instant offense of conviction was a ''sex offense''). The exclusionary criteria identified by the Commission were again informed by extensive data analyses and public comment. The Commission was also informed by existing legislation, including the congressionally established criteria for the statutory safety valve at 18 U.S.C. 3553(f) and the recent firearms legislation set forth in the Bipartisan Safer Communities Act.

Subpart 2—Implementation of 28 U.S.C. 994(j)

Subpart 2 of Part B of the amendment revises the Commentary to § 5C1.1 (Imposition of a Term of Imprisonment) that addresses ''nonviolent first offenders.'' New Application Note 10(A) provides that if the defendant received an adjustment under new § 4C1.1 and the defendant's applicable guideline range is in Zone A or B of the Sentencing Table, a sentence other than a sentence of imprisonment, in accordance with subsection (b) or (c)(3), is generally appropriate. New Application Note 10(B) adds a corresponding departure provision providing that a departure, including a departure to a sentence other than a sentence of imprisonment, may be appropriate if the offender received an adjustment under new § 4C1.1 and the applicable guideline range overstates the gravity of the offense because the offense of conviction is not a crime of violence or an otherwise serious offense.

The changes to the Commentary to § 5C1.1 respond to Congress's directive to the Commission at 28 U.S.C. 994(j), directing the Commission to ensure that the guidelines reflect the general appropriateness of imposing a sentence other than imprisonment in cases in which the defendant is a first offender who has not been convicted of a crime of violence or an otherwise serious offense. The Commission determined that the revised commentary serves Congress's intent in promulgating section 994(j) while providing appropriate limitations and guidance through reliance on the criteria set forth in new § 4C1.1 and the specific statutory language set forth in section 994(j).

Subpart 3—Additional Changes

Subpart 3 of Part B of the amendment makes a corresponding change to subsection (b)(2)(A) of § 4A1.3 (Departures Based on Inadequacy of Criminal History Category (Policy Statement)) to provide that a departure below the lower limit of the applicable guideline range for Criminal History Category I is prohibited, ''unless otherwise specified.'' The amendment also revises an explanatory note in Chapter One, Part A, Subpart 1(4)(d) (Probation and Split Sentences) to detail amendments to the *Guidelines Manual* related to the implementation of 28 U.S.C. 994(j), first offenders, and ''zero-point offenders.''

Part C—Impact of Simple Possession of Marihuana Offenses

Part C of the amendment revises the Commentary to § 4A1.3 (Departures Based on Inadequacy of Criminal History Category (Policy Statement)) to include sentences resulting from possession of marihuana offenses as an example of when a downward departure from the defendant's criminal history may be warranted. Specifically, Part C provides that a downward departure may be warranted if the defendant received criminal history points from a sentence for possession of marihuana for personal use, without an intent to sell or distribute it to another person. Most commenters, including the Department of Justice, supported this change. *See* Letter from Jonathan J. Wroblewski, Dir., Crim. Div., U.S. Dep't of Just., to Hon. Carlton W. Reeves, Chair, U.S. Sent'g Comm'n (Feb. 27, 2023), *in* U.S. Sent'g Comm'n, 2022–2023 Amendment Cycle Proposed Amendments/Public Comment (2023); see also U.S. Sent'g Comm'n, 2022–2023 Amendment Cycle Proposed Amendments/Public Comment (2023) (providing numerous public comment supporting the amendment).

The Commission also relied upon its recently published report on the impact of simple possession of marihuana offenses on sentencing. *See* U.S. Sent'g Comm'n, Weighing the Impact of Simple Possession of Marijuana: Trends and Sentencing in the Federal System (2023), available at *https://www.ussc.gov/research/research-reports/weighing-impact-simple-possession-marijuana.* In that study, the Commission found that 4,405 federal offenders (8.0%) received criminal history points under the federal sentencing guidelines for prior marihuana possession sentences in fiscal year 2021. Most such prior sentences were for state court convictions resulting in less than 60 days in prison or non-custodial sentences. The Commission also found informative that ten percent (10.2%) of these 4,405 offenders had no other criminal history points, and that for 40 percent (40.1%) of the 4,405 offenders (1,765), the criminal history points for prior marihuana possession sentences resulted in a higher Criminal History Category.

9. Amendment: The Commentary to § 2L1.2 captioned ''Application Notes'' is amended in Note 2, in the paragraph that begins '' 'Crime of violence' means'', by inserting after ''territorial jurisdiction of the United States.'' the following: '' 'Robbery' is the unlawful taking or obtaining of personal property

from the person or in the presence of another, against his will, by means of actual or threatened force, or violence, or fear of injury, immediate or future, to his person or property, or property in his custody or possession, or the person or property of a relative or member of his family or of anyone in his company at the time of the taking or obtaining. The phrase 'actual or threatened force' refers to force that is sufficient to overcome a victim's resistance.''.

Section 4B1.2(a) is amended—

by inserting at the beginning the following new heading ''*Crime of Violence.*—'';

and in paragraph (1) by striking ''another,'' and inserting ''another;''.

Section 4B1.2(b) is amended by striking the following:

''The term 'controlled substance offense' means an offense under federal or state law, punishable by imprisonment for a term exceeding one year, that prohibits the manufacture, import, export, distribution, or dispensing of a controlled substance (or a counterfeit substance) or the possession of a controlled substance (or a counterfeit substance) with intent to manufacture, import, export, distribute, or dispense.'',

and inserting the following:

''*Controlled Substance Offense.*—The term 'controlled substance offense' means an offense under federal or state law, punishable by imprisonment for a term exceeding one year, that—

(1) prohibits the manufacture, import, export, distribution, or dispensing of a controlled substance (or a counterfeit substance) or the possession of a controlled substance (or a counterfeit substance) with intent to manufacture, import, export, distribute, or dispense; or

(2) is an offense described in 46 U.S.C. 70503(a) or § 70506(b).''.

Section 4B1.2(c) is amended by inserting at the beginning the following new heading ''*Two Prior Felony Convictions.*—''.

Section 4B1.2 is amended by inserting at the end the following two new subsections (d) and (e):

''(d) *Inchoate Offenses Included.*—The terms 'crime of violence' and 'controlled substance offense' include the offenses of aiding and abetting, attempting to commit, or conspiring to commit any such offense.

(e) *Additional Definitions.*—

(1) *Forcible Sex Offense.*—'Forcible sex offense' includes where consent to the conduct is not given or is not legally valid, such as where consent to the conduct is involuntary, incompetent, or coerced. The offenses of sexual abuse of a minor and statutory rape are included only if the sexual abuse of a minor or statutory rape was (A) an offense described in 18 U.S.C. 2241(c) or (B) an offense under state law that would have been an offense under section 2241(c) if the offense had occurred within the special maritime and territorial jurisdiction of the United States.

(2) *Extortion.*—'Extortion' is obtaining something of value from another by the wrongful use of (A) force, (B) fear of physical injury, or (C) threat of physical injury.

(3) *Robbery.*—'Robbery' is the unlawful taking or obtaining of personal property from the person or in the presence of another, against his will, by means of actual or threatened force, or violence, or fear of injury, immediate or future, to his person or property, or property in his custody or possession, or the person or property of a relative or member of his family or of anyone in his company at the time of the taking or obtaining. The phrase 'actual or threatened force' refers to force that is sufficient to overcome a victim's resistance.

(4) *Prior Felony Conviction.*—'Prior felony conviction' means a prior adult federal or state conviction for an offense punishable by death or imprisonment for a term exceeding one year, regardless of whether such offense is specifically designated as a felony and regardless of the actual sentence imposed. A conviction for an offense committed at age eighteen or older is an adult conviction. A conviction for an offense committed prior to age eighteen is an adult conviction if it is classified as an adult conviction under the laws of the jurisdiction in which the defendant was convicted (*e.g.,* a federal conviction for an offense committed prior to the defendant's eighteenth birthday is an adult conviction if the defendant was expressly proceeded against as an adult).''.

The Commentary to § 4B1.2 captioned ''Application Notes'' is amended in Note 1—

in the heading by striking ''*Definitions.*—'' and inserting ''*Further Considerations Regarding 'Crime of Violence' and 'Controlled Substance Offense'.*—'';

by striking the first three paragraphs as follows:

'' 'Crime of violence' and 'controlled substance offense' include the offenses of aiding and abetting, conspiring, and attempting to commit such offenses.

'Forcible sex offense' includes where consent to the conduct is not given or is not legally valid, such as where consent to the conduct is involuntary, incompetent, or coerced. The offenses of sexual abuse of a minor and statutory rape are included only if the sexual abuse of a minor or statutory rape was (A) an offense described in 18 U.S.C. 2241(c) or (B) an offense under state law that would have been an offense under section 2241(c) if the offense had occurred within the special maritime and territorial jurisdiction of the United States.

'Extortion' is obtaining something of value from another by the wrongful use of (A) force, (B) fear of physical injury, or (C) threat of physical injury.'';

and by striking the last paragraph as follows:

'' 'Prior felony conviction' means a prior adult federal or state conviction for an offense punishable by death or imprisonment for a term exceeding one year, regardless of whether such offense is specifically designated as a felony and regardless of the actual sentence imposed. A conviction for an offense committed at age eighteen or older is an adult conviction. A conviction for an offense committed prior to age eighteen is an adult conviction if it is classified as an adult conviction under the laws of the jurisdiction in which the defendant was convicted (*e.g.,* a federal conviction for an offense committed prior to the defendant's eighteenth birthday is an adult conviction if the defendant was expressly proceeded against as an adult).''.

Reason for Amendment: This amendment is a result of the Commission's work on § 4B1.2 (Definitions of Terms Used in Section 4B1.1) regarding several application issues that have arisen in the context of the career offender guideline. As part of this study, the Commission considered varying case law interpreting certain guideline definitions and commentary to the guideline. Informed by the case law, public comment and relevant sentencing data, this amendment specifically addresses application issues regarding the meaning of ''robbery'' and ''extortion'' and the treatment of inchoate offenses. The amendment also makes necessary changes to further implement the congressional directive at 28 U.S.C. 994(h).

The amendment makes several changes to address a circuit conflict regarding the authoritative weight afforded to certain commentary to § 4B1.2. The commentary to § 4B1.2 prior to the amendment provided that the definitions of ''crime of violence'' and ''controlled substance offense'' include the offenses of aiding and abetting, conspiring, and attempting to commit such offenses. Although most circuits had previously held that this commentary was authoritative under *Stinson* v. *United States,* 508 U.S. 36

(1993), several courts have now concluded that the guideline definition of ''controlled substance offense'' does not include inchoate offenses because such offenses are not expressly included in the guideline text. *See United States* v. *Dupree,* 57 F.4th 1269 (11th Cir. 2023) (*en banc*); *United States* v. *Campbell,* 22 F.4th 438 (4th Cir. 2022); *United States* v. *Nasir,* 17 F.4th 459 (3d Cir. 2021) (*en banc*); *United States* v. *Havis,* 927 F.3d 382 (6th Cir. 2019) (*en banc*); *United States* v. *Winstead,* 890 F.3d 1082 (D.C. Cir. 2018). Several courts held that the Commission exceeded its authority under *Stinson* when it attempted to incorporate inchoate offenses into § 4B1.2(b)'s definition through the commentary, finding that the commentary can only interpret or explain the guideline, it cannot expand its scope by adding qualifying offenses. *See, e.g., Havis,* 927 F.3d at 385–87. More recently, courts have relied on *Kisor* v. *Wilkie,* 139 S. Ct. 2400 (2022), to hold that guideline commentary should not be afforded deference unless the guideline text is genuinely ambiguous. *See, e.g., Dupree,* 57 F.4th at 1275. Applying the *Kisor* holding to the guidelines, courts have concluded that the plain language definition of ''controlled substance offense'' in § 4B1.2 unambiguously excludes inchoate offenses. Similarly, courts have held that ''crime of violence'' excludes conspiracies because the § 4B1.2 commentary does not warrant *Kisor* deference. *See, e.g., United States* v. *Abreu,* 32 F.4th 271, 277–78 (3d Cir. 2022).

The amendment addresses this circuit conflict by moving, without change, the commentary including certain inchoate and accessory offenses in the definitions of ''crime of violence'' and ''controlled substance offense'' to the text of the guideline. While not the subject of the circuit conflict, the amendment also moves the definitions of enumerated offenses (*i.e.,* ''forcible sex offense'' and ''extortion'') and ''prior felony conviction'' from the commentary to a new subsection (e) in the guideline to avoid similar challenges to their applicability.

The amendment next addresses a concern that Hobbs Act robbery offenses no longer qualify as ''crimes of violence'' under § 4B1.2. In 2016, the Commission amended § 4B1.2 to, among other things, delete the ''residual clause'' and revise the ''enumerated clause'' by moving enumerated offenses that were previously listed in the commentary to the guideline itself. Although the guideline generally relies on existing case law for purposes of defining most enumerated offenses, the amendment added to the Commentary to § 4B1.2 definitions for two of the enumerated offenses: ''forcible sex offense'' and ''extortion.'' Consistent with the Commission's goal of focusing the career offender and related enhancements on the most dangerous offenders, the amendment narrowed the generic definition of extortion by limiting it to offenses having an element of force or an element of fear or threat ''of physical injury,'' as opposed to non-violent threats such as injury to reputation. As such, extortion is defined as ''obtaining something of value from another by the wrongful use of (A) force, (B) fear of physical injury, or (C) threat of physical injury.''

After the 2016 amendment, every Court of Appeals addressing the issue under the guidelines has held that Hobbs Act robbery is not a ''crime of violence'' under § 4B1.2, reasoning that neither generic robbery nor the guidelines definition of extortion encompass threats against property while the Hobbs Act defines ''robbery'' as, among other things, ''the unlawful taking or obtaining of personal property . . . by means of actual or threatened force, or violence, or fear of injury, immediate or future, to his person or *property* . . . .'' *See* 18 U.S.C. 1951(b)(1) (emphasis added); *United States* v. *Chappelle,* 41 F.4th 102 (2d Cir. 2022); *United States* v. *Scott,* 14 F.4th 190 (3d Cir. 2021); *United States* v. *Prigan,* 8 F.4th 1115 (9th Cir. 2021); *United States* v. *Green,* 996 F.3d 176 (4th Cir. 2021); *Bridges* v. *United States,* 991 F.3d 793 (7th Cir. 2021); *United States* v. *Eason,* 953 F.3d 1184 (11th Cir. 2020); *United States* v. *Camp,* 903 F.3d 594 (6th Cir. 2018); *United States* v. *O'Connor,* 874 F.3d 1147 (10th Cir. 2017).

The amendment amends § 4B1.2 to add to the new subsection (e) a definition of ''robbery'' that mirrors the ''robbery'' definition at 18 U.S.C. 1951(b)(1) and makes a conforming change to § 2L1.2 (Illegal Reentry), which also includes robbery as an enumerated offense. The Commission views the recent decisions holding that Hobbs Act robbery is not a crime of violence under the guidelines as an unintended consequence of the 2016 amendment to the career offender guideline meant to remove threats to reputation. In addition, the Commission conducted an analysis of recent cases and found that the Hobbs Act robberies overwhelmingly involved violence.

The amendment clarifies that ''actual or threatened force'' for purposes of the new ''robbery'' definition is ''force sufficient to overcome a victim's resistance.'' The Commission concludes that such definition, relying on the Supreme Court's decision in *Stokeling* v. *United States,* 139 S. Ct. 544 (2019), would eliminate potential litigation over the meaning of actual or threatened force in this context and is consistent with the level of force necessary for a robbery under the force clause.

Finally, the amendment revises the definition of ''controlled substance offense'' in § 4B1.2(b) to include ''an offense described in 46 U.S.C. 70503(a) or § 70506(b).'' The directive at 28 U.S.C. 994(h) instructs the Commission to assure that ''the guidelines specify a term of imprisonment at or near the maximum term authorized'' for offenders who are 18 years or older and have been convicted of a felony that is, and have previously been convicted of two or more felonies that are, among other things, ''an offense described in . . . chapter 705 of title 46.'' *See* 28 U.S.C. 994(h). In 2016, Congress enacted the Coast Guard Authorization Act of 2015, Public Law 114–120 (2016), which amended Chapter 705 of Title 46 by adding two new offenses to section 70503(a), in subparagraphs (2) and (3). Following this statutory change, these two new offenses are not covered by the pre-amendment definition of ''controlled substance offense'' in § 4B1.2 as required by the directive.

10. Amendment: Section 3D1.2(d) is amended by striking ''§§ 2G1.1, 2G2.1;'' and inserting ''§§ 2G1.1, 2G1.3, 2G2.1;''.

The Commentary to § 5F1.7 captioned ''Background'' is amended—

by striking ''six months'' and inserting ''6 months'';

by striking ''as the Bureau deems appropriate. 18 U.S.C. 4046.' '' and inserting ''as the Bureau deems appropriate.' 18 U.S.C. 4046.'';

and by striking the final paragraph as follows:

''The Bureau of Prisons has issued an operations memorandum (174–90 (5390), November 20, 1990) that outlines eligibility criteria and procedures for the implementation of this program (which the Bureau of Prisons has titled 'intensive confinement program'). Under these procedures, the Bureau will not place a defendant in an intensive confinement program unless the sentencing court has approved, either at the time of sentencing or upon consultation after the Bureau has determined that the defendant is otherwise eligible. In return for the successful completion of the 'intensive confinement' portion of the program, the defendant is eligible to serve the remainder of his term of imprisonment in a graduated release program comprised of community

corrections center and home confinement phases.'',

and inserting the following:

''In 1990, the Bureau of Prisons issued an operations memorandum (174–90 (5390), November 20, 1990) that outlined eligibility criteria and procedures for the implementation of a shock incarceration program (which the Bureau of Prisons titled the 'intensive confinement program'). In 2008, however, the Bureau of Prisons terminated the program and removed the rules governing its operation. *See* 73 FR 39863 (July 11, 2008).''.

Reason for Amendment: This two-part amendment responds to miscellaneous guideline application issues.

First, the amendment revises subsection (d) of § 3D1.2 (Grouping of Closely Related Counts) to provide that multiple counts involving more than one victim sentenced under § 2G1.3 (Promoting a Commercial Sex Act or Prohibited Sexual Conduct with a Minor; Transportation of Minors to Engage in a Commercial Sex Act or Prohibited Sexual Conduct; Travel to Engage in Commercial Sex Act or Prohibited Sexual Conduct with a Minor; Sex Trafficking of Children; Use of Interstate Facilities to Transport Information about a Minor) are explicitly excluded from grouping under § 3D1.2(d). Subsection 3D1.2(d) provides that certain guidelines are excluded from the operation of the grouping rules in Chapter Three, Part D (Multiple Counts). Among the guidelines specifically excluded under § 3D1.2(d) is § 2G1.1 (Promoting a Commercial Sex Act or Prohibited Sexual Conduct with an Individual Other than a Minor). When § 2G1.3 was promulgated in 2004, some offenses that were originally referenced to § 2G1.1 were moved to the new § 2G1.3, but § 2G1.3 was not added to the list of excluded guidelines at § 3D1.2(d). *See* USSG App. C, amend. 664 (effective date: Nov. 1, 2004). The amendment corrects that oversight and treats § 2G1.3 similarly to § 2G1.1.

Second, the amendment updates the Commentary to § 5F1.7 (Shock Incarceration Program (Policy Statement)) to reflect that the Bureau of Prisons (BOP) no longer operates a shock incarceration program. The Commentary to § 5F1.7 describes the authority of the BOP to operate a shock incarceration program and the procedures that the BOP established in 1990 regarding operation of such a program. However, the BOP terminated its shock incarceration program and removed the rules governing its operation in 2008. The amendment updates the Commentary to § 5F1.7 to reflect that shock incarceration is no longer a potential sentencing option, foreclosing any potential confusion on its current availability.

11. Amendment: The Commentary to § 1B1.1 captioned ''Application Notes'' is amended in Note 1(E) by striking ''(*e.g.* a defendant'' and inserting ''(*e.g.,* a defendant''.

The Commentary to § 1B1.3 captioned ''Background'' is amended by striking ''the guidelines in those Chapters'' and inserting ''the guidelines in those chapters''.

The Commentary to § 1B1.4 captioned ''Background'' is amended by striking ''in imposing sentence within that range'' and inserting ''in imposing a sentence within that range''.

The Commentary to § 1B1.10 captioned ''Background'' is amended by striking ''Title 18'' and inserting ''title 18''.

The Commentary to § 1B1.11 captioned ''Background'' is amended by striking ''133 S. Ct. 2072, 2078'' and inserting ''569 U.S. 530, 533''.

The Commentary to § 2A4.2 captioned ''Statutory Provisions'' is amended by striking ''§§ 876,'' and inserting ''§§ 876(a),''.

The Commentary to § 2A6.1 captioned ''Statutory Provisions'' is amended by striking ''876,'' and inserting ''876(c),''.

The Commentary to § 2B3.2 captioned ''Statutory Provisions'' is amended by striking ''§§ 875(b), 876,'' and inserting ''§§ 875(b), (d), 876(b), (d),''.

The Commentary to § 2D1.1 captioned ''Application Notes'' is amended—

in Note 8(A) by striking ''the statute (21 U.S.C. 841(b)(1)), as the primary basis'' and inserting ''the statute (21 U.S.C. 841(b)(1)) as the primary basis'', and by striking ''fentanyl, LSD and marihuana'' and inserting ''fentanyl, LSD, and marihuana'';

in Note 8(D)—

under the heading relating to Schedule I or II Opiates, by striking the following:

''1 gm of Heroin = 1 kg
1 gm of Dextromoramide = 670 gm
1 gm of Dipipanone = 250 gm
1 gm of 1-Methyl-4-phenyl-4-propionoxypiperidine/MPPP = 700 gm
1 gm of 1-(2-Phenylethyl)-4-phenyl-4-acetyloxypiperidine/PEPAP = 700 gm
1 gm of Alphaprodine = 100 gm
1 gm of Fentanyl (N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl] Propanamide) = 2.5 kg
1 gm of a Fentanyl Analogue = 10 kg
1 gm of Hydromorphone/Dihydromorphinone = 2.5 kg
1 gm of Levorphanol = 2.5 kg
1 gm of Meperidine/Pethidine = 50 gm
1 gm of Methadone = 500 gm
1 gm of 6-Monoacetylmorphine = 1 kg
1 gm of Morphine = 500 gm
1 gm of Oxycodone (actual) = 6700 gm
1 gm of Oxymorphone = 5 kg
1 gm of Racemorphan = 800 gm
1 gm of Codeine = 80 gm
1 gm of Dextropropoxyphene/Propoxyphene-Bulk = 50 gm
1 gm of Ethylmorphine = 165 gm
1 gm of Hydrocodone (actual) = 6700 gm
1 gm of Mixed Alkaloids of Opium/Papaveretum = 250 gm
1 gm of Opium = 50 gm
1 gm of Levo-alpha-acetylmethadol (LAAM) = 3 kg'',

and inserting the following:

''1 gm of 1-(2-Phenylethyl)-4-phenyl-4-acetyloxypiperidine (PEPAP) = 700 gm
1 gm of 1-Methyl-4-phenyl-4-propionoxypiperidine (MPPP) = 700 gm
1 gm of 6-Monoacetylmorphine = 1 kg
1 gm of Alphaprodine = 100 gm
1 gm of Codeine = 80 gm
1 gm of Dextromoramide = 670 gm
1 gm of Dextropropoxyphene/Propoxyphene-Bulk = 50 gm
1 gm of Dipipanone = 250 gm
1 gm of Ethylmorphine = 165 gm
1 gm of Fentanyl (N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl] Propanamide) = 2.5 kg
1 gm of a Fentanyl Analogue = 10 kg
1 gm of Heroin = 1 kg
1 gm of Hydrocodone (actual) = 6,700 gm
1 gm of Hydromorphone/Dihydromorphinone = 2.5 kg
1 gm of Levo-alpha-acetylmethadol (LAAM) = 3 kg
1 gm of Levorphanol = 2.5 kg
1 gm of Meperidine/Pethidine = 50 gm
1 gm of Methadone = 500 gm
1 gm of Mixed Alkaloids of Opium/Papaveretum = 250 gm
1 gm of Morphine = 500 gm
1 gm of Opium = 50 gm
1 gm of Oxycodone (actual) = 6,700 gm
1 gm of Oxymorphone = 5 kg
1 gm of Racemorphan = 800 gm'';

under the heading relating to Cocaine and Other Schedule I and II Stimulants (and their immediate precursors), by striking the following:

''1 gm of Cocaine = 200 gm
1 gm of N-Ethylamphetamine = 80 gm
1 gm of Fenethylline = 40 gm
1 gm of Amphetamine = 2 kg
1 gm of Amphetamine (Actual) = 20 kg
1 gm of Methamphetamine = 2 kg
1 gm of Methamphetamine (Actual) = 20 kg
1 gm of ''Ice'' = 20 kg
1 gm of Khat = .01 gm
1 gm of 4-Methylaminorex ('Euphoria') = 100 gm

1 gm of Methylphenidate (Ritalin) = 100 gm
1 gm of Phenmetrazine = 80 gm
1 gm Phenylacetone/P_2P (when possessed for the purpose of manufacturing methamphetamine) = 416 gm
1 gm Phenylacetone/P_2P (in any other case) = 75 gm
1 gm Cocaine Base ('Crack') = 3,571 gm
1 gm of Aminorex = 100 gm
1 gm of N-N-Dimethylamphetamine = 40 gm
1 gm of N-Benzylpiperazine = 100 gm'',

and inserting the following:

''1 gm of 4-Methylaminorex ('Euphoria') = 100 gm
1 gm of Aminorex = 100 gm
1 gm of Amphetamine = 2 kg
1 gm of Amphetamine (actual) = 20 kg
1 gm of Cocaine = 200 gm
1 gm of Cocaine Base ('Crack') = 3,571 gm
1 gm of Fenethylline = 40 gm
1 gm of 'Ice' = 20 kg
1 gm of Khat = .01 gm
1 gm of Methamphetamine = 2 kg
1 gm of Methamphetamine (actual) = 20 kg
1 gm of Methylphenidate (Ritalin) = 100 gm
1 gm of N-Benzylpiperazine = 100 gm
1 gm of N-Ethylamphetamine = 80 gm
1 gm of N-N-Dimethylamphetamine = 40 gm
1 gm of Phenmetrazine = 80 gm
1 gm of Phenylacetone (P_2P) (when possessed for the purpose of manufacturing methamphetamine) = 416 gm
1 gm of Phenylacetone (P_2P) (in any other case) = 75 gm'';

under the heading relating to Synthetic Cathinones (except Schedule III, IV, and V Substances), by striking ''a synthetic cathinone'' and inserting ''a Synthetic Cathinone'';

under the heading relating to LSD, PCP, and Other Schedule I and II Hallucinogens (and their immediate precursors), by striking the following:

''1 gm of Bufotenine = 70 gm
1 gm of D-Lysergic Acid Diethylamide/ Lysergide/LSD = 100 kg
1 gm of Diethyltryptamine/DET = 80 gm
1 gm of Dimethyltryptamine/DM = 100 gm
1 gm of Mescaline = 10 gm
1 gm of Mushrooms containing Psilocin and/or
Psilocybin (Dry) = 1 gm
1 gm of Mushrooms containing Psilocin and/or
Psilocybin (Wet) = 0.1 gm
1 gm of Peyote (Dry) = 0.5 gm
1 gm of Peyote (Wet) = 0.05 gm
1 gm of Phencyclidine/PCP = 1 kg
1 gm of Phencyclidine (actual)/PCP (actual) = 10 kg
1 gm of Psilocin = 500 gm
1 gm of Psilocybin = 500 gm
1 gm of Pyrrolidine Analog of Phencyclidine/PHP = 1 kg
1 gm of Thiophene Analog of Phencyclidine/TCP = 1 kg
1 gm of 4-Bromo-2,5-Dimethoxyamphetamine/DOB = 2.5 kg
1 gm of 2,5-Dimethoxy-4-methylamphetamine/DOM = 1.67 kg
1 gm of 3,4-Methylenedioxyamphetamine/MDA = 500 gm
1 gm of 3,4-Methylenedioxymethamphetamine/ MDMA = 500 gm
1 gm of 3,4-Methylenedioxy-N-ethylamphetamine/MDEA = 500 gm
1 gm of Paramethoxymethamphetamine/ PMA = 500 gm
1 gm of 1-Piperidinocyclohexanecarbonitrile/ PCC = 680 gm
1 gm of N-ethyl-1-phenylcyclohexylamine (PCE) = 1 kg'',

and inserting the following:

''1 gm of 1-Piperidinocyclohexanecarbonitrile (PCC) = 680 gm
1 gm of 4-Bromo-2,5-Dimethoxyamphetamine (DOB) = 2.5 kg
1 gm of 2,5-Dimethoxy-4-methylamphetamine (DOM) = 1.67 kg
1 gm of 3,4-Methylenedioxyamphetamine (MDA) = 500 gm
1 gm of 3,4-Methylenedioxymethamphetamine (MDMA) = 500 gm
1 gm of 3,4-Methylenedioxy-N-ethylamphetamine (MDEA) = 500 gm
1 gm of Bufotenine = 70 gm
1 gm of D-Lysergic Acid Diethylamide/ Lysergide (LSD) = 100 kg
1 gm of Diethyltryptamine (DET) = 80 gm
1 gm of Dimethyltryptamine (DM) = 100 gm
1 gm of Mescaline = 10 gm
1 gm of Mushrooms containing Psilocin and/or
Psilocybin (dry) = 1 gm
1 gm of Mushrooms containing Psilocin and/or
Psilocybin (wet) = 0.1 gm
1 gm of N-ethyl-1-phenylcyclohexylamine (PCE) = 1 kg
1 gm of Paramethoxymethamphetamine (PMA) = 500 gm
1 gm of Peyote (dry) = 0.5 gm
1 gm of Peyote (wet) = 0.05 gm
1 gm of Phencyclidine (PCP) = 1 kg
1 gm of Phencyclidine (PCP) (actual) = 10 kg
1 gm of Psilocin = 500 gm
1 gm of Psilocybin = 500 gm
1 gm of Pyrrolidine Analog of Phencyclidine (PHP) = 1 kg
1 gm of Thiophene Analog of Phencyclidine (TCP) = 1 kg'';

under the heading relating to Schedule I Marihuana, by striking the following:

''1 gm of Marihuana/Cannabis, granulated, powdered, etc. = 1 gm
1 gm of Hashish Oil = 50 gm
1 gm of Cannabis Resin or Hashish = 5 gm
1 gm of Tetrahydrocannabinol, Organic = 167 gm
1 gm of Tetrahydrocannabinol, Synthetic = 167 gm'',

and inserting the following:

''1 gm of Cannabis Resin or Hashish = 5 gm
1 gm of Hashish Oil = 50 gm
1 gm of Marihuana/Cannabis (granulated, powdered, etc.) = 1 gm
1 gm of Tetrahydrocannabinol (organic) = 167 gm
1 gm of Tetrahydrocannabinol (synthetic) = 167 gm'';

under the heading relating to Synthetic Cannabinoids (except Schedule III, IV, and V Substances), by striking ''a synthetic cannabinoid'' and inserting ''a Synthetic Cannabinoid'', and by striking '' 'Synthetic cannabinoid,' for purposes of this guideline'' and inserting '' 'Synthetic Cannabinoid,' for purposes of this guideline'';

under the heading relating to Schedule I or II Depressants (except gamma-hydroxybutyric acid), by striking ''except gamma-hydroxybutyric acid'' both places such term appears and inserting ''except Gamma-hydroxybutyric Acid'';

under the heading relating to Gamma-hydroxybutyric Acid, by striking ''of gamma-hydroxybutyric acid'' and inserting ''of Gamma-hydroxybutyric Acid'';

under the heading relating to Schedule III Substances (except ketamine), by striking ''except ketamine'' in the heading and inserting ''except Ketamine'';

under the heading relating to Ketamine, by striking ''of ketamine'' and inserting ''of Ketamine'';

under the heading relating to Schedule IV (except flunitrazepam), by striking ''except flunitrazepam'' in the heading and inserting ''except Flunitrazepam'';

under the heading relating to List I Chemicals (relating to the manufacture of amphetamine or methamphetamine), by striking ''of amphetamine or methamphetamine'' in the heading and inserting ''of Amphetamine or Methamphetamine'';

under the heading relating to Date Rape Drugs (except flunitrazepam, GHB, or ketamine), by striking ''except flunitrazepam, GHB, or ketamine'' in the heading and inserting ''except Flunitrazepam, GHB, or Ketamine'', by striking ''of 1,4-butanediol'' and inserting ''of 1,4-Butanediol'', and by striking ''of gamma butyrolactone'' and inserting ''of Gamma Butyrolactone'';

in Note 9 in the Typical Weight Per Unit (Dose, Pill, or Capsule) Table, under the heading relating to Hallucinogens, by striking the following:

''MDA 250 mg
MDMA 250 mg
Mescaline 500 mg
PCP* 5 mg
Peyote (dry) 12 gm
Peyote (wet) 20 gm
Psilocin* 10 mg
Psilocybe mushrooms (dry) 5 gm
Psilocybe mushrooms (wet) 50 gm
Psilocybin* 10 mg
2,5-Dimethoxy-4-methylamphetamine (STP, DOM)* 3 mg'',

and inserting the following:

''2,5-Dimethoxy-4-methylamphetamine (STP, DOM)* 3 mg
MDA 250 mg
MDMA 250 mg
Mescaline 500 mg
PCP* 5 mg
Peyote (dry) 12 gm
Peyote (wet) 120 gm
Psilocin* 10 mg
Psilocybe mushrooms (dry) 5 gm
Psilocybe mushrooms (wet) 50 gm
Psilocybin* 10 mg'';

and in Note 21, by striking ''Section § 5C1.2(b)'' and inserting ''Section 5C1.2(b)''.

The Commentary to § 2D1.1 captioned ''Background'' is amended by striking ''Public Law 103–237'' and inserting ''Public Law 104–237'', and by inserting after ''to change the title of the Drug Equivalency Tables to the 'Drug Conversion Tables.' '' the following: ''*See* USSG App. C, Amendment 808 (effective November 1, 2018).''.

The Commentary to § 2D2.3 captioned ''Background'' is amended by striking ''Section 6482'' and inserting ''section 6482''.

Section 2G2.1(b)(6)(A) is amended by striking ''engage sexually explicit conduct'' and inserting ''engage in sexually explicit conduct''.

The Commentary to § 2H3.1 captioned ''Application Notes'' is amended in Note 5(B) by striking ''(*e.g.* physical harm'' and inserting ''(*e.g.,* physical harm''.

The Commentary to § 2K2.4 captioned ''Statutory Provisions'' is amended by striking ''§§ 844(h)'' and inserting ''§§ 844(h), (o)''.

The Commentary to § 2M1.1 captioned ''Background'' is amended by striking ''this Part'' and inserting ''this part''.

The Commentary to § 2M4.1 captioned ''Statutory Provisions'' is amended by striking ''50 U.S.C. App. § 462'' and inserting ''50 U.S.C. § 3811''.

The Commentary to § 2M5.1 captioned ''Statutory Provisions'' is amended by striking ''50 U.S.C. App. §§ 2401–2420'' and inserting ''50 U.S.C. § 4601–4623. For additional statutory provision(s), *see* Appendix A (Statutory Index)''.

The Commentary to § 2M5.1 captioned ''Application Notes'' is amended—

in Note 3 by striking ''50 U.S.C. App. § 2410'' and inserting ''50 U.S.C. § 4610'';

and in Note 4 by striking ''50 U.S.C. App. 2405'' and inserting ''50 U.S.C. § 4605''.

The Commentary to § 2M5.3 captioned ''Application Notes'' is amended in Note 1, in the paragraph that begins '' 'Specially designated global terrorist' has'', by striking ''§ 594.513'' and inserting ''§ 594.310''.

The Commentary to § 2M6.1 captioned ''Application Notes'' is amended in Note 1—

by striking the following paragraph:

'' 'Restricted person' has the meaning given that term in 18 U.S.C. § 175b(d)(2).'',

and by striking the following paragraph:

'' 'Vector' has the meaning given that term in 18 U.S.C. § 178(4).''.

The Commentary to § 2T1.1 captioned ''Application Notes'' is amended—

in Note 6, in the paragraph that begins '' 'Gross income' has'', by striking ''§ 1.61'' and inserting ''§ 1.61–1'';

and in Note 7 by striking ''Subchapter C corporation'' and inserting ''subchapter C corporation''.

The Commentary to § 2T1.1 captioned ''Background'' is amended by striking ''the treasury'' and inserting ''the Treasury''.

Chapter Two, Part T, Subpart 2 is amended in the introductory commentary by striking ''Parts I–IV of Subchapter J of Chapter 51 of Subtitle E of Title 26'' and inserting ''parts I–IV of subchapter J of chapter 51 of subtitle E of title 26, United States Code''.

Chapter Two, Part T, Subpart 3 is amended in the introductory commentary by striking ''Subpart'' both places such term appears and inserting ''subpart''.

Chapter Three, Part A is amended in the introductory commentary by striking ''Part'' and inserting ''part''.

The Commentary to § 3A1.1 captioned ''Background'' is amended by striking ''Section 280003'' and inserting ''section 280003''.

The Commentary to § 3A1.2 captioned ''Application Notes'' is amended in Note 3 by striking ''the victim was a government officer or employee, or a member of the immediate family thereof'' and inserting ''the victim was a government officer or employee, a former government officer or employee, or a member of the immediate family thereof''.

Chapter Three, Part B is amended in the introductory commentary by striking ''Part'' and inserting ''part''.

The Commentary to § 3C1.1 captioned ''Application Notes'' is amended in Note 4(I) by striking ''Title 18'' and inserting ''title 18''.

Chapter Three, Part D is amended in the introductory commentary by striking ''Part'' each place such term appears and inserting ''part''.

The Commentary to § 3D1.1 captioned ''Application Notes'' is amended in Note 2 by striking ''Part'' both places such term appears and inserting ''part''.

The Commentary to § 3D1.1 captioned ''Background'' is amended by striking ''Chapter 3'' and inserting ''Chapter Three'', and by striking ''Chapter 4'' and inserting ''Chapter Four''.

The Commentary to § 3D1.2 captioned ''Background'' is amended by striking ''Part'' both places such term appears and inserting ''part''.

The Commentary to § 3D1.3 captioned ''Background'' is amended by striking ''Part'' and inserting ''part''.

The Commentary to § 3D1.4 captioned ''Background'' is amended by striking ''Part'' and inserting ''part''.

The Commentary to § 4A1.3 captioned ''Application Notes'' is amended in Note 2(C)(v) by striking ''this Chapter'' and inserting ''this chapter''.

The Commentary to § 4B1.1 captioned ''Background'' is amended by striking ''Title 28'' and inserting ''title 28''.

The Commentary to § 5C1.1 captioned ''Application Notes'' is amended in Note 1 by striking ''this Chapter'' and inserting ''this chapter''.

The Commentary to § 5E1.1 captioned ''Application Notes'' is amended in Note 1 by striking ''Chapter'' both places such term appears and inserting ''chapter''; by striking ''Title 18'' both places such term appears and inserting ''title 18''; and by striking ''Subchapter C'' and inserting ''subchapter C''.

The Commentary to § 5E1.1 captioned ''Background'' is amended by striking ''Title 18'' and inserting ''title 18''.

The Commentary to § 5E1.3 captioned ''Background'' is amended by striking ''Title 18'' and inserting ''title 18'', and by striking ''The Victims'' and inserting ''the Victims''.

The Commentary to § 5E1.4 captioned ''Background'' is amended by striking ''Titles'' and inserting ''titles''.

The Commentary to § 5G1.3 captioned ''Background'' is amended by striking ''132 S. Ct. 1463, 1468'' and inserting ''566 U.S. 231, 236'', and by striking ''132 S. Ct. at 1468'' and inserting ''566 U.S. at 236''.

Chapter Five, Part H is amended in the introductory commentary by striking ''Part'' each place such term appears and inserting ''part''.

Chapter Six, Part A is amended in the introductory commentary by striking ''Part'' and inserting ''part''.

Chapter Seven, Part A, Subpart 3(b) (Choice between Theories) is amended by striking ''Title 21'' and inserting ''title 21''.

The Commentary to § 8A1.2 captioned ''Application Notes'' is amended in Note 3(G) by striking '' 'Prior criminal adjudication' means'' and inserting '' 'Criminal Adjudication' means''.

The Commentary to § 8B1.1 captioned ''Background'' is amended by striking ''Title 18'' and inserting ''title 18''.

The Commentary to § 8B2.1 captioned ''Application Notes'' is amended in Note 1, in the paragraph that begins '' 'Governing authority' means'', by striking ''means the (A) the Board'' and inserting ''means (A) the Board''.

The Commentary to § 8C2.5 captioned ''Application Notes'' is amended in Note 1 by striking '' 'prior criminal adjudication' '' and inserting '' 'criminal adjudication' ''.

The Commentary to § 8C3.2 captioned ''Application Note'' is amended in Note 1 by striking ''the period provided for payment shall in no event exceed five years'' and inserting ''the period provided for payment shall be the shortest time in which full payment can reasonably be made''.

Section 8C3.3(a) is amended by striking ''its ability'' and inserting ''the ability of the organization''.

The Commentary to § 8E1.1 captioned ''Background'' is amended by striking ''Title 18'' and inserting ''title 18''.

Appendix A (Statutory Index) is amended—

by striking the following line reference:

''18 U.S.C. § 876 2A4.2, 2A6.1, 2B3.2, 2B3.3'';

by inserting before the line referenced to 18 U.S.C. 877 the following new line references:

''18 U.S.C. § 876(a) 2A4.2, 2B3.2
18 U.S.C. § 876(b) B3.2
18 U.S.C. § 876(c) 2A6.1
18 U.S.C. § 876(d) 2B3.2, 2B3.3'';

in the line referenced to 25 U.S.C. 450d by striking ''§ 450d'' and inserting ''§ 5306'';

by striking the following line references:

''33 U.S.C. § 1227(b) 2J1.1, 2J1.5
33 U.S.C. § 1232(b)(2) 2A2.4'';

by inserting before the line referenced to 46 U.S.C. App. § 1707a(f)(2) the following new line references:

''46 U.S.C. § 70035(b) 2J1.1, 2J1.5
46 U.S.C. § 70036(b) 2A2.4'';

by striking the following line references:

''50 U.S.C. App. § 462 2M4.1
50 U.S.C. App. § 527(e) 2X5.2
50 U.S.C. App. § 2410 2M5.1'';

and by inserting before the line referenced to 52 U.S.C. 10307(c) the following new line references:

''50 U.S.C. § 3811 2M4.1
50 U.S.C. § 3937(e) 2X5.2
50 U.S.C. § 4610 2M5.1''.

Reason for Amendment: This amendment makes technical, stylistic, and other non-substantive changes to the *Guidelines Manual.*

First, the amendment makes clerical changes to correct typographical errors in the following guidelines and commentary: § 1B1.1 (Application Instructions); § 1B1.3 (Relevant Conduct (Factors that Determine the Guideline Range)); § 1B1.4 (Information to be Used in Imposing Sentence (Selecting a Point Within the Guideline Range or Departing from the Guidelines)); § 1B1.10 (Reduction in Term of Imprisonment as a Result of Amended Guideline Range (Policy Statement)); § 2D2.3 (Operating or Directing the Operation of a Common Carrier Under the Influence of Alcohol or Drugs); § 2G2.1 (Sexually Exploiting a Minor by Production of Sexually Explicit Visual or Printed Material; Custodian Permitting Minor to Engage in Sexually Explicit Conduct; Advertisement for Minors to Engage in Production); § 2H3.1 (Interception of Communications; Eavesdropping; Disclosure of Certain Private or Protected Information); § 2M1.1 (Treason); § 2T1.1 (Tax Evasion; Willful Failure to File Return, Supply Information, or Pay Tax; Fraudulent or False Returns, Statements, or Other Documents); the Introductory Commentary to Chapter Two, Part T, Subpart 2 (Alcohol and Tobacco Taxes); the Introductory Commentary to Chapter Two, Part T, Subpart 3 (Customs Taxes); the Introductory Commentary to Chapter Three, Part A (Victim-Related Adjustments); § 3A1.1 (Hate Crime Motivation or Vulnerable Victim); the Introductory Commentary to Chapter Three, Part B (Role in the Offense); § 3C1.1 (Obstructing or Impeding the Administration of Justice); the Introductory Commentary to Chapter Three, Part D (Multiple Counts); § 3D1.1 (Procedure for Determining Offense Level on Multiple Counts); § 3D1.2 (Groups of Closely Related Counts); § 3D1.3 (Offense Level Applicable to Each Group of Closely Related Counts); § 3D1.4 (Determining the Combined Offense Level); § 4A1.3 (Departures Based on Inadequacy of Criminal History Category (Policy Statement)); § 4B1.1 (Career Offender); § 5C1.1 (Imposition of a Term of Imprisonment); § 5E1.1 (Restitution); § 5E1.3 (Special Assessments); § 5E1.4 (Forfeiture); the Introductory Commentary to Chapter Five, Part H (Specific Offender Characteristics); the Introductory Commentary to Chapter Six, Part A (Sentencing Procedures); Chapter Seven, Part A (Introduction to Chapter Seven); § 8B1.1 (Restitution—Organizations); § 8B2.1 (Effective Compliance and Ethics Program); § 8C3.3 (Reduction of Fine Based on Inability to Pay); and § 8E1.1 (Special Assessments—Organizations).

Second, the amendment makes clerical changes to the Commentary to §§ 1B1.11 (Use of Guidelines Manual in Effect on Date of Sentencing (Policy Statement)) and 5G1.3 (Imposition of a Sentence on a Defendant Subject to an Undischarged Term of Imprisonment or Anticipated State Term of Imprisonment), to update citations of Supreme Court cases. In addition, the amendment makes technical changes to (1) the Commentary to § 2K2.4 (Use of Firearm, Armor-Piercing Ammunition, or Explosive During or in Relation to Certain Crimes), to add a missing reference to 18 U.S.C. 844(o); (2) the Commentary to § 2M6.1 (Unlawful Activity Involving Nuclear Material, Weapons, or Facilities, Biological Agents, Toxins, or Delivery Systems, Chemical Weapons, or Other Weapons Of Mass Destruction; Attempt or Conspiracy), to delete the definitions of two terms that are not currently used in the guideline; (3) the Commentary to §§ 2M5.3 (Providing Material Support or Resources to Designated Foreign Terrorist Organizations or Specially Designated Global Terrorists, or For a Terrorist Purpose) and 2T1.1 (Tax Evasion; Willful Failure to File Return, Supply Information, or Pay Tax; Fraudulent or False Returns, Statements, or Other Documents), to correct references to the Code of Federal Regulations; and (4) the Commentary to § 3A1.2 (Official Victim), to add missing content in Application Note 3.

Third, the amendment makes technical changes to the Commentary to §§ 2A4.2 (Demanding or Receiving Ransom Money), 2A6.1 (Threatening or

Harassing Communications; Hoaxes; False Liens), and 2B3.2 (Extortion by Force or Threat of Injury or Serious Damage), and to Appendix A (Statutory Index), to provide references to the specific applicable provisions of 18 U.S.C. 876 (Mailing threatening communications).

Fourth, the amendment makes certain stylistic and technical changes to the Commentary to § 2D1.1 (Unlawful Manufacturing, Importing, Exporting, or Trafficking). It revises the Drug Conversion Tables at Application Note 8(D) and the Typical Weight Per Unit Table at Application Note 9 to reorganize the controlled substances contained therein in alphabetical order to make the tables more user-friendly. The amendment also makes minor changes to the controlled substance references to promote consistency in the use of capitalization, commas, parentheticals, and slash symbols throughout the Drug Conversion Tables. In addition, the amendment makes clerical changes throughout the Commentary to correct certain typographical errors. It also amends the Background Commentary to add a specific reference to Amendment 808, which replaced the term ''marihuana equivalency'' with the new term ''converted drug weight'' and changed the title of the ''Drug Equivalency Tables'' to ''Drug Conversion Tables.''

Fifth, the amendment makes clerical changes to reflect the editorial reclassification of certain sections of the United States Code. Effective December 1, 2015, the Office of Law Revision Counsel eliminated the Appendix to title 50 of the United States Code and transferred the non-obsolete provisions to new chapters 49 to 57 of title 50 and to other titles of the United States Code. To reflect the new section numbers of the reclassified provisions, the amendment makes changes to § 2M4.1 (Failure to Register and Evasion of Military Service), § 2M5.1 (Evasion of Export Controls; Financial Transactions with Countries Supporting International Terrorism), and Appendix A. Similarly, effective September 1, 2016, the Office of Law Revision Counsel also transferred certain provisions from chapter 14 of title 25 of the United States Code to four new chapters in title 25 to improve the organization of the title. To reflect these changes, the amendment makes further changes to Appendix A.

Sixth, the amendment makes technical changes to the commentary of several guidelines in Chapter Eight (Sentencing of Organizations). It replaces the term ''prior criminal adjudication,'' as found and defined in Application Note 3(G) of § 8A1.2 (Application Instructions—Organizations), with ''criminal adjudication'' to better reflect how that term is used throughout Chapter Eight. The amendment also makes conforming changes to the Commentary to § 8C2.5 (Culpability Score) to account for the new term. In addition, the amendment revises Application Note 1 of § 8C3.2 (Payment of the Fine—Organizations) to reflect the current language of subsection (d) of 18 U.S.C. 3572 (Imposition of a sentence of fine and related matters), providing that if the court permits other than immediate payment of a fine or other monetary payment, the period provided for payment shall be the shortest time in which full payment can reasonably be made.

Finally, the amendment makes clerical changes to provide updated references to certain sections of the United States Code that were redesignated by legislation. The Frank LoBiondo Coast Guard Authorization Act of 2018, Pub. L. 115–282 (2018) (hereinafter ''the Act''), among other things, established a new chapter 700 (Ports and Waterway Safety) in subtitle VII (Security and Drug Enforcement) of title 46 (Shipping) of the United States Code. Section 401 of the Act repealed the Ports and Waterways Safety Act of 1972, previously codified in 33 U.S.C. 1221–1232b, and restated its provisions with some revisions in the new chapter 700 of title 46, specifically at 46 U.S.C. 70001–70036. Appendix A includes references to Chapter Two guidelines for both former 33 U.S.C. 1227(b) and 1232(b). The amendment revises Appendix A to delete the references to 33 U.S.C. 1227(b) and 1232(b) and replace them with updated references to 46 U.S.C. 70035(b) and 70036(b). The Act did not make substantive revisions to either of these provisions.

(2) Request for Comment on Parts A and B Of Amendment 8, Relating to ''STATUS POINTS'' and Certain ''Zero–Point''Offenders

On April 27, 2023, the Commission submitted to the Congress amendments to the sentencing guidelines, policy statements, official commentary, and Statutory Index, which become effective on November 1, 2023, unless Congress acts to the contrary. Such amendments and the reason for each amendment are included in this notice.

Section 3582(c)(2) of title 18, United States Code, provides that ''in the case of a defendant who has been sentenced to a term of imprisonment based on a sentencing range that has subsequently been lowered by the Sentencing Commission pursuant to 28 U.S.C. 994(o), upon motion of the defendant or the Director of the Bureau of Prisons, or on its own motion, the court may reduce the term of imprisonment, after considering the factors set forth in section 3553(a) to the extent that they are applicable, if such a reduction is consistent with applicable policy statements issued by the Sentencing Commission.'' Pursuant to 28 U.S.C. 994(u), ''[i]f the Commission reduces the term of imprisonment recommended in the guidelines applicable to a particular offense or category of offenses, it shall specify in what circumstances and by what amount the sentences of prisoners serving terms of imprisonment for the offense may be reduced.'' The Commission lists in subsection (d) of § 1B1.10 (Reduction in Term of Imprisonment as a Result of Amended Guideline Range (Policy Statement)) the specific guideline amendments that the court may apply retroactively under 18 U.S.C. 3582(c)(2).

Amendment 8, pertaining to criminal history, has the effect of lowering guideline ranges. The Commission intends to consider whether, pursuant to 18 U.S.C. 3582(c)(2) and 28 U.S.C. 994(u), Parts A and B of this amendment, relating to the impact of ''status points'' at § 4A1.1 (Criminal History Category) and offenders with zero criminal history points at new § 4C1.1 (Adjustment for Certain Zero-Point Offenders), should be included in § 1B1.10(d) as an amendment that may be applied retroactively to previously sentenced defendants. In considering whether to do so, the Commission will consider, among other things, a retroactivity impact analysis and public comment. Accordingly, the Commission seeks public comment on whether it should make Parts A and B of Amendment 8 available for retroactive application. To help inform public comment, the retroactivity impact analysis will be made available to the public as soon as practicable.

The Background Commentary to § 1B1.10 lists the purpose of the amendment, the magnitude of the change in the guideline range made by the amendment, and the difficulty of applying the amendment retroactively to determine an amended guideline range under § 1B1.10(b) as among the factors the Commission considers in selecting the amendments included in § 1B1.10(d). To the extent practicable, public comment should address each of these factors.

The Commission seeks comment on whether it should list Parts A and B of Amendment 8, addressing the impact of ''status points'' at § 4A1.1 and offenders

with zero criminal history points at new § 4C1.1, in § 1B1.10(d) as changes that may be applied retroactively to previously sentenced defendants. For each of these parts, the Commission requests comment on whether that part should be listed in § 1B1.10(d) as an amendment that may be applied retroactively.

If the Commission does list one or both such parts of the amendment in § 1B1.10(d) as an amendment that may be applied retroactively to previously sentenced defendants, should the Commission provide further guidance or limitations regarding the circumstances in which, and the amount by which, sentences may be reduced?

[FR Doc. 2023–09332 Filed 5–2–23; 8:45 am]

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Part V

Environmental Protection Agency

40 CFR Part 751

Methylene Chloride; Regulation Under the Toxic Substances Control Act (TSCA); Proposed Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 751

[EPA–HQ–OPPT–2020–0465; FRL–8155–02–OCSPP]

RIN 2070–AK70

Methylene Chloride; Regulation Under the Toxic Substances Control Act (TSCA)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to address the unreasonable risk of injury to human health presented by methylene chloride under its conditions of use as documented in EPA's June 2020 Risk Evaluation for Methylene Chloride and November 2022 revised risk determination for methylene chloride prepared under the Toxic Substances Control Act (TSCA). TSCA requires that EPA address by rule any unreasonable risk of injury to health or the environment identified in a TSCA risk evaluation and apply requirements to the extent necessary so that the chemical no longer presents unreasonable risk. Methylene chloride, also known as dichloromethane, is acutely lethal, a neurotoxicant, a likely human carcinogen, and presents cancer and non-cancer risks following chronic exposures as well as acute risks. Central nervous system depressant effects can result in loss of consciousness and respiratory depression, resulting in irreversible coma, hypoxia, and eventual death, including 85 documented fatalities from 1980 to 2018, a majority of which were occupational fatalities (see Unit II.A.). Nevertheless, methylene chloride is still a widely used solvent in a variety of consumer and commercial applications including adhesives and sealants, automotive products, and paint and coating removers. To address the identified unreasonable risk, EPA is proposing to: prohibit the manufacture, processing, and distribution in commerce of methylene chloride for consumer use; prohibit most industrial and commercial uses of methylene chloride; require a workplace chemical protection program (WCPP), which would include a requirement to meet inhalation exposure concentration limits and exposure monitoring for certain continued conditions of use of methylene chloride; require recordkeeping and downstream notification requirements for several conditions of use of methylene chloride; and provide certain time-limited exemptions from requirements for uses of methylene chloride that would otherwise significantly disrupt national security and critical infrastructure.

DATES: Comments must be received on or before July 3, 2023. Under the Paperwork Reduction Act, comments on the information collection provisions are best assured of consideration if the Office of Management and Budget (OMB) receives a copy of your comments on or before June 2, 2023.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPPT–2020–0465, through the Federal eRulemaking Portal at *https://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT:

For technical information contact: Ingrid Feustel, Existing Chemicals Risk Management Division, Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; telephone number 202–564–3199; email address: *MethyleneChlorideTSCA@epa.gov;*

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554–1404; email address: *TSCA-Hotline@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. Does this action apply to me?

You may be potentially affected by the proposed action if you manufacture (defined under TSCA to include import), process, distribute in commerce, use, or dispose of methylene chloride or products containing methylene chloride. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities include:

- Other Chemical and Allied Products Merchant Wholesalers (NAICS code 424690);
- Crude Petroleum Extraction (NAICS code 211120);
- All Other Basic Organic Chemical Manufacturing (NAICS code 325199);
- Other Chemical and Allied Products Merchant Wholesalers (NAICS code 424690);
- Petroleum Bulk Stations and Terminals (NAICS code 424710);
- Other Basic Inorganic Chemical Manufacturing (NAICS code 325180);
- Testing Laboratories (NAICS code 541380);
- Hazardous Waste Treatment and Disposal (NAICS code 562211);
- Solid Waste Combustors and Incinerators (NAICS code 562213);
- Materials Recovery Facilities (NAICS code 562920);
- Paint and Coating Manufacturing (NAICS code 325510);
- Air and Gas Compressor Manufacturing (NAICS code 333912);
- Gasket, Packing, and Sealing Device Manufacturing (NAICS code 339991);
- Residential Remodelers (NAICS code 236118);
- Commercial and Institutional Building Construction (NAICS code 236220);
- Plumbing, Heating, and Air-Conditioning Contractors (NAICS code 238220);
- Painting and Wall Covering Contractors (NAICS code 238320);
- All Other Miscellaneous Manufacturing (NAICS code 339999);
- Automotive Parts and Accessories Stores (NAICS code 441310);
- All Other Miscellaneous Store Retailers (except Tobacco Stores) (NAICS code 453998);
- Other Support Activities for Air Transportation (NAICS code 488190);
- All Other Automotive Repair and Maintenance (NAICS code 811198);
- Commercial and Industrial Machinery and Equipment (except Automotive and Electronic) Repair and Maintenance (NAICS code 811310);
- Footwear and Leather Goods Repair (NAICS code 811430);
- Adhesive Manufacturing (NAICS code 325520);
- All Other Miscellaneous Chemical Product and Preparation Manufacturing (NAICS code 325998);
- Audio and Video Equipment Manufacturing (NAICS code 334310);
- Reupholstery and Furniture Repair (NAICS code 811420);
- All Other Rubber Product Manufacturing (NAICS code 326299);
- All Other Miscellaneous Textile Product Mills (NAICS code 314999);
- All Other Miscellaneous Fabricated Metal Product Manufacturing (NAICS code 332999);
- Oil and Gas Field Machinery and Equipment Manufacturing (NAICS code 333132);

- Bare Printed Circuit Board Manufacturing (NAICS code 334412);
- Other Electronic Component Manufacturing (NAICS code 334419);
- All Other Miscellaneous Electrical Equipment and Component Manufacturing (NAICS code 335999);
- Printing Machinery and Equipment Manufacturing (NAICS code 333244);
- Petroleum Refineries (NAICS code 324110);
- Petroleum Lubricating Oil and Grease Manufacturing (NAICS code 324191);
- Painting and Wall Covering Contractors (NAICS code 238320);
- Welding and Soldering Equipment Manufacturing (NAICS code 333992);
- New Car Dealers (NAICS code 441110);
- Used Car Dealers (NAICS code 441120);
- Drycleaning and Laundry Services (except Coin-Operated) (NAICS code 812320); and
- Doll, Toy, and Game Manufacturing (NAICS code 339930).

This action may also affect certain entities through pre-existing import certification and export notification rules under TSCA. Persons who import any chemical substance governed by a final TSCA section 6(a) rule are subject to the TSCA section 13 (15 U.S.C. 2612) import certification requirements and the corresponding regulations at 19 Code of Federal Regulations (CFR) 12.118 through 12.127; see also 19 CFR 127.28. Those persons must certify that the shipment of the chemical substance complies with all applicable rules and orders under TSCA. The EPA policy in support of import certification appears at 40 CFR part 707, subpart B. In addition, any persons who export or intend to export a chemical substance that is the subject of this proposed rule are subject to the export notification provisions of TSCA section 12(b) (15 U.S.C. 2611(b)), and must comply with the export notification requirements in 40 CFR part 707, subpart D.

If you have any questions regarding the applicability of this proposed action to a particular entity, consult the technical information contact listed under **FOR FURTHER INFORMATION CONTACT**.

B. What is the Agency's authority for taking this action?

Under TSCA section 6(a) (15 U.S.C. 2605(a)), if the U.S. Environmental Protection Agency, hereinafter EPA or ''the Agency,'' determines through a TSCA section 6(b) risk evaluation that a chemical substance presents an unreasonable risk of injury to health or the environment, EPA must by rule apply one or more requirements listed in section 6(a) to the extent necessary so that the chemical substance or mixture no longer presents such risk.

C. What action is the Agency taking?

Pursuant to TSCA section 6(b), EPA determined that methylene chloride presents an unreasonable risk of injury to health, without consideration of costs or other non-risk factors, including an unreasonable risk to potentially exposed or susceptible subpopulations identified as relevant to the 2020 Risk Evaluation for Methylene Chloride by EPA, under the conditions of use (Refs. 1, 2). A detailed description of the conditions of use that drive EPA's determination that methylene chloride presents an unreasonable risk is included in Unit III.B.2. Accordingly, to address the unreasonable risk, EPA is proposing, under TSCA section 6(a) to:

(i) Prohibit the manufacture, processing, and distribution of methylene chloride for all consumer use, as outlined in Unit IV.A.3.;

(ii) Prohibit most industrial and commercial use of methylene chloride, as outlined in Unit IV.A.2.;

(iii) Require a WCPP, including inhalation exposure concentration limits and related workplace exposure monitoring and exposure controls, for ten conditions of use of methylene chloride (including manufacture; processing as a reactant; laboratory use; industrial or commercial use in aerospace and military paint and coating removal from safety-critical, corrosion-sensitive components by Federal agencies and their contractors; industrial or commercial use as a bonding agent for acrylic and polycarbonate in mission-critical military and space vehicle applications, including in the production of specialty batteries for such by Federal agencies and their contractors; and disposal), as outlined in Unit IV.A.1.;

(iv) Require recordkeeping and downstream notification requirements for manufacturing, processing, and distribution in commerce of methylene chloride, as outlined in Unit IV.A.4.;

(v) Provide a 10-year time-limited exemption under TSCA section 6(g) for civilian aviation from the prohibition addressing the use of methylene chloride for paint and coating removal to avoid significant disruptions to critical infrastructure, as outlined in Unit IV.A.5., with conditions for this exemption to include compliance with the WCPP described in Unit IV.A.1.; and

(vi) Provide a 10-year time-limited exemption under TSCA section 6(g) for emergency use of methylene chloride in furtherance of National Aeronautics and Space Administration's mission for specific conditions which are critical or essential and for which no technically and economically feasible safer alternative is available, as outlined in Unit IV.A.5., with conditions for this exemption to include compliance with the WCPP described in Unit IV.A.1.

EPA notes that all TSCA conditions of use of methylene chloride (other than the use of methylene chloride in consumer paint and coating removers, which was subject to separate action under TSCA section 6 (84 FR 11420, March 27, 2019)) are subject to this proposal. Condition of use is defined in TSCA to mean the circumstances under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of. EPA is requesting public comment on all aspects of this proposal.

D. Why is the Agency taking this action?

Under TSCA section 6(a), ''[i]f the Administrator determines in accordance with subsection (b)(4)(A) that the manufacture, processing, distribution in commerce, use or disposal of a chemical substance or mixture, or that any combination of such activities, presents an unreasonable risk of injury to health or the environment, the Administrator shall by rule. . . apply one or more of the [section 6(a)] requirements to such substance or mixture to the extent necessary so that the chemical substance no longer presents such risk.'' Methylene chloride was the subject of a risk evaluation under TSCA section 6(b)(4)(A) that was issued in June 2020 (2020 Risk Evaluation for Methylene Chloride) (Ref. 1). In addition, EPA issued a revised unreasonable risk determination for methylene chloride in November 2022 (Ref. 2) determining that methylene chloride, as a whole chemical substance, presents an unreasonable risk of injury to health under the conditions of use. As a result, EPA is proposing to take action to the extent necessary so that methylene chloride no longer presents such risk. The unreasonable risk is described in Unit III.B.1. and the conditions of use that drive the unreasonable risk for methylene chloride are described in Unit III.B.2.

EPA emphasizes that some of the adverse effects from methylene chloride exposure can be immediately experienced and only for a short duration; others, however, can result in sudden death. Other effects may result in long-term impacts and should likewise be considered significant. Methylene chloride's hazards are well established. Fatalities from acute methylene chloride exposures have

been documented and pose a serious public health threat; these fatalities led the agency to prohibit the manufacture, processing, and distribution of methylene chloride for use in consumer paint and coating removers in 2019 (84 FR 11420, March 27, 2019) (FRL–9989–29). This proposed rule would eliminate the unreasonable risk to human health from the remaining conditions of use of methylene chloride, as identified in the 2020 Risk Evaluation for Methylene Chloride and the revised unreasonable risk determination for methylene chloride in November 2022.

EPA is not proposing a complete ban on methylene chloride. The agency recognizes that continued use of methylene chloride in one of the TSCA conditions of use may complement the agency's efforts to address climate-damaging hydrofluorocarbons (HFCs) under the American Innovation and Manufacturing Act of 2020 (AIM Act), thereby supporting human health and environmental protection under these programs, and that, for these HFC-related, reactant processing uses, workplace controls to address unreasonable risk can be implemented. Therefore, while addressing the unreasonable risk, this rule proposes to allow methylene chloride's continued use in tandem with additional worker protections for the production of HFC–32, one of the regulated substances that are subject to a phasedown under the AIM Act. While HFC–32 is one of the regulated substances subject to the phasedown in production and consumption by 85% over the next 15 years, HFC–32 is likely to be used to facilitate the transition from certain other HFCs and HFC blends with higher global warming potentials in certain applications. EPA expects that, by allowing for the continued use of methylene chloride in the production of HFC–32, this approach would complement EPA's work under the AIM Act. For many of the conditions of use for which EPA is proposing workplace controls under a WCPP, data was submitted during the risk evaluation and Small Business Advocacy Review (SBAR process that indicates some facilities may already be in compliance with the proposed methylene chloride Existing Chemical Exposure Limit (ECEL). Additionally, the requirements in this proposal would prohibit uses that account for approximately one third of the total annual production volume of methylene chloride generated (TSCA and non-TSCA uses), leaving a sufficient supply in circulation to provide a source for these critical or essential uses for which EPA is proposing to allow continued use (Unit IV.A.), either under a WCPP or through a TSCA section 6(g) exemption (Ref. 3).

E. What are the estimated incremental impacts of this Action?

EPA has prepared an Economic Analysis of the potential incremental impacts associated with this rulemaking that can be found in the rulemaking docket (Ref. 3). As described in more detail in the Economic Analysis (Ref. 3) and in Units VI.D. and X.D., EPA's analysis of the incremental, non-closure-related costs of this proposed rule is estimated to be $13.2 million annualized over 20 years at a 3% discount rate and $14.5 million annualized over 20 years at a 7% discount rate. These costs take compliance with implementation of a WCPP for certain conditions of use into consideration, which would include an ECEL of 2 ppm (8 mg/m^3) for inhalation exposures as an 8-hour time-weighted average (TWA), applicable personal protective equipment (PPE) requirements, and reformulation costs of numerous products. In addition to the monetized costs discussed previously there are unknown economic impacts of potential firm closures in the furniture refinishing industry as discussed in the Economic Analysis. Potential average lost profits range from $14,000 (one firm closing) to $67 million under the extreme and unlikely assumption of a complete sector shutdown (Ref. 3). EPA had also received comments following SBAR meetings where submitted exposure measurements indicated an ability to achieve ECEL levels, suggesting that a WCPP for certain uses is achievable; this is further discussed in Unit V.A.1. Unquantified costs exist, including determining the best substitute for the firm's specific needs and how a different product may impact a firm's existing workflow (*e.g.,* does a different adhesive take longer to dry) and how a firm may work through the hierarchy of controls to comply with a WCPP. Although some costs cannot be quantified, they are not necessarily less important than the quantified costs. The most notable unquantified cost is change in labor and wait times within applications for which methylene chloride use is more efficient than substitute methods or alternative chemicals for achieving desired results. Additionally, in the unique case of furniture refinishing (within the commercial paint and coating removal condition of use), alternatives to products containing methylene chloride may not be economically viable and may cause damage to the substrate, and thus the prohibition of this use could impact the sector significantly. After publication of the proposed rule for methylene chloride in paint and coating removal (82 FR 7464, January 19, 2017) (FRL–9958–57), EPA, in collaboration with the Small Business Administration's Office of Advocacy, conducted a workshop on furniture refinishing in Boston, Massachusetts, on September 12, 2017 (82 FR 41256, August 30, 2017) (FRL–9966–83) to address information gaps for the furniture refinishing sector identified in that proposed rule. The workshop was well attended by over 100 furniture refinishing experts, industry professionals, nongovernmental organizations, academic experts, and State and Federal Government partners (Ref. 4). The informative discussion among the participants and invited speakers touched on the commercial and consumer use of methylene chloride in furniture refinishing, the potential effects that regulation may have on businesses, alternatives to methylene chloride, health risks associated with methylene chloride, and labeling of consumer and commercial products (speaker presentations, transcript notes, and public comments are available in the docket EPA–HQ–OPPT–2017–0139).

EPA estimates that as many as 5,000 furniture refinishers still use methylene chloride, a majority of which are small businesses. While the amount of methylene chloride paint removers used per firm for furniture refinishing can vary greatly, industry stakeholder information indicates one 55-gallon drum every two months (Ref. 4). This would result in an estimated 2.3 million gallons of formulated paint remover used annually. The amount of methylene chloride included in this estimate would depend on the percent in formulation used by the furniture refinishing firms. The impact of a prohibition of methylene chloride for furniture refinishing could result in the closure of an unknown number of the 5,000 potentially affected furniture refinishing firms using methylene chloride in the baseline.

Based on the estimated revenues per firm presented in Table 3–1 of the Economic Analysis and the 5,000 estimated number of furniture refinishing firms using methylene chloride (see Table 6–12 in the Economic Analysis), the total revenue for furniture refinishing firms using methylene chloride is approximately $1.8 billion. According to IRS (2013) data, profit in this sector is about 3.8% of sales. Therefore, closure of affected furniture refinishing firms using methylene chloride following this

rulemaking has an upper bound for economic impacts of $1.8 billion in total revenue, and $67 million in terms of the total profit, under the assumption that all affected firms fully close. A detailed discussion of potential economic impacts as a result of varying percentages of furniture refinishing firms closing is provided in the Economic Analysis in section 7.11 (Ref. 3).

EPA identified many alternative products for paint and coating removers, though many may require longer periods of time, replacement of equipment, or rework of processes in order to work for furniture refinishing uses. These may not be appropriate alternatives as they could damage the wood substrate. Mechanical or thermal methods (*i.e.,* sanding, media blasting, and heat guns) are also potential alternatives for this sector, though they likewise they require different processes, and often require more time (Refs. 3, 4, 5, 6). For furniture refinishing, as with other commercial uses, the health benefits that would result from prohibiting this use of methylene chloride, including deaths avoided, are further discussed in the Economic Analysis (Ref. 3).

The actions proposed in this rule are expected to achieve health benefits for the American public, some of which can be monetized and others that, while tangible and significant, cannot be monetized. Although some benefits cannot be quantified, they are not necessarily less important than the quantified benefits. The monetized benefits of this rule are approximately $17.7 million to $18.5 million annualized over 20 years at a 3% discount rate and $13.4 million to $13.9 million annualized over 20 years at a 7% discount rate. The monetized benefits only include potential reductions in risk of liver cancer, lung cancer, and potential deaths avoided from acute methylene chloride exposure. Non-monetized benefits include potential reductions in central nervous system depressant effects; these effects include loss of consciousness and respiratory depression that may result in irreversible coma and hypoxia. Risks from acute exposures to methylene chloride can lead to workplace accidents and are precursors to the more severe central nervous system effects (up to and including death). Other non-monetized benefits include reductions in liver disease (including vacuolization, necrosis, hemosiderosis and hepatocellular degeneration), immune system compromise, and irritation and burns (Ref. 3).

II. Background

A. Overview of Methylene Chloride

Methylene chloride is acutely lethal, a neurotoxicant, and a likely human carcinogen. This proposed rule is specifically intended to address the unreasonable risk of injury to health that EPA has identified in the 2020 Risk Evaluation for Methylene Chloride and unreasonable risk determination, as described in Unit III.B.2. Methylene chloride is a colorless liquid and a volatile chemical with a sweet odor resembling chloroform. It is produced in and imported into the United States. Methylene chloride is manufactured, processed, distributed in commerce, used, and disposed of as part of many industrial, commercial, and consumer conditions of use. As outlined in Unit III.B.1., methylene chloride is a widely used solvent in a variety of consumer and commercial applications including adhesives and sealants, automotive products, and paint and coating removers. Some evidence suggests that in recent years, use of methylene chloride has been declining in certain sectors (Ref. 3), particularly for consumer products, as the hazards of methylene chloride are well known, and certain uses are highly regulated. As further described in Unit II.B. and in the regulatory appendix (Ref. 7), these regulations include EPA's 2019 rule addressing unreasonable risk to consumers from methylene chloride use in consumer paint and coating removal by prohibiting manufacturing, processing, and distribution in commerce of methylene chloride for consumer use in paint and coating removal (84 FR 11420, March 27, 2019) (FRL–9989–29).

The total aggregate production volume of methylene chloride ranged from 100 million to 500 million pounds between 2016 and 2019 according to Chemical Data Reporting (CDR) (Ref. 8). One notable high-volume use accounting for approximately one-fifth of all methylene chloride annual production volume is processing as a reactant, which includes the manufacture of hydrofluorocarbons (HFCs) (Ref. 1). This condition of use is described in Unit III.B.2., with a description of proposed requirements to address unreasonable risk in Unit III.B.3, and V.1. An estimated 35% of the annual production volume of methylene chloride is for pharmaceutical uses, which are not subject to TSCA and would not be regulated by this rule (15 U.S.C. 2602(2)(B)(vi); 21 U.S.C. 321(g)(1)).

B. Regulatory Actions Pertaining to Methylene Chloride

Because of its adverse health effects, methylene chloride is subject to numerous State, Federal, and international regulations restricting and regulating its use. A summary of EPA regulations pertaining to methylene chloride, as well other Federal, State, and international regulations, is in the docket (Refs. 1, 7).

C. Consideration of Occupational Safety and Health Administration (OSHA) Occupational Health Standards in TSCA Risk Evaluations and TSCA Risk Management Actions

TSCA requires EPA to evaluate whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator, under the conditions of use. Conditions of use are the circumstances, as determined by the Administrator, under which a chemical is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of. If EPA determines through risk evaluation that a chemical substance presents an unreasonable risk, TSCA section 6 requires EPA to issue regulations applying one or more control requirements to the extent necessary so that the chemical substance no longer presents such risk. Although EPA must consider, and in some cases factor-in, to the extent practicable, non-risk factors as part of TSCA section 6(a) rulemaking (see TSCA section 6(c)(2)), EPA must nonetheless still ensure that the selected regulatory requirements apply ''to the extent necessary so that the chemical substance or mixture no longer presents [unreasonable] risk.'' 15 U.S.C. 2605(a). This risk-based requirement is distinguishable from approaches mandated by other laws, including the Occupational Safety and Health Act (OSH Act), which includes both significant risk and feasibility (technical and economic) assessments in its rulemaking.

Congress intended for EPA to consider occupational risks from chemicals it evaluates under TSCA, among other potential exposures, as relevant and appropriate. As noted previously, section 6(b) of TSCA requires EPA to evaluate risks to potentially exposed or susceptible subpopulations identified as relevant by the Administrator. TSCA section 3(12)

defines the term ''potentially exposed or susceptible subpopulation'' as ''a group of individuals within the general population identified by the Administrator who, due to either greater susceptibility or greater exposure, may be at greater risk than the general population of adverse health effects from exposure to a chemical substance or mixture, such as infants, children, pregnant women, workers, or the elderly.''

The OSH Act similarly requires OSHA to evaluate risk specific to workers prior to promulgating new or revised standards and requires OSHA standards to substantially reduce significant risk to the extent feasible, even if workers are exposed over a full working lifetime. *See* 29 U.S.C. 655(b)(5); *Indus. Union Dep't, AFL–CIO* v. *Am. Petroleum Inst.,* 448 U.S. 607, 642 (1980) (plurality opinion).

Thus, the standards for chemical hazards that OSHA promulgates under the OSH Act share a broadly similar purpose with the standards that EPA promulgates under TSCA section 6(a). The control measures OSHA and EPA require to satisfy the objectives of their respective statutes may also, in many circumstances, overlap or coincide. However, as this section outlines, there are important differences between EPA's and OSHA's regulatory approaches and jurisdiction, and EPA considers these differences when deciding whether and how to account for OSHA requirements (such as those described in Unit II.B.2.) when evaluating and addressing potential unreasonable risk to workers so that compliance requirements are clearly explained to the regulated community.

1. OSHA Requirements

OSHA's mission is to ensure that employees work in safe and healthful conditions. The OSH Act establishes requirements that each employer comply with the General Duty Clause of the Act (29 U.S.C. 654(a)), as well as with occupational safety and health standards issued under the Act.

a. General Duty Clause of the OSH Act

The General Duty Clause of the OSH Act requires employers to keep their workplaces free from recognized hazards that are causing or are likely to cause death or serious physical harm to employees. The General Duty Clause is cast in general terms, and does not establish specific requirements like exposure limits, personal protective equipment (PPE)), or other specific protective measures that EPA could potentially consider when developing its risk evaluations or risk management requirements. OSHA, under limited circumstances, has cited the General Duty Clause for regulating exposure to chemicals. To prove a violation of the General Duty Clause, OSHA must prove employer or industry recognition of the hazard, that the hazard was causing or likely to cause death or serious physical harm, and a feasible method to eliminate or materially reduce the hazard was available. In rare situations, OSHA has cited employers for violation of the General Duty Clause where exposures were below a chemical-specific permissible exposure limit (PEL). In such situations, OSHA must demonstrate that the employer had actual knowledge that the PEL was inadequate to protect its employees from death or serious physical harm. Because of the heavy evidentiary burden on OSHA to establish violations of the General Duty Clause, it is not frequently used to cite employers for employee exposure to chemical hazards.

b. OSHA Standards

OSHA standards are issued pursuant to the OSH Act and are found in title 29 of the CFR. There are separate standards for general industry, construction, maritime and agriculture sectors, general standards applicable to a number of sectors (*e.g.,* OSHA's Respiratory Protection standard), and a methylene chloride standard. OSHA has numerous standards that apply to employers who operate chemical manufacturing and processing facilities, as well as to downstream employers whose employees may be occupationally exposed to hazardous chemicals.

OSHA sets legally enforceable limits on the airborne concentrations of hazardous chemicals, referred to as PELs, established for employers to protect their workers against the health effects of exposure to hazardous substances (29 CFR parts 1910, Subpart Z; 1915, Subpart Z; 1926, Subparts D and Z). Under section 6(a) of the OSH Act, OSHA was permitted an initial 2-year window after the passage of the Act to adopt ''any national consensus standard and any established Federal standard.'' 29 U.S.C. 655(a). OSHA used this authority in 1971 to establish PELs that were adopted from Federal health standards originally set by the Department of Labor through the Walsh-Healy Act, in which approximately 400 occupational exposure limits were selected based on the American Conference of Governmental Industrial Hygienists (ACGIH) 1968 list of Threshold Limit Values (TLVs). In addition, about 25 exposure limits recommended by the American Standards Association (now called the American National Standards Institute) (ANSI) were adopted as PELs.

Following the 2-year window provided under section 6(a) of the OSH Act for adoption of national consensus and existing Federal standards, OSHA has issued health standards following the requirements in section 6(b) of the Act. OSHA has established approximately 30 PELs under section 6(b)(5) as part of comprehensive substance-specific standards that include additional requirements for protective measures such as use of PPE, establishment of regulated areas, exposure assessment, hygiene facilities, medical surveillance, and training. These ancillary provisions in substance-specific OSHA standards further mitigate residual risk that could be present due to exposure at the PEL.

Though many OSHA PELs have not been updated since they were established in 1971, the methylene chloride PEL was last updated as part of the OSHA methylene chloride standard in 1997. In many instances, scientific evidence has accumulated suggesting that the current limits of many PELs are not sufficiently protective. On October 10, 2014, OSHA published a **Federal Register** document in which it recognized that many of its PELs are outdated and inadequate for ensuring protection of worker health (79 FR 61384). In addition, health standards issued under section 6(b)(5) of the OSH Act must reduce significant risk only to the extent that it is technologically and economically feasible to do so. OSHA's legal requirement to demonstrate that its section 6(b)(5) standards are technologically and economically feasible at the time they are promulgated often precludes OSHA from imposing exposure control requirements sufficient to ensure that the chemical substance no longer presents a significant risk to workers.

In sum, the great majority of OSHA's chemical standards are outdated or do not sufficiently reduce significant risk to workers. They would, in either case, be unlikely to address unreasonable risk to workers within the meaning of TSCA, since TSCA section 6(b) unreasonable risk determinations may account for unreasonable risk to more sensitive endpoints and working populations than OSHA's risk evaluations typically contemplate, and EPA is obligated to apply TSCA section 6(a) risk management requirements to the extent necessary so that the unreasonable risk is no longer presented.

Because the requirements and application of TSCA and OSHA regulatory analyses differ, and because

OSHA's chemical-specific standards are decades old and may include outdated assumptions regarding the most sensitive end-point and/or the technological and economic feasibility of the standards, it is necessary for EPA to conduct risk evaluations and, where it finds unreasonable risk to workers, develop risk management requirements for chemical substances that OSHA also regulates, and it is expected that EPA's findings and requirements may sometimes diverge from OSHA's. However, it is also appropriate that EPA consider the chemical standards that OSHA has already developed to limit the compliance burden to employers by aligning management approaches required by the agencies, where alignment will adequately address unreasonable risk to workers. The following section discusses EPA's consideration of OSHA standards in its risk evaluation and management strategies under TSCA.

2. Consideration of OSHA Standards in TSCA Risk Evaluations

When characterizing the risk during risk evaluation under TSCA, EPA believes it is appropriate to evaluate the levels of risk present in scenarios where no mitigation measures are assumed to be in place for the purpose of determining unreasonable risk (see Unit II.C.2.a.). (It should be noted that there are some cases where scenarios may reflect certain mitigation measures, such as in instances where exposure estimates are based on monitoring data at facilities that have existing engineering controls in place.) In addition, EPA believes it is appropriate to also evaluate the levels of risk present in scenarios considering applicable OSHA requirements (*e.g.,* chemical-specific PELs and/or chemical-specific standards with PELs and additional ancillary provisions), as well as scenarios considering industry or sector best practices for industrial hygiene that are clearly articulated to the Agency. By characterizing risks using scenarios that reflect different levels of mitigation, EPA risk evaluations can help inform potential risk management actions by providing information that could be used during risk management to tailor risk mitigation appropriately to address any unreasonable risk identified (see Unit II.C.2.b. and Unit II.C.3.).

a. Risk Characterization for Unreasonable Risk Determination

When making unreasonable risk determinations as part of TSCA risk evaluations, EPA cannot assume as a general matter that all workers are always equipped with and appropriately using sufficient PPE, although it does not question the public comments received on the 2020 Risk Evaluation for Methylene Chloride regarding the occupational safety practices often followed by industry respondents. When characterizing the risk to human health from occupational exposures during risk evaluation under TSCA, EPA believes it is appropriate to evaluate the levels of risk present in baseline scenarios where PPE is not assumed to be used by workers. This approach of not assuming PPE use by workers considers the risk to potentially exposed or susceptible subpopulations (workers and occupational non-users) who may not be covered by OSHA standards, such as self-employed individuals and public sector workers who are not covered by a State Plan. Mitigation scenarios included in the EPA risk evaluation (*e.g.,* scenarios considering use of PPE) likely represent current practice in many facilities where companies effectively address worker and bystander safety requirements. However, the Agency cannot assume that all facilities will have adopted these practices for the purposes of making the TSCA risk determination.

Therefore, EPA makes its determinations of unreasonable risk based on scenarios that do not assume compliance with OSHA standards, including any applicable exposure limits or requirements for use of respiratory protection or other PPE. Making unreasonable risk determinations based on such scenarios should not be viewed as an indication that EPA believes there are no occupational safety protections in place at any location, or that there is widespread noncompliance with applicable OSHA standards. Rather, it reflects EPA's recognition that unreasonable risk may exist for subpopulations of workers that may be highly exposed because they are not covered by OSHA standards, such as self-employed individuals and public sector workers who are not covered by an OSHA State Plan, or because their employer is out of compliance with OSHA standards, or because EPA finds unreasonable risk for purposes of TSCA notwithstanding existing OSHA requirements.

b. Risk Evaluation To Inform Risk Management Requirements

In addition to the scenarios described previously, EPA risk evaluations may characterize the levels of risk present in scenarios considering applicable OSHA requirements (*e.g.,* chemical-specific PELs and/or chemical-specific health standards with PELs and additional ancillary provisions) as well as scenarios considering industry or sector best practices for industrial hygiene that are clearly articulated to the Agency. EPA's evaluation of risk under scenarios that, for example, incorporate use of engineering or administrative controls, or PPE, serves to inform its risk management efforts. Characterizing risks using scenarios that reflect different levels of mitigation can help inform potential risk management actions by providing information that could be used during risk management to tailor risk mitigation to address worker exposures where the Agency has found unreasonable risk. In particular, as discussed later in this unit, EPA can use the information developed during its risk evaluation to determine whether alignment of EPA's risk management requirements with existing OSHA requirements or industry best practices will adequately address unreasonable risk as required by TSCA.

3. Consideration of OSHA Standards in TSCA Risk Management Actions

When undertaking risk management actions, EPA: (1) Develops occupational risk mitigation measures to address any unreasonable risk identified by EPA, striving for consistency with applicable OSHA requirements and industry best practices, including appropriate application of the National Institute for Occupational Safety and Health (NIOSH) hierarchy of controls (Ref. 9) (hereafter referred to as ''hierarchy of controls''), when those measures would address an unreasonable risk; and (2) Ensures that EPA requirements apply to all potentially exposed workers in accordance with TSCA requirements. Consistent with TSCA section 9(d), EPA consults and coordinates TSCA activities with OSHA and other relevant Federal agencies for the purpose of achieving the maximum applicability of TSCA while avoiding the imposition of duplicative requirements.

Informed by the mitigation scenarios and information gathered during the risk evaluation and risk management process, the Agency might propose rules that require risk management practices that may be already common practice in many or most facilities. Adopting clear, comprehensive regulatory standards will foster compliance across all facilities (ensuring a level playing field) and assure protections for all affected workers, especially in cases where current OSHA standards may not apply to them or not be sufficient to address the unreasonable risk.

4. Methylene Chloride and OSHA Requirements

EPA incorporated the considerations described earlier in this Unit into the 2020 Risk Evaluation for Methylene Chloride, the November 2022 revised unreasonable risk determination for methylene chloride, and this rulemaking. Specifically, in the TSCA 2020 Risk Evaluation for Methylene Chloride, EPA presented risk estimates based on workers' exposures with and without respiratory protection. EPA determined that even when respirators are used by workers, most of the conditions of use evaluated presented an unreasonable risk. Additional considerations of OSHA standards in the revised unreasonable risk determination are discussed further in the **Federal Register** notice announcing that document (Ref. 19) (87 FR 67901, November 10, 2022). In Units III.B.3. and V., EPA outlines the importance of considering the hierarchy of controls when developing risk management actions in general, and specifically when determining if and how regulated entities may meet a risk-based exposure limit for methylene chloride. The hierarchy of controls is a prioritization of exposure control strategies from most protective and preferred to least protective and preferred techniques. In order of precedence, they are: elimination of the hazard, substitution with a less hazardous substance, engineering controls, administrative controls such as training or exclusion zones with warning signs, and, finally, use of PPE (Ref. 9). Under the hierarchy of controls, the use of respirators (and all PPE) should only be considered after all other measures have been taken to reduce exposures, and then under the context of the OSHA Respiratory Protection Standard at 29 CFR 1910.134. As discussed in Units III.A.1. and V.A.1., EPA's risk management approach would not rely solely or primarily on the use of respirators to reduce exposures to workers so that methylene chloride does not present unreasonable risk; instead, EPA is proposing prohibitions for or affecting most conditions of use and a WCPP for certain industrial and commercial uses. The WCPP would require consideration of the hierarchy of controls before use of respirators and other PPE. The WCPP is discussed in full in Units IV.A.1. and V.A. As discussed further in Unit V.A.1., for many of the conditions of use for which EPA is proposing a WCPP, data was submitted during the risk evaluation and SBAR process that indicates some facilities may already be in compliance with the proposed methylene chloride ECEL.

In accordance with the approach described earlier in Unit II.C.3., EPA intends for this regulation to be as consistent as possible with the current OSHA standard for methylene chloride, with additional requirements as necessary to address the unreasonable risk. Notable differences between the WCPP and the OSHA standard are the exposure limits and the action levels. The WCPP would include an Existing Chemical Exposure Limit (ECEL) of 2 ppm as an 8-hour TWA to address unreasonable risk for chronic cancer and non-cancer inhalation endpoints, and acute non-cancer endpoints, as well as an EPA Short Term Exposure Limit (EPA STEL) of 16 ppm as a 15-minute TWA to address any peak exposures which may result in additional unreasonable risk from acute inhalation. A regulated entity must comply with both the 8-hour TWA ECEL and the 15-minute TWA EPA STEL to completely address the unreasonable risk. EPA recognizes that for methylene chloride, the ECEL and EPA STEL would be significantly lower than the OSHA PEL (25 ppm as an 8-hour TWA) and STEL (125 ppm). In addition to the distinctions in statutory requirements described in this Unit, EPA has identified factors contributing to the differences in these levels, outlined here (Ref. 14).

EPA considers the methylene chloride ECEL to represent the best available science under TSCA section 26(h), since it was derived from information in the 2020 Risk Evaluation for Methylene Chloride, which is the result of a rigorous systematic review process that investigated the entirety of the reasonably available current literature in order to identify all relevant adverse health effects. Additionally, by using the information from the 2020 Risk Evaluation for Methylene Chloride, the ECEL incorporates advanced modeling and peer-reviewed methodologies, including accounting for exposures to potentially exposed or susceptible subpopulations, as required by TSCA.

The ECEL is an 8-hour occupational inhalation exposure limit based on the point of departure of the endpoint that drives the unreasonable risk determination (chronic non-cancer liver effects, in the case of methylene chloride), and takes into consideration the uncertainties identified in the 2020 Risk Evaluation for Methylene Chloride (Ref. 11). The ECEL represents the concentration at or below which an adult human, including a member of a potentially exposed or susceptible subpopulation, would be unlikely to suffer adverse effects if exposed for a working lifetime. EPA has determined as a matter of risk management policy that ensuring exposures remain at or below the ECEL will eliminate- any unreasonable risk of injury to health. In addition to the ECEL, as part of this rulemaking, EPA is setting an ECEL-action level, a value half of the ECEL, that would trigger additional monitoring action to ensure that workers are not exposed to concentrations above the ECEL.

The OSHA PEL is an 8-hour time-weighted average (TWA) based on an employee's average airborne exposure in any 8-hour work shift of a 40-hour work week that shall not be exceeded (Ref. 12). OSHA is required to promulgate a standard that reduces significant risk to the extent that it is technologically and economically feasible to do so (81 FR 16285).

For methylene chloride, the ECEL is based on the most sensitive point of departure (POD) across acute, chronic non-cancer, and cancer endpoints. As demonstrated in the ECEL memo, chronic liver toxicity is the basis of the methylene chloride ECEL (Ref. 11). Both inhalation and oral studies identified liver effects as sensitive non-cancer effects linked with exposure to methylene chloride in animals. Overall, based on limited human evidence and strong evidence in multiple animal species from highly rated studies based on systematic review, the weight of the scientific evidence supported EPA's finding that non-cancer liver effects follow methylene chloride exposure.

EPA used liver lesions in rats as indicated by cellular vacuolization in Nitschke *et al.,* 1988 as the basis of the chronic non-cancer POD. Study data was run through a physiological-based pharmacokinetic (PBPK) model to more accurately account for both inter-species differences and human variability. Internal PBPK-modeled doses were also benchmark-dose modeled in order to better refine the POD estimate, resulting in a human equivalent concentration (HEC) of 4.8 ppm based on continuous exposure with a benchmark margin of exposure (MOE) (equal to the product of all uncertainty factors) of 10. The resulting ECEL is 2 ppm.

The EPA STEL is based on decreased visual performance identified in an acute inhalation study on human subjects. Putz *et al.* (1979) is a well-conducted study of 12 volunteers that identified decreased visual peripheral performance after 1.5 hour of exposure to 195 ppm (200 ppm nominal) (Ref. 13). Because this study used a single concentration, it is not amenable to dose-response modeling, so EPA used

the lowest observed adverse effects concentration (LOAEC) of 195 ppm. Adjusting to a more appropriate exposure duration of 8-hour for occupational scenarios resulted in a HEC of 80 ppm with benchmark MOE of 30. The resulting acute exposure limit is 16 ppm, eight times higher than the overall ECEL.

The OSHA PEL for methylene chloride was adopted in 1971 and updated in 1997 (62 FR 1494, January 10, 1997). The OSHA PEL is set at 25 ppm, based on cancer from the same National Toxicology Program (1986) study cited for cancer effects in the 2020 Methylene Chloride Risk Evaluation (Ref. 14) (though EPA found this was not the most sensitive POD, and thus set an ECEL of 2 ppm, based on non-cancer liver effects from Nitschke *et al.,* 1988 (Refs. 15, 16)).

The OSHA PEL utilized a PBPK model to derive lifetime excess risk estimates for cancer. The PEL was set at 25 ppm based on estimated lifetime risk of 2.4 to 3.6 cases per 1000 or 2.4–$3.66x10^{-3}$ (E^{-3}) at that exposure level. EPA used a benchmark of 1 in 10,000 (10^{-4}) for individuals in industrial and commercial work environments for purposes of the unreasonable risk determination for methylene chloride (Ref. 2), and at that cancer risk level EPA calculates the exposure limit based on cancer to be approximately 42 ppm—almost double the OSHA PEL. OSHA acknowledges that the 10^{-3} threshold is ''100 to 1000 times higher than the risk levels generally regarded by other Federal Agencies as on the boundary between significant and insignificant risk'' and notes that ''even at the final PELs, the risks to workers clearly remain significant.'' (62 FR 1494, January 10, 1997).The 1997 decision to not derive a PEL lower than 25 ppm was based on economic and technical analysis, with OSHA stating, ''because of the lack of documented feasibility data for potential PELs of less than 25 ppm, OSHA has concluded that there is not enough information available to support lowering the 8-hour TWA PEL or STEL further at this time'' (62 FR 1494, January 10, 1997).

As for non-cancer liver effects that are the basis of the ECEL, OSHA determined that ''chronic exposure to [methylene chloride] caused toxic effects in rat and mouse liver and cancer in mouse liver. These studies appear to have been well conducted and the differences in toxicity observed across studies were likely due to differences in dose or route of exposure . . . [L]imited evidence supports the hypothesis that [methylene chloride] causes human hepatotoxicity, based on the data in the Ott study. The remaining studies and case reports do not provide clear evidence of a causative role of [methylene chloride] in hepatotoxicity. The Agency [OSHA] has set the exposure limits based on cancer and [central nervous system] effects and has not reached final conclusions on this issue'' (62 FR 1514–1515, January 10, 1997). As discussed in Units II.D., III.B.A., and VII.D., the ECEL represents the best available science at time of publication of the 2020 Risk Evaluation for Methylene Chloride.

D. Summary of EPA's Risk Evaluation Activities on Methylene Chloride

In July 2017, EPA published the scope of the methylene chloride risk evaluation (82 FR 31592, July 7, 2017) (FRL–9963–57), and, after receiving public comments, published the problem formulation in June 2018 (83 FR 26998, June 11, 2018) (FRL–9978–40). In October 2019, EPA published a draft risk evaluation (84 FR 57866, October 29, 2019) (FRL–9999–69), and, after public comment and peer review by the Science Advisory Committee on Chemicals (SACC), EPA issued the 2020 Risk Evaluation for Methylene Chloride in June 2020 in accordance with TSCA section 6(b) (85 FR 37942, June 24, 2020) (FRL–10011–16). EPA subsequently issued a draft revised TSCA risk determination for methylene chloride (87 FR 39824, July 5, 2022) (9946–01–OCSPP), and, after public notice and receipt of comments, published a Revised Risk Determination for Methylene Chloride in November 2022 (Ref. 2). The 2020 Risk Evaluation for Methylene Chloride and supplemental materials are in docket EPA–HQ–OPPT–2019–0437, and the November 2022 revised unreasonable risk determination and additional materials supporting the risk evaluation process are in docket EPA–HQ–OPPT–2016–0742, on *https://www.regulations.gov.*

1. 2020 Risk Evaluation

In the 2020 Risk Evaluation for Methylene Chloride, EPA evaluated risks associated with 53 conditions of use within the following categories: manufacture (including import), processing, distribution in commerce, industrial and commercial use, consumer use, and disposal (Ref. 1). Descriptions of these conditions of use are in Unit III.B.2. The 2020 Risk Evaluation for Methylene Chloride identified significant adverse health effects associated with short- and long-term exposure to methylene chloride, including central nervous system effects up to and including death from acute inhalation exposures, non-cancer liver effects from chronic inhalation, and cancer from chronic inhalation exposures to methylene chloride, as well as acute central nervous system effects and chronic non-cancer liver effects from dermal exposure. A further discussion of the hazards of methylene chloride is in Unit III.B.1.

2. 2022 Revised Unreasonable Risk Determination

EPA has been revisiting specific aspects of its first ten TSCA existing chemical risk evaluations, including the methylene chloride risk evaluation, to ensure that the risk evaluations upon which risk management decisions are made better align with TSCA's objective of protecting health and the environment. For methylene chloride, EPA revised the original unreasonable risk determination based on the 2020 Risk Evaluation for Methylene Chloride and issued a final revised unreasonable risk determination in November 2022 (Ref. 2). EPA revised the risk determination for the 2020 Risk Evaluation for Methylene Chloride pursuant to TSCA section 6(b) and consistent with Executive Order 13990, (''Protecting Public Health and the Environment and Restoring Science to Tackle the Climate Crisis'') and other Administration priorities (Refs. 17, 18, 19). The revisions consisted of making the risk determination based on the whole-chemical substance instead of by individual conditions of use (which resulted in the revised risk determination superseding the prior ''no unreasonable risk'' determinations (Ref. 2) the withdrawal of the associated TSCA section 6(i)(1) ''no unreasonable risk'' order; and clarifying that the risk determination does not reflect an assumption that all workers are always provided and appropriately wear PPE (Ref. 2).

In determining whether methylene chloride presents unreasonable risk under the conditions of use, EPA considered relevant risk-related factors, including, but not limited to: the effects of the chemical substance on health (including cancer and non-cancer risks) and human exposure to the substance under the conditions of use (including duration, magnitude and frequency of exposure); the effects of the chemical substance on the environment and environmental exposure under the conditions of use; the population exposed (including any potentially exposed or susceptible subpopulations); the severity of hazard (including the nature of the hazard, the irreversibility of the hazard); and uncertainties.

EPA determined that methylene chloride presents an unreasonable risk of injury to health. The unreasonable risk determination is driven by risks to workers and occupational non-users (workers who do not directly handle methylene chloride but perform work in an area where methylene chloride is present) from occupational exposures (*i.e.,* during manufacture, processing, industrial and commercial uses, or disposal), and to consumers and bystanders from consumer use of methylene chloride. EPA did not identify risks of injury to the environment that drive the unreasonable risk determination for methylene chloride. The methylene chloride conditions of use that drive EPA's determination that the chemical substance poses unreasonable risk to health are listed in the unreasonable risk determination (Ref. 2) and also in Unit III.B.2., with descriptions to aid chemical manufacturers, processors, and users in determining how their particular use or activity would be addressed under the proposed regulatory provisions.

While the 2020 Risk Evaluation for Methylene Chloride estimated different risks for occupational non-users and workers, the benchmark (and thus the ECEL and EPA STEL value) is the same for both populations. That is, while workers and occupational non-users may have different exposure patterns, the level of exposure such that risks are no longer unreasonable is the same for both workers and occupational non-users. Thus, for the purposes of risk management, the distinction between worker and occupational non-user is no longer relevant, and both are encompassed by the definition of a potentially exposed person, as outlined in Unit IV.A.1.a. EPA additionally emphasizes that the inclusion of occupational non-users itself does not exceed the scope of those individuals that are already covered by the OSHA PEL, as the methylene chloride OSHA standard applies to all employees within a regulated area, regardless of whether they directly handle methylene chloride.

3. Fenceline Screening Analysis

The 2020 TSCA Risk Evaluation for Methylene Chloride excluded the assessment of certain exposure pathways that were or could be regulated under another EPA-administered statute (see section 1.4.2 of the 2020 Risk Evaluation for Methylene Chloride (Refs. 1, 2)). This resulted in the surface water, drinking water, and ambient air pathways for methylene chloride exposure not being assessed for human health risk to the general population. In June 2021, EPA made a policy announcement on the path forward for TSCA chemical risk evaluations, indicating that EPA would, among other things, examine whether the exclusion of certain exposure pathways from the risk evaluations would lead to a failure to identify and protect fenceline communities (Refs. 10, 20).

In order to assess the potential for risk to the general population in proximity to a facility releasing methylene chloride, EPA developed the TSCA Screening Level Approach for Assessing Ambient Air and Water Exposures to Fenceline Communities Version 1.0, which was presented to the SACC in March 2022, with a report issued by the SACC on May 18, 2022 (Ref. 21). This analysis is discussed in Unit VI.A.

III. Regulatory Approach

A. Background

Under TSCA section 6(a), if the Administrator determines, in accordance with TSCA section 6(b)(4)(A), that the manufacture (including import), processing, distribution in commerce, use, or disposal of a chemical substance or mixture, or any combination of such activities, presents an unreasonable risk of injury to health or the environment, EPA must by rule apply one or more of the following requirements to the extent necessary so that the chemical substance or mixture no longer presents such risk.

- Prohibit or otherwise restrict the manufacturing (including import), processing, or distribution in commerce of the substance or mixture, or limit the amount of such substance or mixture which may be manufactured, processed, or distributed in commerce (section 6(a)(1)).
- Prohibit or otherwise restrict the manufacturing, processing, or distribution in commerce of the substance or mixture for a particular use or above a specific concentration for a particular use (section 6(a)(2)).
- Limit the amount of the substance or mixture which may be manufactured, processed, or distributed in commerce for a particular use or above a specific concentration for a particular use specified (section 6(a)(2)).
- Require clear and adequate minimum warning and instructions with respect to the substance or mixture's use, distribution in commerce, or disposal, or any combination of those activities, to be marked on or accompanying the substance or mixture (section 6(a)(3)).
- Require manufacturers and processors of the substance or mixture to make and retain certain records or conduct certain monitoring or testing (section 6(a)(4)).
- Prohibit or otherwise regulate any manner or method of commercial use of the substance or mixture (section 6(a)(5)).
- Prohibit or otherwise regulate any manner or method of disposal of the substance or mixture, or any article containing such substance or mixture, by its manufacturer or processor or by any person who uses or disposes of it for commercial purposes (section 6(a)(6)).
- Direct manufacturers or processors of the substance or mixture to give notice of the unreasonable risk determination to distributors, certain other persons, and the public, and to replace or repurchase the substance or mixture (section 6(a)(7)).

As described in Unit III.B., EPA assessed how the TSCA section 6(a) requirements could be applied to address the unreasonable risk found to be present in the 2020 Risk Evaluation for Methylene Chloride and the final revised unreasonable risk determination, so that methylene chloride no longer presents such unreasonable risk. EPA's proposed regulatory action and a primary alternative regulatory action are fully discussed in Unit IV. EPA is requesting public comment on the proposed regulatory action and primary alternative regulatory action.

Under the authority of TSCA section 6(g), EPA may consider granting a time-limited exemption for a specific condition of use for which EPA finds that: (1) The specific condition of use is a critical or essential use for which no technically and economically feasible safer alternative is available, taking into consideration hazard and exposure; (2) Compliance with the requirement would significantly disrupt the national economy, national security, or critical infrastructure; or (3) The specific condition of use, as compared to reasonably available alternatives, provides a substantial benefit to health, the environment, or public safety. Further, the Administrator may by rule, extend, modify, or eliminate an exemption if the Administrator determines, on the basis of reasonably available information and after adequate public justification, the exemption warrants extension or modification or is no longer necessary. Based on reasonably available information, EPA has considered the issue and is proposing that a TSCA section 6(g) exemption is warranted for certain

conditions of use, as detailed in Unit IV.A.5. EPA is requesting comment on the proposed rule's section 6(g) exemption provisions and rationale.

TSCA section 6(c)(2)(A) requires EPA, in proposing and promulgating section 6(a) rules, to consider and include a statement of effects addressing certain factors, including the costs and benefits and the cost effectiveness of the proposed regulatory action and of the one or more primary alternative regulatory actions considered by the Administrator. Also, under TSCA section 6(c)(2), EPA must consider the effects of the chemical substance or mixture on health or the environment and the magnitude of the exposure, which can include impacts to health or the environment in fenceline communities. TSCA section 6(c)(2) considerations are discussed in Unit VI.

TSCA section 6(c)(2)(C) requires that, in deciding whether to prohibit or restrict in a manner that substantially prevents a specific condition of use and in setting an appropriate transition period for such action, EPA consider, to the extent practicable, whether technically and economically feasible alternatives that benefit health or the environment will be reasonably available as a substitute when the proposed prohibition or restriction takes effect. Unit III.B.4. includes more information regarding EPA's consideration of alternatives, and Unit V. provides more information on EPA's considerations more broadly under TSCA section 6(c)(2).

As described in this Unit, EPA carried out required consultations as described later in this unit and also considered impacts on children's environmental health as part of its approach to developing this TSCA section 6 regulatory action.

1. Consultations

EPA conducted consultations and outreach as part of development of this proposed regulatory action. The Agency held a federalism consultation from October 22, 2020, until January 23, 2021, as part of this rulemaking process and pursuant to Executive Order 13132. This included a background presentation on September 9, 2020, and a consultation meeting on October 22, 2020. During the consultation, EPA met with State and local officials early in the process of developing the proposed action in order to receive meaningful and timely input into its development (Ref. 22). During the consultation, participants and EPA discussed preemption, EPA's authority under TSCA section 6 to regulate identified unreasonable risk, what activities would be potentially regulated in the proposed rule, and the relationship between TSCA and existing statutes—particularly the Clean Water Act (CWA) and Safe Drinking Water Act (SDWA) (Ref. 22).

Methylene chloride is not manufactured (including imported), processed, distributed in commerce, or regulated by Tribal governments. However, EPA consulted with Tribal officials during the development of this proposed action (Ref. 23). The Agency held a Tribal consultation from October 7, 2020, to January 8, 2021, with meetings on November 12 and 13, 2020. Tribal officials were given the opportunity to meaningfully interact with EPA risk managers concerning the current status of risk management. During the consultation, EPA discussed risk management under TSCA section 6(a), findings from the 2020 Risk Evaluation for Methylene Chloride, types of information that would be helpful to inform risk management, principles for transparency during the risk management process, and types of information EPA is seeking from Tribes (Ref. 23). EPA received no written comments as part of this consultation.

In addition to the formal consultations, EPA also conducted outreach to advocates for communities that might be subject to disproportionate exposure to methylene chloride, including underrepresented communities such as minority populations, low-income populations, and Indigenous peoples. EPA's Environmental Justice (EJ) consultation occurred from November 4, 2020, through January 18, 2021. On November 16 and 19, 2020, EPA held public meetings as part of this consultation. These meetings were held pursuant to and in compliance with Executive Orders 12898 and 14008. EPA received three written comments following the EJ meetings, in addition to oral comments provided during the consultations (Refs. 24, 25, 26). In general, commenters supported strong regulation of methylene chloride to protect lower-income communities and workers. Commenters supported strong outreach to affected communities, encouraged EPA to follow the hierarchy of controls in regulating methylene chloride, favored prohibitions, and noted the uncertainties associated with use of PPE (*e.g.,* in some cases, use of PPE did not provide adequate protection given the exposure scenario).

As required by section 609(b) of the Regulatory Flexibility Act (RFA), EPA convened a SBAR Panel to obtain advice and recommendations from Small Entity Representatives (SERs) that potentially would be subject to the rule's requirements. EPA met with SERs before and during Panel proceedings, on November 4, 2020, and January 28, 2021. Panel recommendations are in Unit X.C. and in the Initial Regulatory Flexibility Analysis (Ref. 27); the Panel report is in the docket (Ref. 6).

Units X.C., X.E., X.F., and X.J. provide more information regarding the consultations.

2. Other Stakeholder Consultations

In addition to the formal consultations described in Unit X., EPA attended a Small Business Administration (SBA) Office of Advocacy Environmental Roundtable on September 11, 2020 and held a public webinar on September 16, 2020. At both events EPA staff provided an overview of the TSCA risk management process and the findings in the 2020 Risk Evaluation for Methylene Chloride (Ref. 28). Attendees of these meetings were given an opportunity to voice their concerns regarding the risk evaluation and risk management.

Furthermore, EPA has engaged in discussions with representatives from different industries, non-governmental organizations, technical experts, and users of methylene chloride. A list of external meetings held during the development of this proposed rule is in the docket (Ref. 29); meeting materials and summaries are also in the docket. The purpose of these discussions was to hear from users, academics, manufacturers, and members of the public health community about practices related to commercial and consumer uses of methylene chloride; public health impacts of methylene chloride; the importance of methylene chloride in the various uses subject to this proposed rule; frequently used substitute chemicals or alternative methods; engineering control measures and PPE currently in use or feasibly adoptable; and other risk-reduction approaches that may have already been adopted or considered for industrial, commercial or consumer uses.

3. Children's Environmental Health

The Agency's 2021 Policy on Children's Health (Ref. 30) requires EPA to protect children from environmental exposures by consistently and explicitly considering early life exposures (from conception, infancy, and early childhood and through adolescence until 21 years of age) and lifelong health in all human health decisions through identifying and integrating children's health data and information when conducting risk assessments. TSCA section 6(b)(4)(A) also requires EPA to

conduct risk evaluations ''to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment . . . including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation by the Administrator, under the conditions of use.'' In addition, TSCA section 6(a) requires EPA to apply one or more risk management requirements so that methylene chloride no longer presents an unreasonable risk (which includes unreasonable risk to any relevant potentially exposed or susceptible subpopulations).

The 2020 Risk Evaluation for Methylene Chloride evaluated exposures of infants, toddlers, older children (11 to 15 years and 16 to 20 years), and males and females of reproductive age; while EPA identified exposures to these populations (as bystanders, consumers, or workers) as driving the unreasonable risk for methylene chloride, EPA did not find that the adverse health impacts for these groups was disproportionate in comparison to other populations. While there is some evidence of an association between methylene chloride and developmental neurological effects, the literature contains methodological limitations in human studies and concentration limitations in animal studies, and thus reproductive/development effects were not carried forward to dose-response (Ref. 1).

More specifically, the 2020 Risk Evaluation for Methylene Chloride released in June 2020 considered impacts on both children and adults from occupational and consumer use from inhalation and dermal exposures, as applicable. For occupational use, the risk evaluation considered males (>16 years of age) and females of reproductive age (>16 years of age to less than 50 years of age) for both dermal and inhalation exposures. For consumer use, EPA evaluated dermal exposures for children ages 11 to 15 and 16 to 20 years of age, and the evaluation of bystander exposure from inhalation exposures included infants, toddlers and older children. While risks to children are not disproportionate, effects observed in studies include central nervous system impairment from acute inhalation exposure and liver toxicity from chronic inhalation exposure. The risks described in this section would be addressed by the proposed regulatory action described in Unit IV.

B. Regulatory Assessment of Methylene Chloride

1. Description of Conditions of Use

This Unit describes the TSCA conditions of use that drive the unreasonable risk for methylene chloride. Condition of use descriptions were obtained from EPA sources such as CDR use codes, the 2020 Risk Evaluation for Methylene Chloride and related documents, as well as the Organisation for Economic Co-operation and Development harmonized use codes, and stakeholder engagements. EPA acknowledges that some of the terms here may be defined under other statutes; however, the descriptions in this unit are intended to provide clarity to the regulated entities who will implement the provisions of this rulemaking under TSCA section 6(a).

a. Manufacturing (Includes Import)

i. Domestic Manufacturing

This condition of use refers to manufacturing, or producing, a chemical substance within the United States (including manufacturing for export). Manufacture includes the extraction of a component chemical substance from a previously existing chemical substance or complex combination of chemical substances.

ii. Import

This condition of use refers to the act of causing a chemical substance or mixture to arrive within the customs territory of the United States.

b. Processing

i. Processing as a Reactant

This condition of use refers to processing methylene chloride in chemical reactions for the manufacturing of another chemical substance or product, *e.g.,* difluoromethane, also known as HFC–32, which is used in fluorocarbon blends for refrigerants, and bis-2,2-dinitropropyl-acetal/formal.

ii. Processing: Incorporation Into a Formulation, Mixture, or Reaction Product

This condition of use refers to when methylene chloride is added to a product (or product mixture) prior to further distribution of the product.

iii. Processing: Repackaging

This condition of use refers to the preparation of methylene chloride for distribution in commerce in a different form, state, or quantity. This includes transferring the chemical from a bulk container into smaller containers.

iv. Processing: Recycling

This condition of use refers to the process of treating generated waste streams(*i.e.,* which would otherwise be disposed of as waste) that are collected, either on-site or transported to a third-party site, for commercial purpose. Waste solvents can be restored to a condition that permits reuse via solvent reclamation/recycling. The recovery process may involve an initial vapor recovery or mechanical separation step followed by distillation, purification, and final packaging.

c. Industrial and Commercial Uses

i. Industrial and Commercial Use as Solvent for Batch Vapor Degreasing

This condition of use refers to the process of heating methylene chloride to its volatilization point and using its vapor to remove dirt, oils, greases, and other surface contaminants (such as drawing compounds, cutting fluids, coolants, solder flux, and lubricants) from metal parts, electronics, or other articles in batch open-top vapor degreasers or closed-loop vapor degreasing in industrial or commercial settings.

ii. Industrial and Commercial Use as Solvent for In-line Vapor Degreasing

This condition of use refers to the process of heating methylene chloride to its volatilization point and using its vapors to remove dirt, oils, greases, and other surface contaminants from textiles, glassware, metal surfaces, and other articles using conveyorized or continuous-web vapor degreasing machines in industrial or commercial settings.

iii. Industrial and Commercial Use as Solvent for Cold Cleaning

This condition of use refers to the industrial or commercial use of methylene chloride as a non-boiling solvent in cold-cleaning to dissolve oils, greases, and other surface contaminants from textiles, glassware, metal surfaces, and other articles.

iv. Industrial and Commercial Use as Solvent for Aerosol Spray Degreaser/Cleaner

This condition of use refers to industrial or commercial use of methylene chloride in aerosol degreasing as an aerosolized solvent spray, typically applied from a pressurized can, to remove residual contaminants from fabricated parts or machinery (including circuit boards and electronics).

v. Industrial and Commercial Use in Adhesives, Sealants, and Caulks

This condition of use refers to industrial or commercial use of methylene chloride in adhesives, sealants, and caulks to promote bonding between other substances, promote adhesion of surfaces, or prevent seepage of moisture or air.

vi. Industrial and Commercial Use in Paints and Coatings

This condition of use refers to industrial or commercial use of methylene chloride in paints or coatings applied to surfaces, usually to enhance properties such as water repellency, gloss, fade resistance, ease of application, or foam prevention, etc.

vii. Industrial and Commercial Use in Paint and Coating Removers

This condition of use refers to industrial or commercial use of methylene chloride or methylene chloride-containing products applied to surfaces to remove paint, coatings, and other finishes and to clean the underlying surface, including but not limited to furniture refinishing.

viii. Industrial and Commercial Use in Adhesive and Caulk Removers

This condition of use refers to industrial or commercial use of methylene chloride in products in industrial or commercial settings applied to surfaces to unbind substances or remove sealants and to clean the underlying surface by softening adhesives, caulks, and other glues so they can be removed.

ix. Industrial and Commercial Use in Metal Aerosol Degreasers

This condition of use refers to the industrial or commercial use of methylene chloride in aerosol degreasing as an aerosolized solvent spray, typically applied from a pressurized can, to remove residual contaminants from fabricated parts, machinery, or other metal substrate.

x. Industrial and Commercial Use in Metal Non-Aerosol Degreasers

This condition of use refers to the industrial or commercial use of methylene chloride in liquid degreasing to remove residual contaminants from fabricated parts, machinery, or other metal substrate.

xi. Industrial and Commercial Use in Finishing Products for Fabric, Textiles, and Leather

This condition of use refers to industrial or commercial use of methylene chloride in the finishing of fabrics at fabric or textile mills, including in products that impart color or other desirable properties to fabrics or textiles. The methylene chloride may be added during the manufacturing of the textile or during the finishing, such as pressing of the fabric.

xii. Industrial and Commercial Use in Automotive Care Products (Functional Fluids for Air Conditioners)

This condition of use refers to the industrial or commercial use of methylene chloride for one or more operational properties in a closed system in products intended for automotive care and includes automotive air conditioner refrigerant and as a refrigerant with stop leak sealant.

xiii. Industrial and Commercial Use in Automotive Care Products (Interior Car Care)

This condition of use refers to the industrial or commercial use of methylene chloride in cleaning agents used to remove stains from interior carpets and textiles in automotive vehicles.

xiv. Industrial and Commercial Use in Automotive Care Products (Degreasers)

This condition of use refers to the industrial or commercial use of methylene chloride in liquid or aerosol degreasing to remove residual contaminants from automotive substrates and articles.

xv. Industrial and Commercial Use in Apparel and Footwear Care Products

This condition of use refers to the industrial or commercial use of methylene chloride in apparel and footwear care products as post-market waxes, polishes, or other media and applied to footwear, textiles, or fabrics to impart color or other desirable properties.

xvi. Industrial and Commercial Use in Spot Removers for Apparel and Textiles

This condition of use refers to the industrial or commercial use of methylene chloride or methylene chloride-containing products applied from squeeze bottles, hand-held spray bottles, or spray guns, either before or after a cleaning cycle on apparel and textiles. After application, the methylene chloride or product is removed by manually scraping or flushing away the stain by using a brush, spatula, pressurized air, or steam.

xvii. Industrial and Commercial Use in Liquid Lubricants and Greases

This condition of use refers to the industrial or commercial use of methylene chloride in liquids that reduce friction, heat generation, and wear between surfaces.

xviii. Industrial and Commercial Use in Spray Lubricants and Greases

This condition of use refers to the industrial or commercial use of methylene chloride in sprays that reduce friction, heat generation, and wear between surfaces.

xix. Industrial and Commercial Use in Aerosol Degreasers and Cleaners

This condition of use refers to the industrial or commercial use of methylene chloride in aerosol degreasing as an aerosolized solvent spray, typically applied from a pressurized can, to remove residual contaminants from a fabricated part or other substrate.

xx. Industrial and Commercial Use in Non-Aerosol Degreasers and Cleaners

This condition of use refers to the industrial or commercial use of methylene chloride in liquid degreasing to remove residual contaminants (such as oils, greases, and similar materials) from a fabricated part or other substrate (such as textiles, glassware, products, and other articles).

xxi. Industrial and Commercial Use in Cold Pipe Insulations

This condition of use refers to the industrial or commercial use of methylene chloride when typically applied in aerosolized form in products used in building and construction materials to provide insulation.

xxii. Industrial and Commercial Use as a Solvent That Becomes Part of a Formulation or Mixture

This condition of use refers to industrial or commercial use of methylene chloride added to a product (or product mixture) in an industrial or commercial setting.

xxiii. Industrial and Commercial Use as a Processing Aid

This condition of use refers to the industrial or commercial use of methylene chloride to improve the processing characteristics or the operation of process equipment or to alter or buffer the pH of the substance or mixture, when added to a process or to a substance or mixture to be processed. Processing agents do not become a part of the reaction product and are not intended to affect the

function of a substance or article created.

xxiv. Industrial and Commercial Use as Propellant and Blowing Agent

This condition of use refers to the industrial or commercial use of methylene chloride in the production of polyurethane foam including as a blowing agent and as a solvent for cleaning equipment.

xxv. Industrial and Commercial Use as a Laboratory Chemical

This condition of use refers to the industrial or commercial use of methylene chloride in a laboratory process or in specialized laboratory equipment for instrument calibration/maintenance chemical analysis, chemical synthesis, extracting and purifying other chemicals, dissolving other substances, executing research, development, test and evaluation methods, and similar activities. In response to a request for clarification, EPA agrees that use of methylene chloride in a closed-loop chiller system used to perform FAA-required aviation fuel testing is considered industrial and commercial use as a laboratory chemical (Ref. 31). The analogous use of methylene chloride in a chiller system in the Department of Defense McKinley Climactic Laboratory would likewise be considered industrial and commercial use as a laboratory chemical.

xxvi. Industrial and Commercial Use for Electrical Equipment, Appliance, and Component Manufacturing

This condition of use refers to the industrial or commercial use of methylene chloride in electrical and electronic products; their maintenance; their manufacture, such as in the production of printed circuit boards; and at wholesalers and retail stores.

xxviii. Industrial and Commercial Use for Plastic and Rubber Products Manufacturing

This condition of use refers to the industrial or commercial use of methylene chloride in the manufacture and processing of plastic and rubber products, including in interfacial polymerization for polycarbonate plastic manufacturing.

xxix. Industrial and Commercial Use in Cellulose Triacetate Film Production

This condition of use refers to the industrial or commercial use of methylene chloride as a chemical processor for polycarbonate resins and cellulose triacetate (photographic film).

xxx. Industrial and Commercial Use as Anti-Spatter Welding Aerosol

This condition of use refers to the industrial or commercial use of methylene chloride in formulations to prevent spatter from adhering to metal surfaces during welding.

xxxi. Industrial and Commercial Use for Oil and Gas Drilling, Extraction, and Support Activities

This condition of use refers to the industrial or commercial use of methylene chloride in the extraction, development, and preparation of oil, liquid crude petroleum, and gas. Activities may include exploration for crude petroleum and natural gas, core sampling, drilling wells, operating separator, emulsion breakers, and distilling equipment.

xxxii. Industrial and Commercial Use for Toys, Playgrounds, and Sporting Equipment

This condition of use refers to the industrial or commercial use of methylene chloride in the manufacture of toys intended for children's use (and child-dedicated articles), including fabrics, textiles, and apparel (which may include stuffed toys, blankets, or comfort objects) as well as plastic articles (hard) (which may include dolls, toy cars, toy animals, or teething rings).

xxxiii. Industrial and Commercial Use in Lithographic Printing Plate Cleaner

This condition of use refers to the industrial or commercial use of methylene chloride in lithographic printing for the cleaning of plates and rollers.

xxxiv. Industrial and Commercial Use in Carbon Remover, Wood Floor Cleaner, and Brush Cleaner

This condition of use refers to the industrial or commercial use of methylene chloride in formulated products to remove carbon and other dirt and residues from a variety of surfaces including floors and brushes.

d. Consumer Uses

i. Consumer Use as a Solvent in Aerosol Degreasers/Cleaners

This condition of use refers to consumer use of products containing methylene chloride as a solvent for cleaning or degreasing in the form of an aerosol spray degreaser or cleaner. The products are used to dissolve oils, greases, and similar materials from textiles, glassware, metal surfaces, and other articles.

ii. Consumer Use in Adhesives and Sealants

This condition of use refers to consumer use of methylene chloride in single or two-component products used to fasten other materials together or prevent the passage of liquid or gas.

iii. Consumer Use in Brush Cleaners for Paints and Coatings

This condition of use refers to consumer use of products containing methylene chloride to clean brushes after using them to apply paints or coatings.

iv. Consumer Use in Adhesive and Caulk Removers

This condition of use refers to consumer use of products containing methylene chloride to remove, loosen, or deteriorate any adhesive or caulk from a substrate, such as floor adhesive removal.

v. Consumer Use in Metal Degreasers

This condition of use refers to consumer use of products containing methylene chloride for the degreasing of metals, such as coil cleaners and electronics cleaners.

vi. Consumer Use in Automotive Care Products (Functional Fluids for Air Conditioners)

This condition of use refers to consumer use of products containing methylene chloride for automotive care and includes automotive air conditioner refrigerant and leak sealant.

vii. Consumer Use in Automotive Care Products (Degreasers)

This condition of use refers to consumer use of products containing methylene chloride for automotive care and includes products for degreasing automotive parts, such as brakes, carburetors, engines, and gaskets.

viii. Consumer Use in Lubricants and Greases

This condition of use refers to consumer use of products containing methylene chloride to reduce friction, heat generation, and wear between solid surfaces, such as engines and brakes.

ix. Consumer Use in Cold Pipe Insulation

This condition of use refers to consumer use of products containing methylene chloride used in building and construction materials to provide insulation.

x. Consumer Use in Arts, Crafts, and Hobby Materials Glue

This condition of use refers to consumer use of arts, crafts, and hobby materials, such as glues, containing methylene chloride.

xi. Consumer Use in an Anti-Spatter Welding Aerosol

This condition of use refers to consumer use of products containing methylene chloride to prevent the spatter of the welding from sticking to welding material or a nearby surface (for example, workbenches).

xii. Consumer Use in Carbon Removers and Other Brush Cleaners

This condition of use refers to consumer use of products containing methylene chloride for cleaning applications to remove carbon, inks and paints, grease, or other foreign matter. The cleaning operations include carbon removers (for example, to clean appliances, pots, and pans) and other applications that usually involve the use of a brush (for example, in lithographic printing cleaners, in taxidermy, and in wood and floor cleaners).

e. Disposal

This condition of use refers to the process of disposing generated waste streams of methylene chloride that are collected either on-site or transported to a third-party site for disposal.

f. Terminology in This Proposed Rule

For the purposes of this proposed rulemaking, ''occupational conditions of use'' refers to the TSCA conditions of use described in Units III.B.1.a, b, c, and e. Although EPA identified both industrial and commercial uses in the 2020 Risk Evaluation for Methylene Chloride for purposes of distinguishing scenarios, the Agency clarified then and clarifies now that EPA interprets the authority Congress gave to the Agency to ''regulat[e] any manner or method of commercial use'' under TSCA section 6(a)(5) to reach both industrial and commercial uses.

Additionally, in the 2020 Risk Evaluation for Methylene Chloride, EPA identified and assessed all known, intended, and reasonably foreseen industrial, commercial, and consumer uses of methylene chloride (other than the use of methylene chloride in consumer paint and coating removers, which was subject to separate action under TSCA section 6 (84 FR 11420, March 27, 2019)). EPA determined that all industrial, commercial, and consumer use of methylene chloride evaluated in the 2020 Risk Evaluation for Methylene Chloride drives the unreasonable risk of injury to health. As such, for purposes of this risk management rulemaking, ''consumer use'' refers to all known, intended, or reasonably foreseen methylene chloride consumer uses. Likewise, for the purpose of this risk management rulemaking, ''industrial and commercial use'' refers to all known, intended, or reasonably foreseen methylene chloride industrial and commercial use.

EPA further notes that this proposed rule does not apply to any substance excluded from the definition of ''chemical substance'' under TSCA section 3(2)(B)(ii) through (vi). Those exclusions include, but are not limited to, any pesticide (as defined by the Federal Insecticide, Fungicide, and Rodenticide Act) when manufactured, processed, or distributed in commerce for use as a pesticide; and any food, food additive, drug, cosmetic, or device, as defined in section 201 of the Federal Food, Drug, and Cosmetic Act, when manufactured, processed, or distributed in commerce for use as a food, food additive, drug, cosmetic or device.

EPA is not proposing to incorporate the descriptions in Units III.B.1.a through III.B.1.e. into the regulatory text as definitions. EPA requests comment on whether a definition should be promulgated for each condition of use of methylene chloride and, if so, whether the descriptions in this Unit are consistent with the conditions of use evaluated in the 2020 Risk Evaluation for Methylene Chloride and whether they provide a sufficient level of detail such that they would improve the clarity and readability of the regulation if promulgated.

2. Description of Unreasonable Risk Under the Conditions of Use

EPA has determined that methylene chloride presents an unreasonable risk of injury to human health under the conditions of use based on acute and chronic non-cancer risks and chronic cancer risks. As described in the TSCA section 6(b) 2020 Risk Evaluation for Methylene Chloride, EPA identified non-cancer adverse effects from both acute and chronic inhalation and dermal exposures to methylene chloride, and cancer from chronic inhalation and dermal exposures to methylene chloride (Ref. 1). EPA identified neurotoxicity effects (central nervous system) as the most sensitive endpoint of the non-cancer adverse effects from acute inhalation and dermal exposures, and liver effects as the most sensitive endpoint of the non-cancer adverse effects from chronic inhalation and dermal exposures for all conditions of use. However, EPA also identified additional risks associated with other adverse effects (*e.g.,* other nervous system effects, immune system effects, reproductive and developmental effects, and irritation/burns) resulting from acute and chronic exposures. By targeting the sensitive chronic liver endpoint for risk management, EPA's action will also eliminate the unreasonable risks from acute, chronic non-cancer and cancer endpoints from methylene chloride. EPA also recognizes the severity of the risks from acute inhalation exposures to methylene chloride, because relatively small increases in acute exposure can lead to extreme adverse effects associated with central nervous system suppression, including coma and death. Occupational fatalities linked to methylene chloride have been recorded as recently as June 2020 (Ref. 32). Eighty-five occupational fatalities between 1980 and 2018 have been documented from methylene chloride in paint and coating removal or adhesive and sealant use, and when methylene chloride is being used as a cleaning or degreasing solvent; there has been no linear trend indicating a decrease in fatalities during that time period (Ref. 32). In some instances, while workers were wearing respirators, the respirators were inadequate to protect against methylene chloride inhalation exposure (Ref. 32). Unit VI.A. summarizes the health effects and the magnitude of the exposures in more detail.

To make the unreasonable risk determination for methylene chloride, EPA evaluated exposures to workers, occupational non-users, consumer users, and bystanders using reasonably available monitoring and modeling data for inhalation and dermal exposures. In addition, EPA conducted a screening level analysis to assess risks from the air and water pathways to fenceline communities. A discussion of EPA's analysis and the expected effects of this rulemaking on fenceline communities is in Unit VI.A.

For the 2020 Risk Evaluation for Methylene Chloride, EPA considered potentially exposed or susceptible subpopulations identified as relevant to the risk evaluation by the Agency. There are several groups of individuals with greater exposure to methylene chloride relative to the general population, including: (1) Workers and occupational non-users, and (2) Consumer users and bystanders to consumer use of products containing methylene chloride (Ref. 1). EPA also identified several human subpopulations which may have greater susceptibility than the general population to the hazards of methylene chloride, including individuals with

certain genetic polymorphisms (variant forms of a specific DNA sequence) that may make them more susceptible to getting cancer from methylene chloride, and individuals with cardiac disease and other comorbidities, who may be at increased risk for angina from acute exposures (Ref. 1). All potentially exposed or susceptible subpopulations are included in the quantitative and qualitative analyses described in the 2020 Risk Evaluation for Methylene Chloride and were considered in the determination of unreasonable risk for methylene chloride. As discussed in Units II.D. and VI.A., the 2020 Risk Evaluation for Methylene Chloride excluded the air and water exposure pathways from the published risk evaluations and may have caused some risks to be unaccounted for in the risk evaluation. EPA considers receptors exposed to methylene chloride through those pathways to constitute a subset of the general population and categorizes them as fenceline communities; they may also be considered potentially exposed or susceptible subpopulations. See Unit VI.A. for further discussion on assessing and protecting risk to fenceline communities.

3. Description of TSCA Section 6 Requirements for Risk Management

EPA examined the TSCA section 6(a) requirements (listed in Unit III.A.) to identify which ones have the potential to eliminate the unreasonable risk from methylene chloride. This Unit summarizes the TSCA section 6 considerations for issuing regulations under TSCA section 6(a). Unit V. outlines how EPA applied these considerations specifically to managing the unreasonable risk from methylene chloride.

As required, EPA developed a proposed regulatory action and one primary alternative regulatory action, which are described in Units IV.A. and IV.B., respectively. To identify and select a regulatory action, EPA considered the two routes of exposure driving the unreasonable risk, inhalation and dermal, and the exposed populations. For occupational conditions of use (see Unit III.B.1.f.), EPA considered how it could directly regulate manufacturing (including import), processing, distribution in commerce, industrial and commercial use, or disposal to address the unreasonable risk. EPA does not have direct authority to regulate consumer use. Therefore, EPA considered how it could exercise its authority under TSCA to regulate the manufacturing (including import), processing, and/or distribution in commerce of methylene chloride at different levels in the supply chain to eliminate exposures or restrict the availability of methylene chloride and methylene chloride-containing products for consumer use in order to address the unreasonable risk.

As required by TSCA section 6(c)(2), EPA considered several factors, in addition to identified unreasonable risk, when selecting among possible TSCA section 6(a) requirements. To the extent practicable, EPA factored into its decisions: (i) the effects of methylene chloride on health and the environment, (ii) the magnitude of exposure to methylene chloride of human beings and the environment, (iii) the benefits of methylene chloride for various uses, and (iv) the reasonably ascertainable economic consequences of the rule. In evaluating the reasonably ascertainable economic consequences of the rule, EPA considered (1) The likely effect of the rule on the national economy, small business, technological innovation, the environment, and public health; (2) The costs and benefits of the proposed regulatory action and one or more primary alternative regulatory actions considered; and (3) The cost effectiveness of the proposed regulatory action and of the one or more primary alternative regulatory actions considered. TSCA section 6(c)(2)(A) considerations for methylene chloride are discussed in full in Unit VI., including the statement of effects of the proposed rule with respect to these considerations.

EPA also considered regulatory authorities under statutes administered by other agencies such as the OSH Act, the Consumer Product Safety Act (CPSA), and the Federal Hazardous Substances Act (FHSA), as well as other EPA-administered statutes, to examine (1) Whether there are opportunities for all or part of this risk management action to be addressed under other statutes, such that a referral may be warranted under TSCA section 9(a) or 9(b); or (2) Whether TSCA section 6(a) regulation could include alignment of requirements and definitions in and under existing statutes and regulations to minimize confusion to the regulated entities and the general public.

In addition, EPA followed other TSCA requirements such as considering the availability of alternatives when contemplating prohibition or a substantial restriction (TSCA section 6(c)(2)(C), as outlined in Unit III.B.4.), and setting proposed compliance dates in accordance with the requirements in TSCA section 6(d)(1)(B) (described in the proposed and alternative regulatory action in Unit IV.).

To the extent information was reasonably available, EPA considered pollution prevention strategies and the hierarchy of controls adopted by OSHA and NIOSH, as discussed in Unit II.C.4., when selecting regulatory actions, with the goal of identifying risk management control methods that are permanent, feasible, and effective. EPA also considered how to address the unreasonable risk while providing flexibility to the regulated community where appropriate, and took into account the information presented in the 2020 Risk Evaluation for Methylene Chloride, as well as input from stakeholders (as described in Unit III.A.) and anticipated compliance strategies from regulated entities.

Taken together, these considerations led EPA to the proposed regulatory action and primary alternative regulatory action described in Unit IV. Additional details related to how the requirements in this Unit were incorporated into development of those actions are in Unit V.

As demonstrated by the number of distinct programs addressed in this rulemaking and the structure of this proposed rule in addressing them independently, EPA generally intends the rule's provisions to be severable from each other. EPA expects to provide additional detail on severability in the final rule once the Agency has considered public comments and finalized the regulatory language.

IV. Proposed Regulatory and Alternative Regulatory Actions

This Unit describes the proposed regulatory action by EPA so that methylene chloride will no longer present an unreasonable risk of injury to health. In addition, as indicated by TSCA section 6(c)(2)(A), EPA must consider the costs and benefits and the cost-effectiveness of the proposed regulatory action and one or more primary alternative regulatory actions. In the case of methylene chloride, the proposed regulatory action is described in Unit IV.A. and the alternative regulatory action considered is described in Unit IV.B. An overview of the proposed regulatory action and primary alternative regulatory action for each condition of use is in Unit IV.C.

A. Proposed Regulatory Action

EPA is proposing under TSCA section 6(a) to: Require a WCPP, including inhalation exposure concentration limits and related monitoring, for ten conditions of use, outlined in Unit IV.A.1.; Prohibit most industrial and commercial use of methylene chloride, outlined in Unit IV.A.2.; Prohibit the

manufacture, processing, and distribution in commerce of methylene chloride for all consumer use (other than the use of methylene chloride in consumer paint and coating removers, which was subject to separate action under TSCA section 6 (84 FR 11420, March 27, 2019), outlined in Unit IV.A.3.; Establish recordkeeping and downstream notification requirements, outlined in Unit IV.A.4.; and Provide a 10-year, time-limited exemption under TSCA section 6(g) for paint and coating removal by civilian aviation from a prohibition that would significantly disrupt critical infrastructure, as outlined in Unit IV.A.5., with conditions for this exemption to include compliance with the WCPP described in Unit IV.A.1.

1. Workplace Chemical Protection Program (WCPP)

a. Overview

As described in Unit I., under TSCA section 6(a), 15 U.S.C. 2605(a), EPA is required to issue a regulation applying one or more of the TSCA section 6(a) requirements to the extent necessary so that the unreasonable risk of injury to human health or the environment from a chemical substance is no longer presented. The TSCA section 6(a) requirements provide EPA the authority to limit or prohibit a number of activities, including, but not limited to, restricting or regulating the manufacture, processing, distribution in commerce, commercial use, or disposal of the chemical substance. Given this statutory authority, EPA may find it appropriate in certain circumstances to propose a WCPP for certain occupational (*i.e.,* industrial and commercial) conditions of use. A WCPP encompasses inhalation exposure thresholds, includes monitoring and recordkeeping requirements to verify that those thresholds are not exceeded, and may include other components, such as dermal protection, to ensure that the chemical substance no longer presents unreasonable risk. Under a WCPP, owners or operators have some flexibility, within the parameters outlined in this Unit, regarding how they prevent exceedances of the identified EPA exposure limit thresholds. In the case of methylene chloride, meeting the EPA exposure limit thresholds for certain occupational conditions of use would address the unreasonable risk to potentially exposed persons from inhalation exposure.

EPA uses the term ''potentially exposed person'' in this Unit and in the regulatory text to include workers, occupational non-users, employees, independent contractors, employers, and all other persons in the work area where methylene chloride is present and who may be exposed to methylene chloride under the conditions of use for which a WCPP would apply. EPA's intention is to require a comprehensive WCPP that would address the unreasonable risk from methylene chloride to workers directly handling the chemical or in the area where the chemical is being used. Similarly, the 2020 Risk Evaluation for Methylene Chloride did not distinguish between employers, contractors, or other legal entities or businesses that manufacture, process, distribute in commerce, use, or dispose of methylene chloride. For this reason, EPA uses the term ''owner or operator'' to describe the entity responsible for implementing the WCPP in any workplace where an applicable condition of use described in Units III.B.1.a. through III.B.1.e. and subject to the WCPP is occurring. The term includes any person who owns, leases, operates, controls, or supervises such a workplace.

EPA is proposing a WCPP for the following conditions of use: domestic manufacturing; import; processing as a reactant; processing for incorporation into a formulation, mixture, or reaction product; processing in repackaging; processing in recycling; industrial and commercial use as a laboratory chemical; industrial or commercial use for paint and coating removal from safety-critical, corrosion-sensitive components of aircraft and spacecraft by Federal agencies and their contractors; industrial or commercial use as a bonding agent for acrylic and polycarbonate in mission-critical military and space vehicle applications, including in the production of specialty batteries for such applications by Federal agencies and their contractors; and disposal (EPA's rationale is provided in Unit V.). EPA is additionally proposing to require that uses receiving an exemption under TSCA section 6(g), as outlined in Unit IV.A.5., comply with the WCPP. EPA is proposing that these requirements take effect 180 days after publication of the final rule, at which point entities would be required to conduct initial monitoring (as described in Unit IV.A.1.c.). Additionally, EPA would require the implementation of any needed exposure controls based on initial monitoring and development of an exposure control plan within 1 year of publication of the final rule (Unit IV.A.1.d.). EPA believes these timeframes are achievable because they are consistent with the timeframes in OSHA's 1997 standard for methylene chloride (62 FR 1494, January 10, 1997). EPA is requesting comment on these proposed implementation timeframes for the WCPP requirements.

When considering and developing a WCPP that includes an ECEL, EPA coordinates and consults with other Federal agencies to achieve the maximum enforcement of TSCA while avoiding imposing duplicative requirements, consistent with TSCA section 9(d). For methylene chloride, EPA's streamlined approach for implementing the ECEL would seek to align with, to the extent possible, certain elements of the existing OSHA standard for regulating methylene chloride under 29 CFR 1910.1052. The OSHA PEL, action level, STEL, and ancillary requirements have established a strong precedent for exposure limit threshold requirements within the regulated community. However, the existing PEL and STEL do not eliminate the unreasonable risk identified by EPA under TSCA, and EPA is therefore proposing to apply new, lower, exposure thresholds, derived from the TSCA 2020 Risk Evaluation for Methylene Chloride, while aligning with existing requirements wherever possible (Refs. 1, 11). For methylene chloride, this approach would eliminate the unreasonable risk driven by the conditions of use subject to the WCPP, enable continued industry use where appropriate, and provide the familiarity of a pre-existing framework for the regulated community.

EPA's proposed requirements include specific exposure limits and ancillary requirements necessary for the ECEL's successful implementation as part of a WCPP. Taken together, these WCPP requirements would apply to the extent necessary so that the unreasonable risk driven by the conditions of use listed earlier in this Unit would no longer be presented. EPA's proposal would align with existing requirements from the OSHA methylene chloride standard at 29 CFR 1910.1052 to the extent possible (also summarized in Unit V.A.). As discussed in Unit II.B.3., because the unreasonable risk driven by these occupational conditions of use cannot be addressed entirely through the continued application of the OSHA standard and associated requirements, EPA is proposing additional requirements for lower exposure limits, user notification, recordkeeping, periodic monitoring, and respirator selection criteria as part of the WCPP. EPA acknowledges that the values of the ECEL, the ECEL action level, and the EPA STEL, outlined in Unit IV.A.1.b., may mean that some entities that are

currently in compliance with the OSHA standard will have to increase the frequency and scope of their compliance activities in order to achieve compliance with the requirements being proposed in this action, such as through the implementation of engineering controls to reduce exposures to the extent feasible, periodic exposure monitoring frequency (Unit IV.A.1.c.iii.), establishment of regulated areas (Unit IV.A.1.d.), use of respiratory protection (Unit IV.A.1.e.ii.), and notification of monitoring results (Unit IV.A.1.f.ii.).

This Unit includes a summary of the WCPP, including a description of proposed exposure limits including an ECEL, ECEL action level, and EPA STEL; proposed implementation requirements including monitoring requirements; a description of potential exposure controls, including engineering controls, administrative controls, and PPE as it relates to dermal protections and respirator selection; and additional requirements proposed for recordkeeping, workplace participation, and notification in accordance with the hierarchy of controls. This Unit also describes compliance timeframes for these proposed requirements.

b. Existing Chemical Exposure Limit (ECEL), EPA Action Level (AL), and Short-Term Exposure Limit (STEL)

To reduce exposures in the workplace and address the inhalation exposures to methylene chloride for occupational conditions of use that drive to the unreasonable risk of injury to human health, EPA is proposing an ECEL under TSCA section 6(a) of 2 ppm (8 mg/m^3) as an 8-hour TWA based on the chronic non-cancer human equivalent concentration for liver toxicity. EPA has determined, as a matter of risk management policy, that ensuring exposures remain at or below the ECEL will eliminate the unreasonable risk of injury to health resulting from acute and chronic inhalation exposures for certain occupational conditions of use. EPA's description for how the requirements related to an ECEL would address the unreasonable risk driven by those occupational conditions of use and the rationale for the regulatory approach of a WCPP are in Unit V.A.

If ambient exposures are kept at or below the 8-hour TWA ECEL of 2 ppm and at or below the 15-minute TWA EPA STEL of 16 ppm, a potentially exposed person would be protected against the effects described in Unit III.B.3., including effects resulting from acute exposure (central nervous system depression), chronic non-cancer effects (liver toxicity), and cancer. As an example, the incremental individual cancer risk at the 8-hour ECEL is 5.1×10^{-6}, which is lower than the occupational benchmark for cancer risk of 1×10^{-4} cited in the 2020 Risk Evaluation for Methylene Chloride and the NIOSH Chemical Carcinogen Policy (Ref. 33).

EPA is also proposing to establish an ECEL action level at half of the 8-hour ECEL, or 1 ppm (4 mg/m^3) as an 8-hour time-weighted average. The ECEL action level would be a definitive cut-off point below which certain compliance activities, such as periodic monitoring, would not be required as described further in this Unit. As explained by OSHA, an action level provides employers and employees with confidence that exposure reduction actions could be taken before inhalation exposure to methylene chloride exceeds the inhalation exposure limit (Ref. 34). EPA agrees with this reasoning and, like OSHA, expects the inclusion of an ECEL action level will stimulate innovation within industry to reduce exposures to methylene chloride to levels below the action level (Ref. 34). Therefore, EPA has identified a need for an action level for methylene chloride and is proposing a level that would be half the 8-hour ECEL, which is in alignment with the precedented approach established by OSHA (Ref. 34).

In addition to the 8-hour TWA ECEL, EPA is proposing a STEL of 16 ppm (57 mg/m^3) as a 15-minute TWA. This short-term exposure limit is based on the non-cancer endpoint of central nervous system depression resulting from acute exposures. EPA has also determined, as a matter of risk management policy, that ensuring exposures remain at or below the EPA STEL will eliminate the unreasonable risk of injury to health driven by acute inhalation exposures in an occupational setting. EPA is proposing the EPA STEL for the protection of potentially exposed persons to methylene chloride for shorter durations and at higher concentrations that fall outside the parameters of the ECEL 8-hour time-weighted average. EPA is also proposing the EPA STEL in consideration of the severe and potentially irreversible hazards of such short-term exposures, which, as described in Unit II.B.2., can range from blurred vision to death.

In summary, EPA is proposing that owners or operators must ensure the airborne concentration of methylene chloride within the personal breathing zone of potentially exposed persons remains at or below 2 ppm as an 8-hour TWA ECEL, with an action level identified as 1 ppm as an 8-hour TWA. EPA is also proposing that owners or operators must ensure the airborne concentration of methylene chloride within the personal breathing zone of potentially exposed persons remains at or below a 15-minute TWA, or EPA STEL, of 16 ppm. EPA is proposing the ECEL and EPA STEL for certain occupational conditions of use to ensure that no person is exposed to inhalation of methylene chloride in excess of these concentrations resulting from those conditions of use, thus eliminating the unreasonable risk of injury to human health driven by those conditions of use. For the identified conditions of use for which the concentration thresholds are being proposed, EPA expects that the regulated community has the ability to detect the values for the ECEL, ECEL action level, and EPA STEL because these limits are above the detection limits of methylene chloride monitoring devices that are widely available in commerce, currently in use, and approved by OSHA and NIOSH, which generally range from 0.2 to 0.4 ppm (Ref. 11). EPA's methodology and inputs for the ECEL and EPA STEL values is directly derived from the peer reviewed analysis in the 2020 Risk Evaluation for Methylene Chloride, which was also subject to public comment (Ref 13). As with all aspects of this rulemaking, the public is welcome to comment on the methodology for the ECEL and EPA STEL values.

As discussed further in Unit V.A.1., for many of the conditions of use for which EPA is proposing a WCPP, data was submitted during the risk evaluation and SBAR process that indicates some facilities may already be in compliance with the proposed methylene chloride ECEL. As noted previously in this Unit, EPA expects that, if inhalation exposures for affected occupational conditions of use are kept at or below the ECEL and EPA STEL, potentially exposed persons reasonably likely to be exposed in the workplace would be protected from the unreasonable risk associated with covered occupational conditions of use. EPA is also proposing to require owners or operators to comply with additional requirements that would be needed to ensure successful implementation of the ECEL and EPA STEL.

c. Monitoring Requirements

i. In General

Monitoring requirements are a key component of implementing EPA's proposed requirements for a WCPP. Initial monitoring for methylene chloride is critical for establishing a baseline of exposure for potentially exposed persons; similarly, periodic exposure monitoring assures continued

compliance over time so that potentially exposed persons are not exposed to levels that would result in an unreasonable risk of injury to health. Exposure monitoring could be suspended if certain conditions described in this Unit are met. Also, in some cases, a change in workplace conditions with the potential to impact exposure levels would warrant additional monitoring, which is also described.

EPA proposes to require that owners or operators determine each potentially exposed person's exposure by taking a personal breathing zone air sample of each potentially exposed person's exposure, or by taking personal breathing zone air samples that are representative of each potentially exposed person's exposure. Owners or operators would be permitted to consider personal breathing zone air samples to be representative of each potentially exposed person's exposure when one or more samples are taken for at least one potentially exposed person in each job classification in a work area during every work shift, and the person sampled is expected to have the highest methylene chloride exposure; or when one or more samples are taken which indicate the highest likely 15-minute exposures during such operations for at least one potentially exposed person in each job classification in the work area during every work shift, and the person sampled is expected to have the highest methylene chloride exposure. Personal breathing zone air samples taken during one work shift may be used to represent potentially exposed person exposures on other work shifts where the owner or operator can document that the tasks performed and conditions in the workplace are similar across shifts. These requirements align with the approach taken for characterization of employee exposure in the 1997 OSHA standard for methylene chloride (see 29 CFR 1910.1052(d)(1)(i) and (ii)). EPA also proposes to require that the owner or operator ensure, for initial and periodic monitoring, that their methods and metering results used in performance of the exposure monitoring are accurate to a confidence level of 95% and are within (plus or minus) 25% of airborne concentrations of methylene chloride above the 8-hour TWA ECEL or the 15-minute TWA EPA STEL, or within (plus or minus) 35% for airborne concentrations of methylene chloride at or above the ECEL action level but at or below the 8-hour TWA ECEL. These requirements, including the 35%, would align with the approach taken in the 1997 OSHA standard for methylene chloride (see 29 CFR 1910.1052(d)(1)(iii)). EPA acknowledges that new monitoring methods or technologies may have been developed since 1997 that would allow for greater accuracy, and thus a smaller range for monitoring results, and EPA requests comment on the exposure monitoring accuracy requirements outlined in this Unit. Therefore, while the EPA requirements utilize the values of the ECEL, ECEL action level, and EPA STEL, the approach should be familiar to the regulated community. To ensure compliance for monitoring activities, EPA proposes recordkeeping requirements outlined in this Unit. EPA acknowledges that the 25% buffer for the 8-hour and 15-minute TWA potentially could allow some exposures above the exposure limits proposed here. EPA requests comment on these buffers' effects and any alternatives to account for measurement variance or uncertainty.

ii. Initial Exposure Monitoring

Under the proposed regulation, each owner or operator of a facility engaged in one or more of the conditions of use listed earlier in Unit IV.A.1.a. would be required to perform initial exposure monitoring 180 days after publication of the final rule to determine the extent of exposure of potentially exposed persons to methylene chloride. Initial monitoring would notify owners and operators of the magnitude of possible exposures to potentially exposed persons with respect to their work conditions and environments. Based on the magnitude of possible exposures in the initial exposure monitoring, the owner or operator may need to increase or decrease the frequency of future periodic monitoring, adopt new exposure controls (such as engineering controls, administrative controls, and/or a respiratory protection program), or to continue or discontinue certain compliance activities such as periodic monitoring. In addition, the monitoring sample would be required to be taken when and where the operating conditions are best representative of each potentially exposed person's full-shift exposures. If the owner or operator chooses to use a sample that is representative of potentially exposed persons' full shift exposures (rather than monitor every individual), such sampling should include persons closest to the source of methylene chloride, so that the monitoring results would be representative of the most highly exposed persons in the workplace. Additionally, analogous to the OSHA standard, EPA expects that owners and operators would conduct initial exposure monitoring representative of all tasks a potentially exposed person would be expected to do. EPA understands that certain tasks may occur less frequently or may reflect upset conditions (for example, due to malfunction). EPA is soliciting comments regarding how owners and operators could conduct initial exposure monitoring to ensure that it is representative of all tasks likely to be conducted by potentially exposed persons.

EPA also recognizes that the values for the ECEL action level and EPA STEL may mean that some owners or operators currently in compliance with the OSHA standard would have to re-establish a monitoring baseline. Aligning with the existing OSHA standard (29 CFR 1910.1052(d)(2)) to the extent possible, EPA is proposing that an owner or operator may temporarily forgo initial exposure monitoring if:

(i) An owner or operator could provide EPA with objective data generated during the last 5 years demonstrating that methylene chloride cannot be released in the workplace in airborne concentrations at or above the ECEL action level (1-ppm 8-hour TWA) and above the EPA STEL (16 ppm 15-minute TWA) and that the data represent the highest methylene chloride exposures likely to occur under reasonably foreseeable conditions of manufacturing, processing, use, or disposal, as applicable, including handling of methylene chloride during those activities. The oldest objective data used to demonstrate that exposures are below the ECEL action level and EPA STEL will indicate the beginning of the 5-year cycles of recurring initial exposure monitoring as described in this Unit;

(ii) Where potentially exposed persons are exposed to methylene chloride for fewer than 30 days per year and the owner or operator has measurements by direct-metering devices that give immediate results and provide sufficient information regarding potentially exposed persons' exposures to determine and implement the control measures that are necessary to reduce exposures to below the ECEL action level and EPA STEL.

As described in more detail later in this Unit, unlike the OSHA standards in 29 CFR 1910.1052(d)(2) to (d)(3), the owner or operator must conduct an initial monitoring at least once every 5 years since its last monitoring. This new initial monitoring would have to be representative of all the potentially exposed persons in the workplace and the tasks that they are expected to do. Additionally, if a facility were to

commence one or more conditions of use listed in Unit IV.A.1.a. after the effective date of the rule, the owner or operator would be required to perform initial exposure monitoring within 180 days and would be required to, at a minimum, conduct initial exposure monitoring every 5 years thereafter if methylene chloride is present in the facility. EPA is soliciting comments regarding the proposed requirement for recurring 5-year initial exposure monitoring.

iii. Periodic Exposure Monitoring

EPA's proposal is aligned with elements of the existing OSHA standard (29 CFR 1910.1052(d)(3)) to the extent possible. Based on the results from the initial exposure monitoring, EPA is proposing the following periodic monitoring for owners or operators. These proposed requirements are also outlined in Table 1.

- If all samples taken during the initial exposure monitoring reveal: a concentration below the ECEL action level (1 ppm 8-hour TWA) and at or below the EPA STEL (16 ppm 15-minute TWA), the ECEL and EPA STEL periodic monitoring would not be required, except when additional exposure monitoring (Unit IV.A.1.c.v.) measurements require it.
- If the initial exposure monitoring concentration is: below the ECEL action level (1 ppm 8-hour TWA) and above the EPA STEL (16 ppm 15-minute TWA), the ECEL periodic monitoring would not be required except when additional monitoring (Unit IV.A.1.c.v.) measurements require it, but EPA STEL periodic monitoring would be required every 3 months.
- If the initial exposure monitoring concentration is: at or above the ECEL action level (1 ppm 8-hour TWA) and at or below the ECEL (2 ppm 8-hour TWA), and at or below the EPA STEL (16 ppm 15-minute TWA), the ECEL would be required to be monitored every 6 months.
- If the initial exposure monitoring concentration is: at or above the ECEL action level (1 ppm 8-hour TWA) and at or below the ECEL (2 ppm 8-hour TWA), and above the EPA STEL, the ECEL would be required to be monitored every 6 months and EPA STEL would be required to be monitored every 3 months.
- If the initial exposure monitoring concentration is: above the ECEL (2 ppm 8-hour TWA) and below, at, or above the EPA STEL (16 ppm 15-minute TWA), the ECEL and EPA STEL would be required to be monitored every 3 months.
- The owner or operator would be permitted to alter the periodic exposure monitoring frequency from every 3 months to every 6 months if two consecutive monitoring events taken at least 7 days apart indicate that the potential exposure has decreased to or below the ECEL, but at or above the ECEL action level.
- The owner or operator would be permitted to transition from the periodic exposure monitoring frequency of every 6 months to an initial exposure monitoring frequency of once every 5 years if two consecutive monitoring events taken at least 7 days apart indicate that the potential exposure has decreased below the ECEL action level and at or below the EPA STEL. The second consecutive monitoring event would delineate the new date from which the next 5-year initial exposure monitoring must occur.

In addition to the periodic monitoring standards described earlier, EPA is proposing two additional provisions:

- Based on its monitoring results, if the owner or operator would be required to monitor either the ECEL or EPA STEL in a 3-month interval but does not engage in any of the conditions of use listed in Unit IV.A.1.a. for which the WCPP is proposed over the entirety of those 3 months, the owner or operator would be permitted to forgo the upcoming periodic monitoring event. However, documentation of cessation of use of methylene chloride would be required, and initial monitoring would be required when the owner or operator resumes or starts any of the conditions of use listed in Unit IV.A.1.a. for which the WCPP is proposed.
- Based on its monitoring results, if the owner or operator would be required to monitor the ECEL in a 6-month interval but does not engage in any of the conditions of use listed in Unit IV.A.1.a. for which the WCPP is proposed over the entirety of those 6 months, the owner or operator would be permitted to forgo the upcoming periodic monitoring event. However, documentation of cessation of use of methylene chloride would be required, and initial monitoring would be required when the owner or operator resumes or starts any of the conditions of use listed in Unit IV.A.1.a. for which the WCPP is proposed.
- Initial monitoring would be required to occur at least once every 5 years if methylene chloride is present. EPA requests comment on the timeframes for periodic monitoring outlined in this Unit, particularly whether more frequent monitoring may be possible or recommended.

TABLE 1—PERIODIC MONITORING REQUIREMENTS BASED ON INITIAL EXPOSURE MONITORING RESULTS

Air concentration condition	Periodic monitoring requirement
If the initial exposure monitoring concentration is below the ECEL action level and at or below the EPA STEL.	ECEL and EPA STEL periodic monitoring not required.
If the initial exposure monitoring concentration is below the ECEL action level and above the EPA STEL.	ECEL monitoring not required and EPA STEL monitoring required every 3 months.
If the initial exposure monitoring concentration is at or above the ECEL action level and at or below the ECEL; and at or below the EPA STEL.	ECEL monitoring every 6 months.
If the initial exposure monitoring concentration is at or above the ECEL action level and at or below the ECEL; and above the EPA STEL.	ECEL monitoring every 6 months and EPA STEL monitoring every 3 months.
If the initial exposure monitoring concentration is above the ECEL and below, at, or above the EPA STEL.	ECEL monitoring every 3 months and EPA STEL monitoring every 3 months.
Two consecutive monitoring events have taken place 7 days apart that indicate that potential exposure has decreased from above the ECEL to at or below the ECEL, but at or above the ECEL action level.	Reduce periodic monitoring frequency from every 3 months to every 6 months.
Two consecutive monitoring events have taken place 7 days apart that indicate that potential exposure has decreased to below the ECEL action level and at or below the EPA STEL.	Transition from periodic monitoring frequency of every 6 months to initial monitoring once every 5 years. The second consecutive monitoring event will delineate the new date from which the next 5-year initial exposure monitoring must occur.

TABLE 1—PERIODIC MONITORING REQUIREMENTS BASED ON INITIAL EXPOSURE MONITORING RESULTS—Continued

Air concentration condition	Periodic monitoring requirement
If the owner or operator engages in any of the conditions of use for which WCPP is proposed and is required to monitor either the ECEL or EPA STEL in a 3-month interval, but does not engage in any of those conditions of use for the entirety of the 3-month interval.	The owner or operator may forgo the upcoming periodic monitoring event. However, documentation of cessation of manufacture, processing, use, or disposal of methylene chloride must be maintained, and initial monitoring would be required when the owner or operator resumes or starts any of the conditions of use for which the WCPP is proposed.
Owner or operator engages in any of the conditions of use for which WCPP is proposed and is required to monitor the ECEL in a 6-month interval, but does not engage in any of those conditions of use for the entirety of the 6-month interval.	The owner or operator may forgo the upcoming periodic monitoring event. However, documentation of cessation of manufacture, processing, use, or disposal of methylene chloride must be maintained, and initial monitoring would be required when the owner or operator resumes or starts any of the conditions of use for which the WCPP is proposed.

Note: Additional scenarios in which monitoring may be required are discussed in Unit IV.A.1.c.v.

iv. Minimum Frequency of Exposure Monitoring

EPA is proposing to require that an initial monitoring event be conducted at a minimum frequency of every 5 years by owners or operators using methylene chloride for any condition of use subject to the WCPP. This in contrast to OSHA's standards in 1910.1052(d)(2) to (d)(3) whereby employers would otherwise be permitted to discontinue monitoring indefinitely based on monitoring results. Moreover, EPA is proposing that monitoring requirements could only be made less frequent based on the results of the initial exposure monitoring or the periodic exposure monitoring outlined under Unit IV.A.1.c.iii.

OSHA's standards in 1910.1052(d)(2)(i) through (iii) allow for a discontinuation of initial monitoring which subsequently precludes the need for periodic monitoring unless additional monitoring is required under certain conditions. Given the steep dose response for methylene chloride that may lead up to and include fatalities as a result of inhalation exposure, EPA is instead proposing to require that a minimum initial monitoring frequency be established at 5-year intervals. EPA is requesting public comments on the proposed conditions for periodic monitoring for methylene chloride as part of implementation of the WCPP that differ from OSHA's existing monitoring requirements under 29 CFR 1910.1052.

v. Additional Exposure Monitoring

In addition to initial and periodic monitoring, there are some additional circumstances that would require a new initial exposure monitoring. EPA is proposing that the owner or operator complying with the WCPP would carry out this additional exposure monitoring (analogous to those requirements outlined in 29 CFR 1910.1052(d)(4)) after any change that may reasonably be expected to introduce additional sources of exposure, or result in a change in exposure levels, to methylene chloride. Examples include changes in the production, production volume, use rate, process, control equipment, or work practices that may reasonably be anticipated to cause additional sources of exposure or result in increased exposure levels to methylene chloride; and start-up, shutdown, or malfunction of the facility or facility equipment that may reasonably be anticipated to cause additional sources of exposure or result in increased exposure levels to methylene chloride. This additional exposure monitoring event may result in increased frequency of periodic monitoring. The required additional exposure monitoring should not delay implementation of any necessary cleanup or other remedial action to reduce the exposures to potentially exposed persons.

d. Exposure Control Plan (ECP)

EPA recommends and encourages the use of pollution prevention as a means of controlling exposures whenever practicable. Pollution prevention, also known as source reduction, is any practice that reduces, eliminates, or prevents pollution at its source (*e.g.,* elimination and substitution, as described in the hierarchy of controls). While the WCPP is intended to be non-prescriptive to allow more flexibility to regulated entities than requiring specific prescriptive controls, EPA is proposing to require the use of elimination and substitution, followed by the use of engineering controls, administrative controls, and work practices prior to requiring the use of respirators as a means of controlling inhalation exposures below EPA's ECEL or STEL, in accordance with the hierarchy of controls. If an owner or operator chooses to replace methylene chloride with a substitute, EPA recommends that they carefully review the available hazard and exposure information on the potential substitutes to avoid a substitute chemical that might later be found to present unreasonable risks or be subject to regulation (sometimes referred to as a ''regrettable substitution''). EPA expects that, for conditions of use for which EPA is proposing a WCPP, compliance at most workplaces would be part of an established industrial hygiene program that aligns with the hierarchy of controls. Workplaces that cannot, in accordance with that hierarchy, eliminate the source of methylene chloride emissions or replace methylene chloride with a substitute would be required to use feasible engineering controls, and subsequently feasible administrative controls, to implement process changes to reduce exposures following the hierarchy of controls (Ref. 9). EPA also expects those owners or operators already implementing the OSHA PEL of 25 ppm as an 8-hour TWA would revise their monitoring program to follow EPA's ECEL requirements with EPA's lower ECEL of 2 ppm as an 8-hour TWA and EPA's STEL of 16 ppm as a 15-minute TWA.

Analogous to the OSHA Standard (29 CFR 1910.1052(e)), EPA is proposing to require that the owner or operator demarcate any area where airborne concentrations of methylene chloride are reasonably expected to exceed the ECEL or the EPA STEL. This regulated area would be demarcated using administrative controls, *e.g.,* highly visible signifiers, in multiple languages as appropriate, placed in conspicuous areas, and documented through training and recordkeeping. The owner or operator would be required to restrict access to the regulated area from any potentially exposed person that lacks proper training or is otherwise unauthorized to enter.

EPA proposes to require regulated entities use the hierarchy of controls to the extent feasible and supplement

further protections using PPE, including respirators for potentially exposed persons at risk of inhalation exposure above the ECEL or EPA STEL. If efforts of elimination, substitution, engineering controls, and administrative controls are not sufficient to reduce exposures to or below the ECEL or EPA STEL for all potentially exposed persons in the workplace, EPA proposes to require the owner or operator to use feasible controls (including elimination, substitution, engineering controls, or administrative controls and work practices) to reduce methylene chloride concentrations in the workplace to the lowest levels achievable and, analogous to the requirements under 29 CFR 1910.1052(e)(3), supplement these controls with respiratory protection and PPE as needed to achieve the ECEL before potentially exposed persons enter a regulated area. In such cases, EPA would require that the owner or operator provide potentially exposed persons reasonably likely to be exposed to methylene chloride by inhalation to concentrations above the ECEL or EPA STEL with respirators affording sufficient protection against inhalation risk and appropriate training on the proper use of such respirators, to ensure that their exposures do not exceed the ECEL or EPA STEL, as described in this Unit.

EPA also proposes to require that the owner or operator document their efforts to use elimination, substitution, engineering controls, and administrative controls to reduce exposure to or below the ECEL or EPA STEL in an exposure control plan. In addition, analogous to the requirements under 29 CFR 1910.1052(f)(2), an owner or operator would be prohibited from rotating work schedules to comply with the ECEL 8-hour TWA.

EPA proposes to require that the owner or operator include and document in the exposure control plan or through any existing documentation of the facility's safety and health program developed as part of meeting OSHA requirements or other safety and health standards the following:

(i) Identification of available exposure controls and rationale for using or not using available exposure controls in the following sequence (*i.e.,* elimination and substitution, then engineering controls and administrative controls) to reduce exposures in the workplace to either at or below the ECEL or to the lowest level achievable, and the exposure controls selected based on feasibility, effectiveness, and other relevant considerations;

(ii) If exposure controls were not selected, document the efforts identifying why these are not feasible, not effective, or otherwise not implemented;

(iii) Actions taken to implement exposure controls selected, including proper installation, maintenance, training, or other steps taken;

(iv) Regular inspections, evaluations, and updating of the exposure controls to ensure effectiveness and confirmation that all persons are using them accordingly;

(v) Occurrence and duration of any start-up, shutdown, or malfunction of exposure controls or of facility equipment that causes air concentrations above the ECEL or EPA STEL and subsequent corrective actions taken during start-up, shutdown, or malfunctions to mitigate exposures to methylene chloride; and

(vi) Objective data generated during the previous 5 years, when used to forgo the initial exposure monitoring, must include: the use of methylene chloride being evaluated, the source of objective data, measurement methods, measurement results, and measurement analysis of the use of methylene chloride, and any other relevant data to the operations, processes, or person's exposure.

e. Personal Protective Equipment (PPE)

Where elimination, substitution, engineering, and administrative controls are not feasible or sufficiently protective to reduce the air concentration to or below the ECEL, or if inhalation exposure above the ECEL is still reasonably likely, EPA proposes to set minimum respiratory PPE requirements based on an owner or operator's measured air concentration for one or more potentially exposed persons and the level of PPE needed to reduce exposure to or below the ECEL. In those circumstances, EPA is proposing to require that the owner or operator also comply with OSHA's General Requirements for PPE standard at 29 CFR 1910.132 for application of a PPE program. EPA is also proposing that the owner or operator comply with 29 CFR 1910.134 for proper use, maintenance, fit-testing, and training of respirators. EPA recognizes that there may be limitations in using certain types of PPE or respirator protection for various work scenarios such as cost, time burdens, ergonomic and dexterity considerations, climate, size, and capability.

i. Required Dermal Protection

EPA is proposing to require provision and use of chemically resistant gloves in combination with specific activity training (*e.g.,* glove selection (type, material), expected duration of glove effectiveness, actions to take when glove integrity is compromised, storage requirements, procedure for glove removal and disposal, chemical hazards) for tasks where dermal exposure can be expected to occur. Additionally, EPA is proposing to require owners and operators to continue to comply with relevant sections of the methylene chloride OSHA standard to minimize and protect potentially exposed persons from dermal exposure, including 29 CFR 1910.1052(h) and (i). Additional information related to choosing appropriate gloves can be found in the NIOSH Hazard Alert (Ref. 35) and in appendix F of the 2020 Risk Evaluation for Methylene Chloride (Ref. 1). EPA requests comment on the degree to which additional guidance related to use of gloves might be necessary. Additionally, EPA requests comment on whether EPA should specifically incorporate dermal protection into the exposure control plan and require consideration of the hierarchy of controls for dermal exposures.

ii. Required Respiratory Protection

EPA is proposing the following requirements for respiratory protection, based on the exposure monitoring concentrations measured as an 8-hour TWA that exceeds the ECEL (2 ppm) or 15-minute TWA that exceeds the EPA STEL (16ppm); see also the following table (Table 2). These requirements would apply after all other feasible controls are exhausted or proven ineffective to control inhalation exposure (including elimination, substitution, engineering controls, and administrative controls in accordance with the hierarchy of controls). EPA is proposing to establish minimum respiratory protection requirements, such that any respirator affording the same or a higher degree of protection than the following proposed requirements may be used. While this Unit includes respirator selection requirements for respirators of Assigned Protection Factor (APF) of 1,000 or greater, EPA does not anticipate that respirators beyond APF 25 will be widely or regularly used to address unreasonable risk, particularly when other controls are put in place. EPA anticipates that owners or operators would attempt to minimize respirator costs by reducing inhalation exposures levels so that, if a respirator is needed, a supplied-air respirator could be used in lieu of a self-contained breathing apparatus. Under this proposed regulatory option, as with existing OSHA regulations, air-purifying respirators (in contrast to air-supplied

respirators) would not be permitted as a means of mitigating methylene chloride exposure, as they do not provide adequate respiratory protection against this chemical (Ref. 36). Additionally, EPA acknowledges in Unit V.A.1. that there may be respirator limitations dependent upon the nature of the activity in which methylene chloride is used (*e.g.,* a decreased range of motion or access to a small space could hinder PPE use).

- If the measured exposure concentration is at or below the ECEL (2 ppm 8-hour TWA) and EPA STEL (16 ppm 15-minute TWA): no respiratory protection would be required.
- If the measured exposure concentration is above 2 ppm and less than or equal to 50 ppm (25 times the ECEL): the respirator protection required would be any NIOSH-certified supplied-air respirator (SAR) or airline respirator in a continuous-flow mode equipped with a loose-fitting facepiece or helmet/hood (APF 25).
- If the measured exposure concentration is above 50 ppm and less than or equal to 100 ppm (50 times the ECEL): the respirator protection required would be: (i) Any NIOSH-certified Supplied-Air Respirator (SAR) or airline respirator in a demand mode equipped with a full facepiece (APF 50); or (ii) Any NIOSH-certified Self-Contained Breathing Apparatus (SCBA) in demand-mode equipped with a full facepiece or helmet/hood (APF 50).
- If the measured exposure concentration is unknown or at any value above 100 ppm and up to 2,000 ppm (1,000 times the ECEL): the respirator protection required would be: (i) Any NIOSH-certified Supplied-Air Respirator (SAR) or Airline Respirator in a continuous-flow mode equipped with a full facepiece or certified helmet/hood (APF 1,000); or (ii) Any NIOSH-certified Supplied-Air Respirator (SAR) or Airline Respirator in pressure-demand or other positive-pressure mode equipped with a full facepiece (APF 1,000); or (iii) Any NIOSH-certified Self-Contained Breathing Apparatus (SCBA) in a pressure-demand or other positive-pressure mode equipped with a full facepiece or certified helmet/hood (APF 1,000+).

TABLE 2—RESPIRATORY PROTECTION CONDITIONS AND REQUIREMENTS

Concentration condition	Minimum required respirator protection
At or below the ECEL and EPA STEL	No respirator required.
Above ECEL (2 ppm) and less than or equal to 50 ppm (25 times the ECEL).	Any NIOSH-certified supplied-air respirator (SAR) or airline respirator in a continuous-flow mode equipped with a loose-fitting facepiece or helmet/hood (APF 25).
Above 50 ppm and less than or equal to 100 ppm (50 times the ECEL).	Either (i) any NIOSH-certified Supplied-Air Respirator (SAR) or airline respirator in a demand mode equipped with a full facepiece (APF 50); or (ii) any NIOSH-certified Self-Contained Breathing Apparatus (SCBA) in demand-mode equipped with a full facepiece or helmet/hood (APF 50).
Unknown concentration or at any value above 100 ppm and up to 2,000 ppm (1,000 times the ECEL).	One of (i) any NIOSH-certified Supplied-Air Respirator (SAR) or Airline Respirator in a continuous-flow mode equipped with a full facepiece or certified helmet/hood (APF 1,000); or (ii) any NIOSH-certified Supplied-Air Respirator (SAR) or Airline Respirator in pressure-demand or other positive-pressure mode equipped with a full facepiece (APF 1,000); or (iii) any NIOSH-certified Self-Contained Breathing Apparatus (SCBA) in a pressure-demand or other positive-pressure mode equipped with a full facepiece or certified helmet/hood (APF 10,000).

f. Additional Proposed Requirements

i. Workplace Participation

EPA encourages owners and operators to consult with potentially exposed persons on the development and implementation of exposure control plans and PPE/respirator programs. EPA is proposing to require owners and operators to provide potentially exposed persons regular access to the exposure control plans, exposure monitoring records, PPE program implementation, and respirator program implementation (such as fit-testing and other requirements) described in 29 CFR 1910.134(l). To ensure compliance in workplace participation, EPA is proposing that the owner or operator document the notice to and ability of any potentially exposed person that may reasonably be affected by methylene chloride inhalation exposure to readily access the exposure control plans, facility exposure monitoring records, PPE program implementation, or any other information relevant to methylene chloride inhalation exposure in the workplace.

ii. Notification of Monitoring Results

EPA proposes that when a potentially exposed person's exposure to methylene chloride exceeds the ECEL action level within a regulated area, the owner or operator would be required to inform each potentially exposed person of the quantity, location, manner of use, release, and storage of methylene chloride and the specific operations in the workplace that could result in exposure to methylene chloride, particularly noting where exposures may be above the ECEL or EPA STEL, analogous to those requirements outlined in 29 CFR 1910.1052(l). EPA proposes that the owner or operator must, within 15 working days after receipt of the results of any exposure monitoring, notify each potentially exposed person whose exposure is represented by that monitoring in writing, either individually to each potentially exposed person or by posting the information in an appropriate and accessible location, such as public spaces or common areas, for potentially exposed persons outside of the regulated area (as described in Unit IV.A.1.d.). The notice would be required to identify the ECEL, ECEL action level, and EPA STEL and what they mean in plain language, the exposure monitoring results, and any corresponding respiratory protection required. The notice would also be required to include a description of the actions taken by the owner or operator to reduce inhalation exposures to or below the ECEL, or refer to a document available to the potentially exposed persons which states the actions to be taken to reduce exposures, and to be posted in multiple languages if necessary (*e.g.,* notice must be in a language that the potentially exposed person understands, including a non-English language version representing the language of the largest group of workers who cannot readily comprehend or read English). While 15 working days is consistent with requirements under the OSHA methylene chloride standard, EPA notes that it may be preferable to require more expedient notification of monitoring results, and that precedent exists in some circumstances for faster

notification timeframes (*e.g.,* OSHA requirements for the construction sector require a 5-day timeframe). EPA therefore requests comment on the 15-day timeframe for notification of potentially exposed persons of monitoring results and the possibility for a shorter timeframe, such as 5 days.

iii. Recordkeeping

For each monitoring event of methylene chloride, OSHA requires under 29 CFR 1910.1052(m) that the employer record information including, but not limited to, dates; operations involving exposure; sampling and analytical methods; the number of samples; durations, and results of each sample taken; the type of respirator and PPE worn (if any); the exposed employees' names, work shifts, and job classifications; and exposure of all the employees represented by monitoring, indicating which potentially exposed persons were actually monitored. EPA is requiring that this information is kept by the owner or operator of record for potentially exposed persons. In addition to the requirements outlined in 29 CFR 1910.1052(m)(2), EPA is proposing to require documentation of the following whenever monitoring for the WCPP is required under TSCA section 6(a):

(i) All measurements that may be necessary to determine the conditions (*e.g.,* work site temperatures, humidity, ventilation rates, monitoring equipment type and calibration dates) that may affect the monitoring results;

(ii) All other potentially exposed persons whose exposure monitoring was not measured but whose exposure is intended to be represented by the area or representative sampling monitoring;

(iii) Use of established analytical methods such as those outlined in appendix A of the ECEL memo (Ref. 11) with a limit of detection below the ECEL action level and accuracy of monitoring within 25% for the ECEL and 35% for the EPA STEL, as discussed in Unit IV.A.1.c.ii., so that the owner or operator may identify when the implementation of additional exposure controls is necessary, determine the monitoring frequency according to the requirements described in this Unit, and properly identify and provide persons exposed to methylene chloride with the required respiratory equipment and PPE proposed in this Unit;

(iv) Compliance with the Good Laboratory Practice Standards at 40 CFR part 792;

(v) Information regarding air monitoring equipment, including: type, maintenance, calibrations, performance tests, limits of detection, and any malfunctions.

For owners and operators to demonstrate compliance with the WCPP provisions, EPA is proposing that owners and operators must retain compliance records for 5 years, unless a longer retention time is required under 29 CFR 1910.1020, or other applicable regulations. EPA is requiring the owner or operator to retain records of:

- Exposure control plan;
- Regulated areas and authorized personnel;
- Facility exposure monitoring records;
- Notifications of exposure monitoring results;
- PPE and respiratory protection used and program implementation; and
- Information and training required under 29 CFR 1910.1052 section (l) and appendix A, provided by the owner or operator to each potentially exposed person prior to or at the time of initial assignment to a job involving potential exposure to methylene chloride.

All records required to be maintained by this Unit could be kept in the most administratively convenient form (electronic or paper). The owner or operator would be required to document training or re-training (analogous to 29 CFR 1910.1052(l)(5)) of any potentially exposed person as necessary to ensure that, in the event of monitoring results that indicate exposure or possible exposures above the ECEL action level or the EPA STEL, the potentially exposed person has demonstrated understanding of how to safely use and handle methylene chloride and how to appropriately use required PPE. EPA expects that the content of such training will not exceed what is already required by 29 CFR 1910.1052 section (l) and appendix A. In addition, the owner or operator would be required to update the training and requisite documentation when there is reasonable expectation that exposure may exceed the ECEL action level due to change in tasks or procedures.

g. Compliance Timeframes

With regard to the compliance timeframe for those occupational conditions of use which are subject to the WCPP, EPA is proposing to require that owners and operators establish initial exposure monitoring according to the process outlined in this Unit by [DATE 180 DAYS AFTER DATE OF PUBLICATION OF FINAL RULE IN THE **FEDERAL REGISTER**]. EPA is proposing to require each owner or operator ensure that the airborne concentration of methylene chloride does not exceed the ECEL or EPA STEL for all potentially exposed persons by [DATE 270 DAYS AFTER DATE OF PUBLICATION OF FINAL RULE IN THE **FEDERAL REGISTER**], and if applicable, each owner or operator must provide respiratory protection sufficient to reduce inhalation exposures to below the ECEL or EPA STEL to all potentially exposed persons in the regulated area within 3 months after receipt of the results of any exposure monitoring or within 9 months after the date of publication of the final rule in the **Federal Register** (for any new facilities, or a facility commencing one or more conditions of use listed in Unit IV.A.1.a. after the effective date of the final rule, the timeframe for the requirement for initial exposure monitoring is described earlier in Unit IV.A.1.c.ii.; following that, the requirements and timeframes in this Unit would apply). EPA is also proposing to require owners and operators demarcate a regulated area within 3 months after receipt of any exposure monitoring that indicates exposures exceeding the ECEL or EPA STEL. Owners and operators should proceed accordingly to implement an exposure control plan by [DATE 360 DAYS AFTER DATE OF PUBLICATION OF FINAL RULE IN THE **FEDERAL REGISTER**]. EPA requests comment relative to the ability of owners or operators to conduct initial monitoring by [DATE 180 DAYS AFTER DATE OF PUBLICATION OF FINAL RULE IN THE **FEDERAL REGISTER**], and anticipated timelines for any procedural adjustments needed to comply with the requirements outlined in this Unit. EPA may finalize shorter or longer compliance timeframes based on public comment.

2. Prohibition of Certain Industrial and Commercial Uses

Except for those uses which will continue under the WCPP, EPA is proposing to prohibit industrial and commercial use of methylene chloride, including use of methylene chloride in: solvent for batch vapor degreasing; solvent for in-line vapor degreasing; solvent for cold cleaning; solvent for aerosol spray degreaser/cleaner; adhesives, sealants, and caulks; paints and coatings; paint and coating removers (including furniture refinishers); adhesive and caulk removers; metal aerosol degreasers; metal non-aerosol degreasers; finishing products for fabric, textiles and leather; automotive care products (functional fluids for air conditioners); automotive care products (interior car care); automotive care products (degreasers); apparel and footwear care products; spot removers for apparel and textiles; liquid lubricants and greases; spray lubricants and greases; aerosol

degreasers and cleaners; non-aerosol degreasers and cleaners; cold pipe insulations; solvent that becomes part of a formulation or mixture; processing aid; propellant and blowing agent; electrical equipment, appliance, and component manufacturing; plastic and rubber products manufacturing; cellulose triacetate film production; anti-spatter welding aerosol; oil and gas drilling, extraction, and support activities; toys, playground and sporting equipment; carbon remover, wood floor cleaner, and brush cleaner; and lithographic printing plate cleaner. This does not include manufacturing and processing of methylene chloride for commercial use or industrial and commercial use of methylene chloride as a laboratory chemical, for which EPA is proposing to require compliance with a WCPP for the reasons described in Unit III.B.3. This rationale is discussed further in Unit V.A.1.

As Discussed in Unit III.B.1.f., the restrictions in this proposed rule do not apply to any substance that is excluded from the definition of ''chemical substance'' under TSCA section 3(2)(B)(ii) through (vi). However, EPA requests comment on the impacts, if any, the proposed prohibition described in this Unit, or other aspects of this proposal, may have on the production and availability of any food, food additive, drug, cosmetic, device, or other substance excluded from the definition of ''chemical substance'' under TSCA section 3(2)(B)(ii) through (vi).

As discussed in Unit III.B.3., based on consideration of alternatives, the broad range of work environments and activities, and the severity of the hazards of methylene chloride, EPA determined that prohibition is the best way to address the unreasonable risk from methylene chloride driven by the conditions of use identified in this Unit. EPA requests comment regarding the number of entities that could potentially close as well as associated costs with a prohibition of methylene chloride for certain industrial and commercial conditions of use identified in this Unit. EPA would also like comment on whether it should consider a *de minimis* level of methylene chloride in formulations for certain continuing industrial and commercial uses to account for impurities (*e.g.,* 0.1% or 0.5%) when finalizing the prohibitions described in this Unit, and, if so, what level should be considered *de minimis.*

EPA is proposing that the prohibition for uses described in this section would become effective following prohibitions relevant to these uses in stages of the supply chain before the industrial and commercial use (*e.g.,* manufacturing and processing). This proposal includes restrictions in a staggered schedule for each stage of the supply chain and would come into effect in 90 days for manufacturers, 180 days for processors, 270 days for distributors to retailers, 360 days for all other distributors and retailers, and 450 days for industrial and commercial uses after the publication date of the final rule. When proposing these compliance dates, EPA considered sustained awareness of risks, including acute fatalities, resulting from methylene chloride exposure as well as precedent established by the OSHA standards (62 FR 1494, January 10, 1997). EPA has no information indicating that the proposed compliance dates are not practicable for the activities that would be prohibited, or that additional time is needed for products affected by the proposed restrictions to clear the channels of trade. However, EPA requests comment on whether additional time is needed, for example, for products affected by proposed restrictions to clear the channels of trade. EPA may finalize shorter or longer compliance timeframes based on public comment.

Additionally, EPA recognizes that there may be instances where an ongoing use of methylene chloride that has implications for national security or critical infrastructure as it relates to other Federal agencies (*e.g.,* DOD, NASA) is identified after the methylene chloride rule is finalized, but the final rule prohibits that use. For instances like that, EPA requests comments on an appropriate, predictable process that could expedite reconsideration for uses that Federal agencies or their contractors become aware of after the final rule is issued using the tools available under TSCA, aligning with the requirements of TSCA section 6(g). One example of an approach could be the establishment by rulemaking of a Federal agency category of use that would require implementation of the WCPP and periodic reporting to EPA on details of the use as well as progress in discontinuing the use or finding a suitable alternative. To utilize the category of use a Federal agency would petition EPA, supported by documentation describing the specific use (including documentation of the specific need, service life of any relevant equipment, and specific identification of any applicable regulatory requirements or certifications, as well as the location and quantity of the chemical being used); the implications of cessation of this use for national security or critical infrastructure (including how the specific use would prevent injuries/fatalities or otherwise provide life-supporting functions); exposure control plan; and, for Federal agency uses where similar adoption by the commercial sector may be likely, concrete steps taken to identify, test, and qualify substitutes for the uses (including details on the substitutes tested and the specific certifications that would require updating; and estimates of the time required to identify, test, and qualify substitutes with supporting documentation). EPA requests comment on whether these are the appropriate types of information for use in evaluating this type of category of use, and whether there are other considerations that should apply. EPA would make a decision on the petition within 30 days and publish the decision in the **Federal Register** shortly after. Additionally, during the year following the petition, EPA would take public comment on the approved petition and no later than 180 days after submitting the petition to EPA, the requesting agency would submit monitoring data indicating compliance with the WCPP at each relevant location as well as documentation of efforts to identify or qualify substitutes. In the absence of that confirmatory data, the utilization of the generic Federal agency category of use would expire within one year of the date of receipt by EPA of the petition. EPA could undertake a TSCA section 6(g) rulemaking for those instances where the Federal agency could not demonstrate compliance with the WCPP. This is just one example of a potential process. EPA requests comments on a process that could expedite reconsideration for uses that Federal agencies or their contractors become aware of after the final rule is issued.

3. Prohibition of Manufacturing, Processing, and Distribution of Methylene Chloride for Consumer Use

In the 2020 Risk Evaluation for Methylene Chloride, EPA evaluated consumer use of methylene chloride: as a solvent in aerosol spray degreasers/cleaners; in adhesives and sealants in single component glues and adhesives and sealants in caulks; in paints and coatings in brush cleaners and in adhesive/caulk removers; in metal products in aerosol and non-aerosol degreasers and cleaners; in automotive care products in functional fluids for air conditioners and in degreasers; in lubricants and greases in liquid and spray lubricants and greasers and in aerosol and non-aerosol degreasers and cleaners; in building and construction

materials in cold pipe insulation; in arts, crafts, and hobby materials in crafting glue and cement/concrete; and in other uses such as anti-spatter welding aerosol and in carbon remover and brush cleaner. All consumer uses evaluated in the 2020 Risk Evaluation for Methylene Chloride drive unreasonable risk of injury to health. As such, for purposes of this risk management rulemaking, ''consumer use'' refers to all known, intended, or reasonably foreseen methylene chloride consumer uses. EPA is proposing to prohibit the manufacturing, processing, and distribution in commerce of methylene chloride for all consumer use. (The proposed prohibitions would not extend to the use of methylene chloride in consumer paint and coating removers since that use was not evaluated in the 2020 Risk Evaluation for Methylene Chloride and manufacturing, processing, and distribution for that use are already prohibited. (84 FR 11420 (March 27, 2019)).

As discussed in Unit III.B.3., based on consideration of the severity of the hazards of methylene chloride in conjunction with the limited options available to adequately address the identified unreasonable risk to consumers and bystanders under TSCA section 6(a), EPA is proposing to address the unreasonable risk from consumer use by prohibiting the manufacturing (including import), processing, and distribution in commerce of methylene chloride for consumer use in order to remove methylene chloride and products containing methylene chloride from the market, thereby effectively eliminating instances of consumer use.

Additionally, EPA is proposing to prohibit retailers from distributing in commerce methylene chloride and all methylene chloride-containing products, in order to prevent products intended for industrial and commercial use under the WCPP outlined in Unit IV.A.1. from being purchased by consumers. A retailer is any person or business entity that distributes or makes available products to consumers, including through e-commerce internet sales or distribution. If a person or business entity distributes or makes available any product to at least one consumer, then it is considered a retailer (40 CFR 751.103). For a distributor not to be considered a retailer, the distributor must distribute or make available products solely to commercial or industrial end-users or businesses. Prohibiting manufacturers (including importers), processors, and distributors from distributing methylene chloride, or any products containing methylene chloride, to retailers would prevent retailers from making these products available to consumers, which would help address that part of the unreasonable risk driven by consumer use of methylene chloride (Ref. 37). EPA promulgated a similar prohibition for retailers in the 2019 final rule addressing unreasonable risk from consumer use of methylene chloride in Paint and Coating Removal (84 FR 11420, March 27, 2019), and has not received negative feedback from retailers regarding sales losses. EPA has continued to receive feedback from stakeholders, including small businesses, on particular strategies they suggest could be used to ensure that distribution only occurs to commercial entities, such as requiring a business number (Ref. 6). To that end, EPA would like comment on whether distributors that are not retailers should be required to use tax IDs or other verification methods prior to selling methylene chloride or products containing methylene chloride to ensure consumers are not purchasing methylene chloride or industrial or commercial products containing methylene chloride.

Additionally, during litigation on the 2019 final rule petitioners argued that EPA's definition of ''retailer'' was so broad as to cover all commercial entities, creating supply chain issues for commercial users seeking to attain and use the chemical for commercial activities (*Lab. Council for Latin Am. Advancement* v. *United States Env't Prot. Agency,* 12 F.4th 234 (2d Cir. 2021)). EPA has not found this to be the case; small businesses that are non-retail distributors exist and even participated as small entity representatives consulted as part of the SBAR process for this rulemaking. Nonetheless, EPA is soliciting comment on whether similar supply chain issues for uses that are permitted under the WCPP are anticipated.

EPA is proposing that the prohibitions of manufacturing, processing, and distribution in commerce of methylene chloride for consumer use described in this section would occur in 90 days for manufacturers, 180 days for processers, 270 days for distributing to retailers, and 360 days for all other distributors and retailers after the publication date of the final rule in the **Federal Register**. EPA considered irreversible health effects and risks, such as acute fatalities, associated with methylene chloride when proposing compliance dates. EPA has no information indicating these compliance dates are not practicable for the activities that would be prohibited, or that additional time is needed for products affected by proposed restrictions to clear the channels of trade. However, EPA requests comment on whether additional time is needed, for example, for products affected by proposed restrictions to clear the channels of trade. EPA may finalize shorter or longer compliance timeframes based on public comment. EPA would also like comment on whether it should consider a *de minimis* level of methylene chloride in formulations for certain continuing industrial and commercial uses to account for impurities (*e.g.,* 0.1% or 0.5%) when finalizing these prohibitions, and, if so, what level should be considered *de minimis.*

4. Other Requirements

a. Recordkeeping

For conditions of use that are not otherwise prohibited under this proposed regulation, EPA is also proposing that manufacturers, processors, and distributors maintain ordinary business records, such as invoices and bills-of-lading, that demonstrate compliance with restrictions and other provisions of this proposed regulation; and that they maintain such records for a period of 5 years from the date the record is generated. EPA notes that this 5-year record retention period is an increase from the 3-year requirements for records related to consumer paint and coating removal finalized in the 2019 final rule. However, the 3-year requirement still applies to records generated under that rule. EPA is proposing that this requirement begin at the effective date of the rule (60 days following publication of the final rule in the **Federal Register**). Recordkeeping requirements would ensure that owners or operators can demonstrate compliance with the proposed regulations if necessary. Note that this requirement would expand those recordkeeping requirements promulgated in 2019 at 40 CFR 751.109 affecting manufacturers, processors, and distributors of methylene chloride.

b. Downstream Notification

For conditions of use that are not otherwise prohibited under this proposed regulation, EPA is proposing that manufacturers (including importers), processors, and distributors, excluding retailers, of methylene chloride and methylene chloride-containing products provide downstream notification of certain prohibitions through Safety Data Sheets

(SDSs) by adding to sections 1(c) and 15 of the SDS the following language:

After [DATE 270 DAYS AFTER DATE OF PUBLICATION OF FINAL RULE IN THE **FEDERAL REGISTER**], this chemical/product cannot be distributed in commerce to retailers. After [DATE 360 DAYS AFTER DATE OF PUBLICATION OF FINAL RULE IN THE **FEDERAL REGISTER**], this chemical/product is and can only be distributed in commerce or processed for the following purposes: (1) Processing as a reactant; (2) Processing for incorporation into a formulation, mixture, or reaction product; (3) Processing for repackaging; (4) Processing for recycling; (5) Industrial or commercial use as a laboratory chemical; (6) Industrial or commercial use as a bonding agent for acrylic and polycarbonate in mission-critical military and space applications, including in the production of specialty batteries for such applications that is performed by the Department of Defense, the Department of Homeland Security, or the National Aeronautics and Space Administration or their contractors at locations controlled by the agency or the agency's contractor; (7) Industrial or commercial use for paint and coating removal from safety-critical, corrosion-sensitive components of aircraft and spacecraft that are owned or operated by the U.S. Department of Defense, the National Aeronautics and Space Administration, the U.S. Department of Homeland Security, and the Federal Aviation Administration that is performed by the agency or agency contractors at locations controlled by the agency or the agency's contractor; (8) Industrial or commercial use for paint and coating removal from safety-critical, corrosion-sensitive components of other aircraft and spacecraft until [10 years after date of publication of the final rule in the **Federal Register**], and (9) Disposal.

The intention of downstream notification is to spread awareness throughout the supply chain of the restrictions on methylene chloride under TSCA as well as provide information to commercial end users about allowable uses of methylene chloride. Note that this requirement would amend and add to the downstream notification requirements promulgated in 2019 at 40 CFR 751.107 for paint and coating removers for consumer use, and additionally redesignate that section as 751.111(a). As they become effective, the new amended requirements would supersede those notification requirements promulgated in 2019.

To provide adequate time to update the SDS and ensure that all products in the supply chain include the revised SDS, EPA is proposing a 150-day period for manufacturers and a 210-day period for processors and distributors to implement the proposed SDS changes (following publication of the final rule).

EPA requests comments on the appropriateness of identified compliance timeframes for recordkeeping and downstream notification requirements described in this Unit.

5. TSCA Section 6(g) Exemptions

Under TSCA section 6(g)(1), EPA may grant an exemption from a requirement of a TSCA section 6(a) rule for a specific condition of use of a chemical substance or mixture. TSCA section 6(g)(1)(B) permits such an exemption if EPA finds that compliance with the requirement, as applied with respect to the specific condition of use, would significantly disrupt the national economy, national security, or critical infrastructure.

TSCA section 6(g)(2) requires EPA to analyze the need for the exemption, and to make public the analysis and a statement describing how the analysis was taken into account when proposing an exemption under TSCA section 6(g). To that end, based on discussions and information provided by industry stakeholders, EPA has analyzed the need for different exemptions and is proposing to grant two of them, with conditions as required under TSCA section 6(g)(4) and described in Units IV.A.5.a.ii. and IV.A.5.b.ii. This Unit presents the results of that analysis.

a. Uses of Methylene Chloride for Paint and Coating Removal Essential for Critical Infrastructure

i. Analysis of the Need for TSCA Section 6(g)(1)(B) Exemption for Commercial Aviation and Aerospace

EPA has preliminarily determined that a prohibition on the commercial use of methylene chloride for paint and coating removal from safety-critical, corrosion-sensitive components of aircraft and aerospace vehicles for commercial aviation and aerospace would significantly disrupt the national economy and critical infrastructure. Aviation has been designated by co-sector agencies DHS and DOT as a key subsector in the Transportation Systems Sector, one of 16 designated critical infrastructure sectors. There are no technically feasible alternatives currently available for methylene chloride used in paint and coating removal for safety-critical, corrosion-sensitive components of aircraft and aerospace vehicles. Thus, commercial aviation and aerospace compliance with the proposed ban on methylene chloride use in commercial paint and coating removal would significantly disrupt critical infrastructure.

As explained by a commenter on the 2017 Notice of Proposed Rulemaking (NPRM), all aircraft have similar safety-critical, corrosion-sensitive components of the type described by DOD (Ref. 38). For example, commercial aircraft often contain components, such as landing gear, that are made from high-strength alloy steels. According to this commenter, the aerospace industry, like DOD, has made significant investments in the evaluation of alternative methods and materials for removing coatings. The commenter states that the industry has had some success, depending upon the substrate, surface treatment, and coating system, but investigation continues into both chemical and non-chemical means. Non-chemical methods, such as plastic beads, were not suitable in all instances due to concerns about damaging the substrate. Many alternative chemical strippers were not effective on all coatings, which caused corrosion concerns in some cases. According to this commenter, benzyl alcohol is a qualified alternative paint remover for some paint formulations but cannot be considered a ''drop-in'' replacement for all applications due to performance concerns.

The concerns expressed by this commenter about corrosion-sensitive components on aircraft and aerospace equipment echo the concerns over methylene chloride alternatives expressed by DOD and discussed at length in the preamble to EPA's 2017 proposal. For example, both the commenter and DOD stated that currently available substitute chemicals cannot completely remove certain coatings (Ref. 38). This results in improperly applied, incompletely adhering replacement coatings, which may result in corrosion of underlying critical parts. For another example, according to the commenter and DOD, substitute chemicals are also incompatible with some underlying metallic, nonmetallic, and composite materials, resulting in material damage to critical components, and the potential for an increased risk of catastrophic failure of safety critical parts. The commenter on the 2017 NPRM also stated that the process for evaluating and then adopting alternatives in aviation applications is a multi-year process. According to the commenter, the materials required to remove coatings on aircraft parts must be developed by a material formulator to meet technical performance requirements and must be ''qualified by the Original Equipment Manufacturer (OEM), and then shown to not cause harm to the aircraft or negatively affect performance to the FAA prior to implementation'' (Ref. 38). The commenter stated that this can take years, with no guarantee of success, so

a longer timeframe for aviation and aerospace to make the transition is appropriate. The commenter suggested that 10 years would be a realistic estimate of the time needed.

More recently, Boeing provided information to EPA indicating that the company has invested considerable resources over many years to qualify and implement alternatives to methylene chloride, including a combination of acid, alkaline, and hydrogen peroxide-activated benzyl alcohol removers and plastic media blast (Ref. 31). Boeing continues to evaluate potential alternatives, such as laser ablation, which the company believes will, if implemented, eliminate hazardous waste, address ergonomic challenges and save significant time over traditional paint and coating removal operations. According to Boeing, the company has identified several paint and coating removal applications with no feasible alternatives to methylene chloride (Ref. 31). These include:

- Large parts or parts with complex geometries that cannot undergo media blasting or strip tank immersion either due to size constraints or entrapment concerns, and where hand abrasion is impractical;
- Situations in which selective coating removal is needed, *e.g.,* the preservation of a conversion coating;
- Effective removal of oven-cured paints and coatings;
- Localized removal of coatings on overhaul or rework parts to reveal part markings and serial numbers;
- Stripping of parts preceding non-destructive testing, where other coating removal methods such as media blasting could hide defects; and
- Removal of polyvinyl formal or polyurethane insulating enamel from copper magnet wire.

While there are alternatives available for many applications, the public comments on the 2017 NPRM, and the information provided by Boeing in 2022 demonstrate there are several aviation and aerospace applications for which there are limited alternatives to methylene chloride for paint and coating removal, due to concerns about damage to the substrate, and these limited alternatives take longer to work. EPA has preliminarily determined that lengthening the time that commercial aircraft and spacecraft are out of service due to necessary safety inspections and repairs will have a considerable adverse impact on air travel and other infrastructure elements such as satellite placement. Therefore, EPA has preliminarily determined that requiring commercial aviation and aerospace sectors to comply at this time with the ban on methylene chloride use in paint and coating removal would cause significant disruption to critical infrastructure. In addition, EPA has preliminarily determined that compliance at this time with the proposed ban on the manufacture, processing, and distribution in commerce of methylene chloride for commercial paint and coating removal for these specific commercial aviation and aerospace uses would also result in a significant disruption to critical infrastructure. EPA's proposed conditions for this exemption are described in this Unit, including proposed requirements to comply with the WCPP.

EPA acknowledges that in many cases commercial aviation facilities may be more sophisticated and industrialized than other commercial paint and coating removal operations. However, at the time of proposal, data available to EPA demonstrate that the risks from paint and coating removal in the aviation sector do not differ significantly from other commercial paint and coating removal (Ref. 1). As shown in the 2020 Risk Evaluation for Methylene Chloride, high-end and central tendency estimates for aircraft paint stripping are three orders of magnitude below the benchmark for acute inhalation risks and four orders of magnitude below the benchmark for chronic non-cancer inhalation risks (Ref. 1). Even if use of APF 50 air supplied respirators were assumed, the risks that remain for both high-end and central tendency would be an order of magnitude below the benchmark for both endpoints (Ref. 1). Therefore, while EPA expects that some of these facilities could successfully follow the requirements of the WCPP, based on qualitative information provided by stakeholders, this expectation is not sufficiently supported by monitoring data in the 2020 Risk Evaluation for Methylene Chloride. As a result, there is significant uncertainty whether the requirements of the WCPP could be implemented successfully in this sector for this particular use on a consistent and reliable basis, in part due to the diversity of facilities in this sector. EPA understands that generally large commercial aviation facilities could have industrial hygiene expertise, sophisticated engineering and administrative controls, and experience with rigorous safety requirements and methods for ensuring continuous strong safety records (Ref. 31). However, EPA is concerned about the ability of smaller aircraft repair shops to implement the WCPP over the long term, particularly for this condition of use. While EPA recognizes that the proposed TSCA section 6(g) exemption for commercial aircraft paint and coating removal could also cover these smaller aircraft repair shops, the exemption is time-limited and ultimately would result in these small shops using alternatives to methylene chloride. While Federal agencies and contractors should be regulated under the WCPP, the Agency is proposing that commercial use of methylene chloride for a similar type of paint and coating removal be regulated with a time-limited, conditional exemption under TSCA section 6(g), due to notable differences in the two sectors. Specifically, exposure information assessed by EPA resulted in key differences in risk estimates for paint and coating removal by civilian aviation and DOD (see discussion in this Unit and Unit V.A.1.). Additionally, as described in Unit V.A.1., Federal and Federal contractor facilities are subject to multiple levels of oversight as a result of the governmental and public nature of their activities, while many civilian aviation facilities are not likely to experience the same level of scrutiny. EPA emphasizes that in the absence of information, it must still ensure that unreasonable risks are addressed. Because EPA has found inadequate information to otherwise determine whether the unreasonable risk would be addressed when using methylene chloride under a WCPP for commercial use of methylene chloride for paint and coating removal from safety-critical, corrosion-sensitive components of aircraft and aerospace vehicles for commercial aviation and aerospace, EPA has determined that the proposed exemption under TSCA section 6(g) allowing for time-limited, conditional use of methylene chloride for this critical use is the appropriate approach.

EPA recognizes that in some situations, certain facilities may do both Federal contractor and commercial aviation work and may use methylene chloride for paint and coating removal from safety-critical, corrosion-sensitive components on military, Federal, or commercial aviation. EPA requests comment on whether such co-located activities in a facility should be subject to the WCPP, rather than the exemption under TSCA section 6(g). Additionally, EPA seeks additional information and requests comment on whether it is possible to distinguish between commercial aviation facilities that would be able to meet the WCPP and those that would not, including what criteria should be used for such distinctions (*e.g.,* size of facility, volume

or type of work performed, record of exposure reduction practices). EPA also requests comment on the extent to which specific commercial aviation and aerospace uses or types of facilities could fully comply with the WCPP to address identified unreasonable risk.

ii. Proposed Exemptions for Uses of Methylene Chloride for Paint and Coating Removal That Are Essential for Critical Infrastructure

For the reasons discussed in this Unit, EPA is proposing to provide a 10-year exemption for commercial aviation and commercial aerospace applications from the proposed prohibition on the use of methylene chloride in commercial paint and coating removal. In defining the scope of the exemption to limit the exemption to commercial aviation and aerospace, EPA looked to the definitions and provisions of the Federal Aviation Regulations in title 14 of the CFR. Air carriers and commercial operators are certificated under 14 CFR part 119. Repair stations are certificated under 14 CFR part 145. To effectively prevent significant disruptions to critical infrastructure including commercial aviation and aerospace, EPA would make this exemption available to three different groups of commercial entities. In each case, the exemption would be available only for the use of methylene chloride to remove paint and coatings from safety-critical, corrosion-sensitive components of aircraft or aerospace vehicles. The first group would consist of those facilities that primarily maintain and repair aircraft used by air carriers and commercial operators. More specifically, maintenance and repair facilities operated by air carriers and commercial operators certificated under 14 CFR part 119 would be eligible for the exemption, as would be repair stations certificated under 14 CFR part 145, if their primary business is performing maintenance, preventive maintenance, rebuilding, or alteration of aircraft operated by air carriers and commercial operators certificated under 14 CFR part 119. The second group would consist of manufacturers of aircraft intended for, or capable of being used by, air carriers and commercial operators certificated under 14 CFR part 119. The third group would consist of any person manufacturing or repairing spacecraft, space vehicles, or payloads or similar hardware that is intended for, or used in, commercial space transportation operations subject to 14 CFR chapter III.

The conditions for the proposed exemption would be: (1) The use of methylene chloride for commercial paint or coating removal by certificated air carriers, commercial operators, or repair stations, or by manufacturers of aircraft or aerospace vehicles or hardware, would be limited to the safety-critical, corrosion-sensitive components on aircraft and aerospace vehicles; (2) The use of methylene chloride for paint or coating removal would be required to be performed on the premises of the certificated air carrier or commercial operator or repair station, or of the manufacturer of aircraft or aerospace vehicles or hardware; and (3) The certificated air carrier, commercial operator, repair station, or manufacturer of aircraft or aerospace vehicles and hardware manufacturer would have to comply with the WCPP discussed in Unit IV.A.1.

EPA wishes to make clear that the exemption for the commercial aerospace and aviation industry would only be available for the purpose of paint and coating removal from components of aircraft and spacecraft that are corrosion-sensitive and safety critical components, such as landing gear, gear boxes, turbine engine parts, and other aircraft and spacecraft and components composed of metallic materials (specifically high-strength steel, aluminum, titanium, and magnesium) and composite materials. In addition, these components would have to be of the type that not only require their paint or coatings to be removed for inspection and maintenance but also would be so negatively affected by the use of paint and coating removal chemicals or methods other than methylene chloride that the safety of the system could be compromised. General paint and coating removal on aircraft and spacecraft would not be authorized under this exemption. One commenter on the 2017 proposal suggested that EPA clarify that only the manufacturer of the component may make this determination. In EPA's view, persons availing themselves of the exemption would need to have a reasonable basis to conclude that the components on which methylene chloride is used are corrosion-sensitive and safety critical components within the meaning of the definition. EPA believes such persons could rely, in part, on information supplied by the manufacturer of the component. A determination of whether a particular component of an aircraft or spacecraft is a safety-critical corrosion-sensitive component would be a fact-specific determination that takes into account the substrate and character of the component, the effects of methylene chloride paint or coating remover on the component, and other relevant factors.

The entities subject to the proposed exemption would nonetheless still be subject to the proposed general recordkeeping requirements discussed in Unit IV.A., the WCPP recordkeeping requirements discussed in Unit IV.A.1.f.iii., and requirements to maintain records that demonstrate compliance with the exemption conditions, including the condition that methylene chloride only be used for paint and coating removal from corrosion-sensitive and safety critical components of an aircraft or spacecraft. Pursuant to TSCA section 6(g)(3), if this proposed exemption is finalized, EPA may by rule later extend, modify, or eliminate the exemption, on the basis of reasonably available information and after adequate public justification, if EPA determines the exemption warrants a change. EPA would initiate this rulemaking process (*e.g.,* proposed rule, final rule) at the request of any regulated entity benefiting from such an exemption, as appropriate. The Agency is open to engagement throughout the duration of any TSCA section 6(g) exemption, and emphasizes that to ensure continuity in the event of an extension or modification request, such a request should come at least 2 years prior to the expiration of an exemption.

EPA requests comments on all aspects of the proposed TSCA section 6(g) exemption from the proposed prohibition on use of methylene chloride in commercial paint and coating removal for paint and coating removal essential for critical infrastructure by certificated commercial air carriers, commercial operators, or repair stations, or by manufacturers of aircraft or aerospace vehicles and hardware, noting that the proposed exemptions would be limited to the safety-critical, corrosion-sensitive components on aircraft and aerospace vehicles, including safety-critical components.

b. Certain Emergency Uses of Methylene Chloride for Which No Technically and Economically Feasible Safer Alternative Is Available

i. Analysis of the Need for TSCA Section 6(g)(2)(A) Exemption for NASA Certain Uses in an Emergency

EPA also considered a TSCA section 6(g) exemption for emergency use of methylene chloride in the furtherance of NASA's mission. Under TSCA section 6(g)(1)(A), EPA may ''grant an exemption from a requirement of a . . . rule for a specific condition of use of a chemical substance or mixture, if the Administrator finds that the specific condition of use is a critical or essential use for which no technically and economically feasible safer alternative is

available, taking into consideration hazard and exposure.'' For certain specific conditions of use, EPA proposes that use of methylene chloride by NASA and its contractors in an emergency be exempt from the requirements of this rule because it is a critical or essential use provided that (1) there is an emergency; and (2) NASA selected methylene chloride because there are no technically or economically feasible safer alternatives available during the emergency.

NASA operates on the leading edge of science seeking innovative solutions to future problems where even small volumes of an otherwise prohibited chemical substance could be vital to crew safety and mission success. During interagency review, NASA expressed concerns that there will likely be circumstances where a specific, EPA-prohibited condition of use may be identified by NASA during an emergency as being needed in order to avoid or reduce situations of harm or immediate danger to human health, or the environment, or avoid imperiling NASA space missions. In such cases, it is possible that no technically and economically feasible safer alternative would be available that meets the stringent technical performance requirements necessary to remedy harm or avert danger to human health, the environment, or avoid imperiling NASA space missions.

An emergency is a serious and sudden situation requiring immediate action to remedy harm or avert danger to human health, the environment, or to avoid imperiling NASA space missions. In NASA's case, there may be instances where the emergency use of methylene chloride for specific conditions of use is critical or essential to remedying harm or averting danger to human health, the environment, or avoiding imperiling NASA space missions. Because of the immediate and unpredictable nature of emergencies described in this Unit and of the less forgiving environments NASA operates in that offer little to no margin for error, it is likely that, at the time of finalization of this proposal, alternatives to emergency methylene chloride use may not be available in a timely manner to avoid or reduce harm or immediate danger (Ref. 39). In this way, these emergencies for particular conditions of use meet the criteria for an exemption under TSCA section 6(g)(1)(A), because the emergency use of methylene chloride for listed conditions of use is critical or essential and no technically and economically feasible safer alternative will be available in a timely manner, taking into consideration hazard and exposure.

In support of the TSCA section 6(g)(1)(A) emergency use exemption, NASA submitted detailed criteria which they must use to screen, qualify, and implement materials to be used in spacecraft equipment, as well as historical case studies that outline the loss of life and loss of assets in the discharge of previous missions. In one of several examples detailed, the Apollo I command module fire that claimed the lives of three American astronauts demonstrated the need for careful testing and continuity of materials (Ref. 39). Moreover, due to NASA's rigorous safety testing requirements under various environmental conditions, technically and economically feasible safer alternatives may not be readily available during emergencies and may require certain conditions of use of methylene chloride to alleviate the emergency.

In another example, NASA identified a scenario concerning a mission to the International Space Station (ISS) whereby, during a launch evolution, the countdown was paused immediately prior to launch (T–2 minutes). NASA engineers identified a clogged filter and supply line as the primary issue, which required immediate attention (*i.e.,* line flushing and filter cleaning). In this type of emergency scenario, an already approved chemical substance rated for space system applications is necessary to immediately remedy the situation. Although methylene chloride was not used in this particular incident, if it were needed, in the future to address such an emergency, then the proposed exemption would allow for its lawful use—the countdown would resume and the launch would occur. Conversely, without an exemption under the specific condition of use (*e.g.,* industrial and commercial use in non-aerosol degreasers and cleaners), NASA's use of methylene chloride would be otherwise prohibited, which would put NASA in an untenable position of having to choose to either violate the law or place the mission (and potentially the health and safety of its employees involved in the mission) at risk.

As described in Unit IV.A.5.a., the identification and qualification of compatible materials in the context of aviation is iterative and involves expansive collaboration between original equipment manufacturers, Federal agencies, and qualifying institutions. This is equally, if not more so, the case in the context of human space flight operations undertaken by NASA (Ref. 39). NASA's mission architecture requirements often are developed many years in advance of an actual launch occurring. As part of mission planning, space systems are designed, full scale mock-ups are built, and mission critical hardware is constructed using materials qualified for spaceflight. Once NASA's mission architecture requirements are developed, NASA may need to retain emergency access to methylene chloride because its alternatives may not have yet gone through NASA's rigorous certification process before their use. Allowing NASA to retain emergency use of methylene chloride would reduce the chances that this rule will hinder future space missions for which mission architecture infrastructure is being developed or is already built. While NASA considers alternatives to the chemical substances it currently uses in its space system designs, NASA has not yet identified technically and economically feasible alternatives to proven chemistries in many current applications. While EPA acknowledges that the use of methylene chloride in emergency situations may be necessary in the near term, it is also EPA's understanding that NASA will continue its work to identify and qualify alternatives to methylene chloride. Thus, as with the exemption described in Unit IV.A.5.a., EPA is proposing an exemption duration of 10 years.

ii. Proposed Exemption for Use of Methylene Chloride for Emergency Uses in the Context of Human Space Flight for Certain Uses

For the reasons discussed in this Unit, EPA is proposing a 10-year exemption for emergency use of methylene chloride in furtherance of NASA's mission for the following specific conditions of use: Industrial and commercial use as solvent for cold cleaning; Industrial and commercial use as a solvent for aerosol spray degreaser/cleaner; Industrial and commercial use in adhesives, sealants and caulks; Industrial and commercial use in adhesive and caulk removers; Industrial and commercial use in metal non-aerosol degreasers; Industrial and commercial use in non-aerosol degreasers and cleaners; and Industrial and commercial use as solvent that becomes part of a formulation or mixture. EPA is also proposing to include additional requirements as part of the exemption, pursuant to TSCA section 6(g)(4), including required notification and controls for exposure, to the extent feasible: (1) NASA and its contractors must provide notice to the EPA Administrator of each instance of emergency use within 15 days and; (2) NASA and its contractors would have to comply with the WCPP described in Unit IV.A.1. to the extent feasible.

EPA is proposing to require that NASA notify EPA within 15 days of the emergency use. The notification would include a description of the specific use of methylene chloride in the context of one of the conditions of use for which this exemption is being proposed, an explanation of why the use described qualifies as an emergency, and an explanation with regard to the lack of availability of technically and economically feasible alternatives.

As with the exemption described in Unit IV.A.5.a., EPA expects NASA and its contractors have the ability to implement a WCPP as described in Unit IV.A.1. for the identified uses in the context of an emergency, to some extent even if not to the full extent of WCPP implementation. Therefore, EPA is proposing to require that during emergency use, NASA must comply with the WCPP to the extent technically feasible in light of the particular emergency.

Under the proposed exemption, NASA and its contractors would still be subject to the proposed general recordkeeping requirements discussed in Unit IV.A.

EPA requests comment on this TSCA section 6(g) exemption for continued emergency use of methylene chloride in the furtherance of NASA's mission as described in this Unit, and whether any additional conditions of use should be included, in particular for any uses qualified for space flight for which no technically or economically feasible safer alternative is available. Additionally, EPA requests comment on what would constitute sufficient justification of an emergency.

c. Analysis of the Need for a TSCA Section 6(g) Exemption for Commercial Furniture Refinishing

While EPA in the past has proposed to exclude commercial furniture refinishing from regulation of the use of methylene chloride in commercial paint and coating removal, this proposed rule does not exclude commercial furniture refinishing from the proposed prohibition on the use of methylene chloride for commercial paint and coating removal, because EPA has determined that this use drives the unreasonable risk for methylene chloride, reasonably available information demonstrates that alternative methods or substitute chemicals are available to some extent, and, based on reasonably available information, EPA has not found that a TSCA section 6(g) exemption is warranted for the use of methylene chloride in commercial furniture refinishing.

The 2020 Risk Evaluation for Methylene Chloride identified risks for commercial use of methylene chloride in paint and coating removal, including furniture refinishing, as a result of acute and chronic non-cancer exposures that would not be mitigated by an APF 50 respirator. The 2020 Risk Evaluation for Methylene Chloride identified risks for commercial use of methylene chloride in paint and coating removal, including furniture refinishing, as a result of acute and chronic non-cancer exposures that would not be mitigated by an APF 50 respirator. EPA identified many alternative products for paint and coating removers. However, some may require longer periods of time or rework of equipment and processes in order to work for furniture refinishing uses, or, though they may be used as paint and coating removers in other contexts, may not be appropriate alternatives for use on wood substrates. EPA's consideration of alternatives, including for safety and flammability, is discussed further in Unit V.B., the Economic Analysis, and Alternatives Assessment (Ref. 3, Ref. 40). Mechanical or thermal methods (*i.e.,* sanding, media blasting, or heat guns) are also potential alternatives for this sector, though likewise they may damage the substrate, require different processes, and often requires more time (Refs. 33, 55, 66). While the economic impacts of prohibiting the commercial use of methylene chloride for furniture refinishing may be significant for this sector, it is unclear whether this will result in firm closures, and, if so, how many. Given the magnitude of the risks resulting from this use, including the documented fatalities (Ref. 32), the likely inability of this sector to comply with a WCPP (as described in Unit V.A.), and the availability of some alternatives, EPA determined that a prohibition would be necessary the identified risks that drive the unreasonable risk to health, as discussed in Unit V.A.1. EPA requests comment on all aspects of this preliminary determination that a TSCA section 6(g) exemption is not warranted for the use of methylene chloride in furniture refinishing, including information on the availability of alternatives and the time needed to implement alternatives. EPA emphasizes that the Agency is seeking input regarding whether an exemption is needed and welcomes information related to this condition of use during the public comment period.

B. Primary Alternative Regulatory Action

As indicated by TSCA section 6(c)(2)(A)(iv)(II) through (III), EPA must consider the costs and benefits and the cost effectiveness of the proposed regulatory action and one or more primary alternative regulatory actions considered by the Agency. An overview of the proposed regulatory action and alternative regulatory action for each condition of use is in Unit IV.C.

The primary alternative regulatory action described in this notice combines prohibitions and requirements for a WCPP to address the unreasonable risk from methylene chloride driven by the various conditions of use, as well as time-limited exemptions under TSCA section 6(g) for two uses. While in some ways it is similar to the proposed regulatory action, the primary alternative regulatory action described in this notice would allow a WCPP, including requirements to meet an ECEL and EPA STEL, for several additional conditions of use than would be allowed under the proposed regulatory action. The alternative regulatory action additionally would include longer compliance timeframes for prohibitions and a WCPP, as described in this Unit.

As in the proposed regulatory action described in Unit IV.A.1., EPA's primary alternative regulatory action described in this notice would include WCPP, including requirements to meet an ECEL and EPA STEL for: manufacturing: domestic manufacture; manufacturing: import; processing: as a reactant; processing: incorporation into a formulation, mixture, or reaction product; processing: repackaging; processing: recycling; industrial and commercial use as a laboratory chemical; and disposal.

In addition, the primary alternative regulatory action described in this notice would require a WCPP for additional industrial and commercial conditions of use: industrial and commercial use in finishing products for fabric, textiles, and leather; industrial and commercial use as solvent that becomes part of a formulation or mixture; industrial and commercial use as a processing aid; industrial and commercial use for electrical equipment, appliance, and component manufacturing; industrial and commercial use for plastic and rubber products manufacturing; industrial and commercial use in cellulose triacetate film production; industrial and commercial use for oil and gas drilling, extraction, and support activities; and industrial and commercial use in paint or coating removal from safety-critical, corrosion-sensitive components of aircraft owned or operated by air carriers or commercial operators certificated under 14 CFR part 119.

EPA believes a WCPP may be a viable alternative to the proposed prohibition for these additional industrial and commercial conditions of use because, as discussed in Unit V.A., these conditions of use are generally industrial in nature; owners or operators are likely currently complying with the OSHA methylene chloride standard, so they should be familiar with what is being required to meet the ECEL; and, as far as the Agency is aware, these conditions of use have not resulted in any documented fatalities. Because of the industrial nature of the sectors relevant to these conditions of use, the owner or operator may have the capability to successfully implement a WCPP to ensure that the unreasonable risk, as a result of exposure to methylene chloride, are prevented. However, at the time of proposal, EPA has not yet received any monitoring data or detailed description of methylene chloride involving activities for these conditions of use to confirm that compliance with an ECEL of 2 ppm is possible. Therefore, concerns about the feasibility of implementing an ECEL for these additional industrial and commercial conditions of use, as discussed in Unit V.3., led EPA to propose that they be prohibited (see Unit IV.A.2.). EPA does not have sufficient information to confidently conclude that facilities engaged in these conditions of use could meet the ECEL for methylene chloride.

Therefore, EPA requests comment on the ways in which methylene chloride may be used in the conditions of use that would be prohibited (under the proposed regulatory action) due to concerns about feasibility of implementing an ECEL, and the degree to which users of methylene chloride in these sectors could successfully implement the WCPP, including requirements to meet an ECEL and EPA STEL, described in Unit IV.A.1. EPA is also requesting comment on whether to consider a regulatory alternative that would subject more conditions of use to a WCPP, instead of prohibition, than those currently contemplated in the primary alternative regulatory action. EPA also requests monitoring data and detailed descriptions of methylene chloride involving activities for these conditions of use to determine whether these additional conditions of use could comply with the WCPP such that risks are no longer unreasonable.

Specifically with regards to the condition of use ''Industrial and commercial use as a processing aid,'' EPA notes that the description of this condition of use (in Unit III.B.1.c.xxiii.) covers a broad range of chemical use activities. During the SBAR Panel, one SER provided process descriptions, diagrams, and monitoring data which indicated that particular entity may already be able to meet an ECEL of 2 ppm. This particular entity uses methylene chloride as a heat transfer fluid in a closed system. Information provided to EPA indicated that inhalation exposures were frequently below the ECEL and in some cases below the level of detection, and while dermal exposure were possible, they could be mitigated through use of PPE (Ref. 6). EPA's 2020 Risk Evaluation for Methylene Chloride incorporated exposure estimates from a different type of processing aid application that did not resemble the SER's use, which is highly specialized and may be considered a sub-use of the condition of use as a whole. EPA requests comment on the degree to which other entities using methylene chloride as a processing aid may otherwise comply with the proposed WCPP requirements for methylene chloride. In the case that several entities are able to demonstrate the continued use of methylene chloride without subjecting workers to unreasonable risk is possible, through a combination of monitoring data and process description, EPA acknowledges its willingness to finalize a regulation under which this particular sub-use of the condition of use, or the condition of use as a whole could continue under the WCPP.

Additionally, EPA notes that the alternatives analysis did not specifically identify any alternatives for this condition of use (Ref. 40). This is a limitation of the type of analysis done, which was specifically based on the use of alternative formulations currently on the market, and therefore not applicable to most processing uses. EPA emphasizes that this is not a positive finding that alternatives do not exist for this condition of use. To that end, EPA requests comment on the degree to which alternatives may or may not be available for use of methylene chloride as a heat transfer fluid and in other processing aid applications.

In the event that EPA is not able to identify any alternatives for this condition of use, and additional information is not provided that would allow EPA to determine that the WCPP could address unreasonable risk driven by this condition of use, EPA will consider finalizing a prohibition that allows for an appropriate phaseout in accordance with TSCA section 6(d). Alternatively, in the event that EPA is unable to identify alternatives for this condition of use, and EPA determines through new information provided that prohibition of the use would significantly impact national security or critical infrastructure, EPA will consider an exemption under TSCA section 6(g).

Under the primary alternative regulatory action, EPA would prohibit the manufacture, processing, and distribution in commerce of methylene chloride for all consumer use. Additionally, under the primary alternative regulatory action described in this notice and considered by EPA, other than those conditions of use listed earlier for inclusion under the WCPP, EPA would prohibit the remaining industrial and commercial uses, including two uses for which EPA is proposing the WCPP as the regulatory action: industrial or commercial use for paint and coating removal from safety-critical, corrosion-sensitive components of aircraft and spacecraft by Federal agencies and their contractors; and industrial or commercial use as a bonding agent in the production of specialty batteries for military or space applications by Federal agencies and their contractors. Recordkeeping and downstream notification would be required as described in Unit IV.A.4.

For industrial or commercial use for paint and coating removal from safety-critical, corrosion-sensitive components of aircraft and spacecraft by Federal agencies and their contractors, and industrial or commercial use as a bonding agent in the production of specialty batteries for military or space applications by Federal agencies and their contractors, the alternative regulatory action would include an exemption from the prohibition for 10 years under TSCA section 6(g). For the duration of this exemption, regulated entities would be required to comply with the WCPP to the extent practicable.

For these two uses, EPA has conducted an analysis of the application of this rulemaking and found that a TSCA section 6(g) exemption may be warranted if the primary alternative regulatory action considered by EPA is adopted, in its entirety or in relevant part, in the final rule. Based on discussions with and information provided by industry stakeholders, EPA understands that these two uses of methylene chloride by DoD, NASA, and other Federal agencies are essential for national security and critical infrastructure.

As discussed in greater detail in Unit V.B., EPA is aware that there are specific military uses for which methylene chloride is essential for paint and coating removal and for which there are no suitable alternatives currently available. The military readiness of DOD's warfighting capability is

paramount to ensuring national security, which includes ensuring the maintenance and preservation of DOD's warfighting assets. DOD has identified safety-critical uses of methylene chloride for ensuring military aviation readiness. These consist of the use of methylene chloride for the removal of coatings from safety-critical, corrosion-sensitive military aviation components, such as landing gear, gear boxes, and turbine engine parts, that not only require their coatings be removed for inspection and maintenance but also would be so negatively affected by the use of technically incompatible, substitute paint removal chemicals or methods that the safe performance of the aircraft could be compromised.

EPA has evaluated the effect that a prohibition on methylene chloride for industrial or commercial paint and coating removal could have on military readiness and preliminarily determines that an exemption would be warranted under TSCA section 6(g)(1)(B) to avoid the significant deleterious impacts on national security that compliance with the proposed prohibition could entail, should the primary alternative regulatory action be adopted in the final rule in whole or in part. More specifically, because the available alternatives either cannot be used on certain substrates, such as high-strength steel or magnesium, or take an unacceptably long time to work in certain situations, compliance with the proposed prohibition would result in important military assets being off-line for significantly longer inspection and repair periods, which would significantly disrupt national security.

In addition, as noted by commenters on EPA's 2017 NPRM, there are other Federal agencies that use safety-critical, corrosion-sensitive components on aviation and space applications and stated that the proposed exemption should also apply to those Federal agencies and their contractors. These commenters asserted that, without an exemption for NASA, the Department of Homeland Security (DHS), and the Federal Aviation Administration (FAA), the proposed prohibition on the use of methylene chloride for industrial or commercial paint and coating removal could negatively affect national security and critical infrastructure.

EPA's analysis of the potential impacts on DOD's military readiness and national security is equally applicable to NASA, DHS, and FAA. As stated by commenters on EPA's 2017 NPRM (Ref. 46), aircraft and other assets operated by DHS, NASA, and the FAA also contain safety-critical, corrosion-sensitive components of the type described by DOD, and suitable alternatives to methylene chloride are similarly not available for all applications. Those agencies are also responsible for assets that are essential to national security or constitute critical infrastructure and contain safety-critical, corrosion-sensitive components on which methylene chloride is used for paint and coating removal. The Coast Guard, one of the five Armed Services of the United States, is a military branch within DHS. Like the four Armed Services within DOD, the Coast Guard is also responsible for warfighting assets that may require the use of methylene chloride for the removal of coatings from safety-critical, corrosion-sensitive components. The Coast Guard's military readiness is as important as the military readiness of the four Armed Services within DOD. Similarly, the readiness of U.S. Customs and Border Protection aviation for monitoring and protecting the borders of the United States is an integral part of national security. As for NASA, the United States Space Priorities Framework notes that space systems (*e.g.,* flight components of satellites and space craft) are part of the nation's critical infrastructure and that the United States has significant national security interests in space (Ref. 41). The integrity and performance of our national airspace system, overseen by the FAA, is a matter of both national security and critical infrastructure. FAA-operated aircraft ensure the integrity of instrument approaches to airports and airway procedures that constitute our National Airspace System infrastructure (Ref. 42). The FAA's Flight Program Operations accomplishes this through the airborne inspection of space- and ground-based instrument flight procedures and the validation of electronic signals in space transmitted from ground navigation systems, evaluating accuracy, aeronautical data, human factors fly-ability, and obstacle clearance.

As discussed in Unit V.B., substitute chemicals for paint and coating removal for safety-critical, corrosion-sensitive components are not technically feasible as they have one or more technical limitations; are incompatible with underlying materials; and/or do not support the coating removal requirements of safety inspections, non-destructive inspection, material assessment, or field repair processes. Therefore, EPA has preliminarily determined that DHS, NASA, and FAA compliance with a prohibition on the use of methylene chloride for industrial or commercial paint and coating removal, which would preclude use of methylene chloride for removal of paint and coatings from safety-critical, corrosion-sensitive components of these agencies' aircraft and other assets, would significantly disrupt national security and critical infrastructure in the same way that DOD's compliance with a prohibition would. In addition, due to concerns about impacts to the availability of methylene chloride for use in removing paint and coatings from safety-critical, corrosion-sensitive components, EPA has preliminarily determined that a ban on the manufacture, processing, and distribution in commerce of methylene chloride for industrial or commercial paint and coating removal for these safety-critical, corrosion-sensitive components would also significantly disrupt national security and critical infrastructure. For this reason, if the primary alternative regulatory action considered by EPA is adopted, in its entirety or in relevant part, in the final rule, an exemption under TSCA section 6(g) would be warranted to prevent significant disruption of national security and critical infrastructure.

EPA has also analyzed the need for a TSCA section 6(g) exemption for use of methylene chloride as a bonding agent in the production of specialty batteries for use in critical energy storage applications in military and space exploration settings, including defense applications such as precision guided weapons, military airframes, satellites, space launch vehicles, and spacecraft. According to a maker of these batteries, all major military and space applications, such as aircraft (F–35, B2), radios, and Mars mission equipment, require these batteries to function in very harsh conditions, including operation to −40 °C and storage at −54 °C (Ref. 47). As discussed further in Unit V.B., EPA understands that methylene chloride is a superior bonding agent for this process because of its unique evaporative qualities, and that availability of technologically and economically feasible alternatives to methylene chloride is lacking.

As discussed in this Unit, EPA recognizes that military readiness is paramount to ensuring national security, and that space systems are part of our critical infrastructure and have impacts on national security. Therefore, EPA has preliminarily determined that DOD and NASA compliance with a prohibition on the use of methylene chloride as a bonding agent in the production of specialty batteries for use in critical energy storage applications in military and space exploration settings would significantly disrupt national security and critical infrastructure,

should the primary alternative regulatory action be adopted in the final rule in whole or in part. In addition, due to concerns about impacts to the availability of methylene chloride for use as a bonding agent in the production of these specialty batteries, EPA has preliminarily determined that a prohibition on the manufacture, processing, and distribution in commerce of methylene chloride for use as a bonding agent in the production of specialty batteries for use in critical energy storage applications in military and space exploration settings would also significantly disrupt national security and critical infrastructure. For this reason, if the primary alternative regulatory action considered by EPA is adopted, in its entirety or in relevant part, in the final rule, an exemption under TSCA section 6(g) would be warranted to prevent significant disruption of national security and critical infrastructure.

Given the potential severity of impacts from acute exposures, EPA's proposed regulatory action would include relatively rapid compliance timeframes. However, it is possible that longer timeframes would be needed for entities to come into compliance; therefore, the primary alternative regulatory action described in this notice would include longer timeframes for implementation than the proposed regulatory action. The prohibitions under the primary alternative regulatory action would take effect in 360 days for manufacturers, 450 days for processers, 540 days for distributing to retailers, 630 days for all other distributors and retailers, and 720 days for industrial and commercial users after publication of the final rule in the **Federal Register** (in contrast to 90 days for manufacturers, 180 days for processers, 270 days for distributing to retailers, 360 days for all other distributors and retailers, and 450 days for industrial and commercial users after publication of the final rule in the **Federal Register** in the proposed action described in Unit IV.A.). Similarly, the compliance timeframes for the WCPP under the primary alternative regulatory action would be extended by 6 months in comparison to the proposed action described in Unit IV.A: EPA would require that regulated entities establish initial exposure monitoring according to the process outlined in Unit IV.A. within 12 months, ensure that the airborne concentration of methylene chloride does not exceed the ECEL or EPA STEL within 15 months (and provide respiratory protection if necessary), and implement an exposure control plan within 18 months. EPA requests comment on the ability of regulated entities engaged in the additional conditions of use that would be subject to a WCPP under the primary alternative regulatory action to conduct initial monitoring within 12 months, anticipated timelines for any procedural adjustments needed to comply with the requirements, and the extent to which this option could result in additional exposure, compared the proposed regulatory option as described in Unit IV.A. Overall, EPA requests comment on any advantages or drawbacks for the timelines outlined in this Unit, compared to the timelines identified for the proposed regulatory action in Unit IV.A.

As noted earlier in this Unit, for some conditions of use, both the proposed regulatory action and primary alternative regulatory action would result in a prohibition. EPA emphasizes that for those conditions of use, the primary alternative regulatory action includes a different timeline for implementation of the prohibition, in comparison to the proposed regulatory action. As discussed in more detail in Unit V.A., for those conditions of use, EPA also considered other regulatory approaches available under TSCA section 6(a). However, EPA found that none of these other regulatory approaches would address the unreasonable risk.

Where EPA has determined that a chemical substance presents unreasonable risk under TSCA section 6(b)(4), EPA must undertake rulemaking to ''apply one or more of the [TSCA § 6(a)(1) through (7)] requirements to such substance . . . to the extent necessary so that the chemical substance . . . no longer presents such risk.'' TSCA § 6(a). ''In proposing and promulgating [such] a rule,'' EPA must ''consider and publish a statement based on reasonably available information with respect to . . . the reasonably ascertainable economic consequences of the rule, including consideration of . . . (II) the costs and benefits of the proposed . . . regulatory action and of the [one] or more primary alternative regulatory actions considered by [EPA]; and (III) the cost effectiveness of the proposed regulatory action and of the [one] or more primary alternative regulatory actions considered by [EPA].'' EPA interprets this to mean that Congress intended this ''primary alternative regulatory action'' to be another regulatory option under TSCA § 6(a)(1) through (7) that would meet the requirements of TSCA § 6(a), namely address the unreasonable risk identified under TSCA section 6(b)(4) ''to the extent necessary so that the chemical substance . . . no longer presents such risk.'' Here, the proposed regulatory action is comprised of a mix of proposed options under TSCA section 6(a), each directed at specific conditions of use and with specified timeframes for compliance. The primary alternative regulatory options considered by the Agency would adjust the overall mix of TSCA section 6(a) requirements, including compliance timeframes, resulting in a proposed regulatory action that is more restrictive in some ways and less restrictive in others. For conditions of use where the only options that would address the unreasonable risk are prohibition options under TSCA § 6(a)(2), the proposed option and the primary alternative regulatory option are distinct because implementing prohibitions on differing timetables under TSCA section 6(d) would result in a different mix of regulatory options with different costs, benefits, and cost effectiveness than the proposed regulatory action.

C. Overview of Conditions of Use and Proposed Regulatory Action and Primary Alternative Regulatory Action

The following Table 3 is a side-by-side depiction of the proposed regulatory action with the primary alternative regulatory action for each condition of use. Additionally, timeframes between the proposed and primary alternative regulatory action differ as outlined in Units IV.A. and B; those Units also contain additional details such as exemptions proposed under TSCA section 6(g) and delayed compliance dates under TSCA section 6(d) for specific applications.

TABLE 3—EPA PROPOSED OR ALTERNATIVE ACTION BY CONDITION OF USE

Condition of use	Action	
	Proposed regulatory action	Primary alternative action
Industrial and commercial use as solvent for batch vapor degreasing	Prohibit	Prohibit.
Industrial and commercial use as solvent for in-line vapor degreasing	Prohibit	Prohibit.
Industrial and commercial use as solvent for cold cleaning	Prohibit	Prohibit.
Industrial and commercial use as a solvent for aerosol spray degreaser/cleaner	Prohibit	Prohibit.
Industrial and commercial use in adhesives, sealants and caulks	Prohibit	Prohibit.
Industrial and commercial use in paints and coatings	Prohibit	Prohibit.
Industrial and commercial use in paint and coating removers	Prohibit	Prohibit.
Industrial and commercial use in paint and coating removers from safety critical, corrosion-sensitive components of aircraft and spacecraft owned or operated by DOD, NASA, DHS, FAA.	WCPP	Prohibit, with a 10-year time-limited exemption and interim WCPP.
Industrial and commercial use in paint and coating removers from safety-critical, corrosion-sensitive components of aircraft owned or operated by air carriers or commercial operators.	Prohibit, with a 10-year time-limited exemption and interim WCPP.	WCPP.
Industrial or commercial use as a bonding agent for acrylic and polycarbonate in mission-critical military and space vehicle applications, including in the production of specialty batteries for such applications.	WCPP	Prohibit, with a 10-year time-limited exemption and interim WCPP.
Industrial and commercial use in adhesive and caulk removers	Prohibit	Prohibit.
Industrial and commercial use in metal aerosol degreasers	Prohibit	Prohibit.
Industrial and commercial use in metal non-aerosol degreasers	Prohibit	Prohibit.
Industrial and commercial use in finishing products for fabric, textiles and leather	Prohibit	WCPP.
Industrial and commercial use in automotive care products (functional fluids for air conditioners).	Prohibit	Prohibit.
Industrial and commercial use in automotive care products (interior car care)	Prohibit	Prohibit.
Industrial and commercial use in automotive care products (degreasers)	Prohibit	Prohibit.
Industrial and commercial use in apparel and footwear care products	Prohibit	Prohibit.
Industrial and commercial use in spot removers for apparel and textiles	Prohibit	Prohibit.
Industrial and commercial use in liquid lubricants and greases	Prohibit	Prohibit.
Industrial and commercial use in spray lubricants and greases	Prohibit	Prohibit.
Industrial and commercial use in aerosol degreasers and cleaners	Prohibit	Prohibit.
Industrial and commercial use in non-aerosol degreasers and cleaners	Prohibit	Prohibit.
Industrial and commercial use in cold pipe insulations	Prohibit	Prohibit.
Industrial and commercial use as solvent that becomes part of a formulation or mixture.	Prohibit	WCPP.
Industrial and commercial use as a processing aid	Prohibit	WCPP.
Industrial and commercial use as a propellant and blowing agent	Prohibit	Prohibit.
Industrial and commercial use for electrical equipment, appliance, and component manufacturing.	Prohibit	WCPP.
Industrial and commercial use for plastic and rubber products manufacturing	Prohibit	WCPP.
Industrial and commercial use in cellulose triacetate film production	Prohibit	WCPP.
Industrial and commercial use as anti-spatter welding aerosol	Prohibit	Prohibit.
Industrial and commercial use for oil and gas drilling, extraction, and support activities.	Prohibit	WCPP.
Industrial and commercial use in toys, playground and sporting equipment	Prohibit	Prohibit.
Industrial and commercial use in carbon remover, wood floor cleaner, and brush cleaner.	Prohibit	Prohibit.
Industrial and commercial use in lithographic printing plate cleaner	Prohibit	Prohibit.
Consumer use as solvent in aerosol degreasers/cleaners	Prohibit[1]	Prohibit.[1]
Consumer use in adhesives and sealants	Prohibit[1]	Prohibit.[1]
Consumer use in brush cleaners for paints and coatings	Prohibit[1]	Prohibit.[1]
Consumer use in adhesive and caulk removers[1]	Prohibit[1]	Prohibit.[1]
Consumer use in metal degreasers	Prohibit[1]	Prohibit.[1]
Consumer use in automotive care products (functional fluids for air conditioners)	Prohibit[1]	Prohibit.[1]
Consumer use in automotive care products (degreasers)	Prohibit[1]	Prohibit.[1]
Consumer use in lubricants and greases	Prohibit[1]	Prohibit.[1]
Consumer use in cold pipe insulation	Prohibit[1]	Prohibit.[1]
Consumer use in arts, crafts, and hobby materials glue	Prohibit[1]	Prohibit.[1]
Consumer use in an anti-spatter welding aerosol	Prohibit[1]	Prohibit.[1]
Consumer use in carbon removers and other brush cleaners	Prohibit[1]	Prohibit.[1]
Manufacturing (Domestic manufacturing)	WCPP	WCPP.
Manufacturing (Import)	WCPP	WCPP.
Processing: processing as a reactant	WCPP	WCPP.
Processing: incorporation into a formulation, mixture, or reaction product	WCPP	WCPP.
Processing: repackaging	WCPP	WCPP.
Processing: recycling	WCPP	WCPP.
Industrial and commercial use as a laboratory chemical	WCPP	WCPP.
Disposal	WCPP	WCPP.

[1] Prohibit manufacture, processing, and distribution in commerce for the consumer use.

V. Rationale for the Proposed Regulatory and Primary Alternative Regulatory Actions

This Unit describes how the considerations described in Unit III.B.3. were applied when selecting among the TSCA section 6(a) requirements to arrive at the proposed and primary alternative regulatory actions described in Unit IV.A. and B.

A. Consideration of Risk Management Requirements Available Under TSCA Section 6(a)

1. Workplace Chemical Protection Program (WCPP)

One option EPA considered for occupational conditions of use was establishing a WCPP, which would include an ECEL and related required implementation measures, such as monitoring. As described in Unit IV.A.1., the WCPP for methylene chloride would be non-prescriptive, in the sense that owners and operators would not be required to use specific equipment or engineering controls prescribed by EPA to achieve the exposure concentration limit. Rather, a performance-based exposure limit would enable owners and operators to determine how to most effectively meet the exposure limits based on conditions at their workplace, aligned with the hierarchy of controls. However, due to the low exposure levels and stringent requirements in the WCPP necessary to address the unreasonable risk from methylene chloride, EPA identified only a relatively small number of conditions of use where the Agency expects the WCPP can be successfully implemented.

The central components of the WCPP are the ECEL and EPA STEL. EPA has determined as a matter of risk management policy that ensuring exposures remain at or below the ECEL and EPA STEL would eliminate any unreasonable risk of injury to health driven by inhalation exposures for occupational conditions of use subject to the WCPP.

In the case of methylene chloride, EPA has calculated the ECEL for methylene chloride to be 2 ppm (8 mg/m^3) for inhalation exposures as an 8-hour TWA in workplace settings, based on the chronic non-cancer human equivalent concentration for liver toxicity from inhalation exposures. This is the concentration at which an adult human, including a member of a susceptible subpopulation, would be unlikely to suffer adverse effects if exposed for a working lifetime (Ref. 11). EPA chose the chronic non-cancer liver toxicity endpoint as the basis for this exposure limit as it is the most sensitive of the endpoints identified, and therefore will be protective of both acute and chronic cancer inhalation endpoints over the course of a working day and lifetime.

However, the well-established and severe acute hazard identified for methylene chloride, from blurred vision to death, can be experienced in much shorter timeframes. Therefore, EPA determined a short-term exposure limit, or EPA STEL, of 16 ppm (57 mg/m^3) as a 15-minute TWA, based on the non-cancer endpoint of central nervous system depression resulting from acute exposures, was necessary in order to ensure the unreasonable risk was fully addressed in occupational settings (Ref. 11).

Once EPA identified the appropriate risk-based inhalation limits to address identified unreasonable risk, EPA carefully considered the appropriateness of such a program for each occupational condition of use of methylene chloride, in the context of the unreasonable risk.

Particular factors related to work activities that may make it difficult for certain conditions of use to comply with an ECEL are worth further discussion. One example includes work activities that may take place in the field, such as on-site paint removal or the use of adhesives in construction or renovation, making it challenging to establish a regulated area and conduct monitoring. In other contexts, the donning of air-supplied respirators would create challenges for movement and feasibility of work activities that may take place in small, enclosed spaces. Similarly, work activities that require a high range of motion or for some other reason could create challenges for the implementation of respiratory PPE are not good candidates for a WCPP, such as use as an anti-spatter welding aerosol, where use of a welding mask would impede the donning of an air-supplied respirator.

EPA also considered the feasibility of exposure reduction sufficient to address the unreasonable risk, even in facilities currently complying with the OSHA methylene chloride standard. While EPA acknowledges the regulated community's expected familiarity with OSHA PELs generally, as well as facilities' past and ongoing actions to implement the methylene chloride PEL and corresponding methods of compliance in OSHA's methylene chloride standard, EPA's exposure limits would be a full order of magnitude lower than the OSHA PEL. (The differences between the ECEL and EPA STEL and the OSHA PEL are discussed in more detail in Unit II.C.4.) This creates a significant amount of uncertainty as to the ability of facilities engaging in most industrial and commercial conditions of use to meet the ECEL and EPA STEL (and associated action levels) without relying on the use of PPE (or as discussed previously, if the nature of the activity precludes use of PPE required to meet such a level), and, therefore, whether exposures could be reduced in a manner aligned with the hierarchy of controls, because under that hierarchy PPE is considered a measure of last resort.

EPA understands that this uncertainty extends to the applicability of respirators as well. Although respirators, specifically SCBAs, could reduce exposures to levels that are protective of non-cancer and cancer risks, not all workers may be able to wear respirators. Individuals with impaired lung function due to asthma, emphysema, or chronic obstructive pulmonary disease, for example, may be physically unable to wear a respirator. OSHA requires that a determination regarding the ability to use a respirator be made by a physician or other licensed health-care professional, and annual fit testing is required for tight-fitting, full-face piece respirators to provide the required protection. Individuals with facial hair, such as beards or sideburns that interfere with a proper face-to-respirator seal, cannot wear tight fitting respirators. In addition, respirators may also present communication problems, vision problems, worker fatigue, and reduced work efficiency (63 FR 1152, January 8, 1998). According to OSHA, ''improperly selected respirators may afford no protection at all (for example, use of a dust mask against airborne vapors), may be so uncomfortable as to be intolerable to the wearer, or may hinder vision, communication, hearing, or movement and thus pose a risk to the wearer's safety or health'' (63 FR 1189 through 1190).

In contrast to considerations that would weigh against the likelihood of a facility within a condition of use to successfully implement WCPP, there are certain considerations that indicate a condition of use is a good fit for effective risk management via WCPP. Based on reasonably available information, including monitoring data, and information related to considerations described previously in this Unit, EPA's confidence that requirements to meet an ECEL and EPA STEL can be implemented is highest for highly standardized and industrialized settings, such as where methylene chloride is used in a closed system.

For example, one of the conditions of use for which EPA is proposing to require compliance with the WCPP is processing of methylene chloride as a reactant. A large volume of methylene chloride is processed for this condition of use, which almost entirely goes towards the manufacture of the hydrofluorocarbon HFC–32 (Refs. 3, 44). Monitoring data and exposure information submitted by industry, including by small entity representatives as part of the SBAR process, suggests that methylene chloride exposures in some facilities may already be below levels that would be consistent with the proposed ECEL (Refs. 6, 45, 46). Additionally, HFC–32 is one of the regulated substances identified in the AIM Act. Among other things, the AIM Act authorizes EPA to address listed HFCs in three main ways: phasing down HFC production and consumption through an allowance allocation program; facilitating sector-based transitions to next-generation technologies; and issuing certain regulations for purposes of maximizing reclamation and minimizing releases of HFCs and their substitutes from equipment and ensuring the safety of technicians and consumers. EPA anticipates that many entities currently using HFCs with higher global warming potential will transition to alternatives with lower global warming potential as requirements under the AIM Act take effect. HFC–32, while being one regulated substance subject to the overall phasedown in production and consumption of regulated substances under the AIM Act, is likely to be used to facilitate the transition from other HFCs and HFC blends with higher global warming potential in certain applications. By allowing for the continued, controlled use of methylene chloride in the manufacture of HFC–32, efforts to shift to chemicals with lower global warming potential would not be impeded by this rulemaking. Allowing this use to continue, subject to compliance with the WCPP, would complement industry's ongoing effort to abate the use of hydrofluorocarbons with higher global warming potential.

An additional strong candidate for WCPP is industrial and commercial use of methylene chloride as a laboratory chemical. Laboratory settings are expected to be more conducive to the implementation of engineering controls such as fume hoods to ventilate vapors and adequately reduce overall exposure to methylene chloride consistent with the hierarchy of controls.

For both these conditions of use (processing of methylene chloride as a reactant and industrial and commercial use as a laboratory chemical), the 2020 Risk Evaluation for Methylene Chloride indicates that only small reductions in exposure are needed for WCPP compliance. Based on analysis in the 2020 Risk Evaluation for Methylene Chloride describing expected exposures with and without use of PPE, EPA identified an air-supplied respirator of APF 25 as the minimum respiratory PPE that is sufficient to mitigate the unreasonable risk driven by both of these conditions of use (note for OSHA APF 25 is the minimum allowable respiratory PPE for methylene chloride, as filter and cartridge respirators are not protective against methylene chloride vapors). This suggested that, for these conditions of use, the reductions in exposure required to achieve a level that would not present unreasonable risk may be less than in other instances, which, together with other considerations previously described, including monitoring data indicating exposures near or below the ECEL, adds to EPA's confidence that facilities engaging in these two conditions of use could meet the WCPP requirements. Additionally, industrial and commercial use of methylene chloride as a laboratory chemical is necessary to provide for the analysis of monitoring samples required to demonstrate compliance with the WCPP under this proposed regulation.

An additional candidate for the WCPP is paint and coating removal from safety-critical, corrosion-sensitive components on military and Federal aviation. Regarding military aviation, as part of interagency collaboration with the DOD on the NPRM issued in January 2017 (Ref. 47), EPA was made aware that there are specific military uses for which methylene chloride is essential for paint and coating removal for which there are no suitable alternatives currently available (see further discussion in Unit V.B.). These consist of the use of methylene chloride for the removal of coatings from corrosion-sensitive components on military aviation, including safety-critical components made of specialty metallic, nonmetallic, and composite materials. More specifically, this includes components such as landing gear, gear boxes, turbine engine parts, and other military aircraft components composed of metallic materials (specifically high-strength steel, aluminum, titanium, and magnesium) and composite materials that require their coatings be removed for inspection and maintenance. Similarly, as stated by commenters on EPA's 2017 NPRM (Ref. 38), aircraft and other assets operated by DHS, NASA, and the FAA also contain safety-critical, corrosion-sensitive components of the type described by DOD, and suitable alternatives to methylene chloride are similarly not available for all applications.

As described further in Unit V.B., EPA concluded that under TSCA section 6(c)(2)(C) that technologically and economically feasible alternatives that benefit health or the environment would not be readily available as a substitute for these specific safety-critical uses on corrosion-sensitive components. However, under TSCA section 6(a), EPA must still address identified risks such that they are no longer unreasonable. EPA considered the appropriateness of the WCPP for this subset of activities under industrial or commercial use of methylene chloride for commercial paint and coating removal, and emphasizes that this consideration was made very narrowly for the use of methylene chloride for paint and coating removal for safety-critical, corrosion-sensitive components, and not for more general use of methylene chloride in paint and coating removal by Federal agencies or their contractors, or for aircraft or spacecraft paint and coating removal more broadly. Rather, EPA's consideration of the appropriateness of the WCPP takes into account the specifics of the components from which the coatings are being removed (and thus the lack of suitable alternatives for this particular subset of uses), and the relevant paint and coating removal processes. EPA notes that these activities are expected to take place in highly industrialized facilities in which regulated areas may already be established, for compliance with current regulations for methylene chloride or other chemicals, and that the paint and coating removal work in these facilities would not take place in small or enclosed spaces (rather, parts would frequently be removed for coating removal) (Ref. 48). Additionally, EPA considered whether exposures could feasibly be reduced sufficiently so that the risks were no longer unreasonable. To that end, during the risk evaluation for methylene chloride, DOD submitted additional monitoring data for their particular activities involving use of methylene chloride for paint and coating removal. EPA's risk evaluation shows that, in comparison with other uses of methylene chloride for paint and coating removal, the magnitude of exposure, and thus the risks, are much lower for DOD's specified use. More specifically, EPA's risk evaluation found that central tendency risks for DOD uses of methylene chloride for commercial

paint and coating removal do not exceed the acute or chronic non-cancer inhalation benchmarks, and high-end risks for those same endpoints could be addressed using the minimum allowable PPE for methylene chloride (Ref. 1). In addition to exposure reductions, EPA also considered whether other components of the WCPP could be effectively implemented, including development of exposure reduction plans, exposure monitoring, administrative controls, and workplace participation. During the development of this proposed rulemaking, discussions with DOD confirmed what was suggested by EPA's risk evaluation—that is, the remaining uses by DOD and other Federal agencies (*e.g.,* DHS, NASA, and FAA) of methylene chloride for paint and coating removal for safety-critical, corrosion-sensitive components are highly industrialized and take place in controlled settings with numerous protections for workers already in place. In this way, use of methylene chloride for the removal of coatings from corrosion-sensitive components on military aviation, including safety-critical components made of specialty metallic, nonmetallic, and composite materials resembles other uses of methylene chloride for which the WCPP is being proposed, such as laboratory use. EPA further expects that Federal and Federal contractor facilities are subject to multiple levels of oversight as a result of the governmental and public nature of their activities, while civilian aviation facilities are not likely to experience the same level of scrutiny. Federal Government procurement is also subject to the Federal Acquisition Regulations System in Title 49 of the CFR, which prescribes, among other things, health and environmental management and oversight requirements for Federal contracts. For this reason, EPA is proposing a WCPP for this particular subset of the methylene chloride commercial paint and coating remover condition of use. EPA requests comment and further information regarding the Agency's expectations that Federal and Federal contractor facilities would be subject to a higher level of oversight than non-Federal or contractor facilities, and that existing or expected controls would be successful in achieving the requirements of the WCPP.

Similarly, EPA has examined the use of methylene chloride as a bonding agent for acrylic and polycarbonate in mission-critical military and space vehicle applications by Federal agencies and their contractors (Ref. 43) and is proposing WCPP for this subset of the commercial use of methylene chloride in adhesives condition of use. Mission-critical applications potentially include fabrication of fixtures and enclosures for scientific research; production of optically clear articles such as space vehicle windows, space suit helmet components, or elements of extraterrestrial habitats; or sealing the plastic cases of specialty batteries.

A stakeholder that produces lithium and silver oxide zinc batteries described how they are used in critical energy storage applications in military and space exploration settings, including defense applications such as precision guided weapons, military airframes, satellites, space launch vehicles, and spacecraft. (The stakeholder also described use of these batteries in medical devices; EPA notes that the TSCA definition of ''chemical substance'' excludes, under TSCA section 3(2)(B)(vi), ''any food, food additive, drug, cosmetic, or device . . . when manufactured, processed, or distributed in commerce for use as a food, food additive, drug, cosmetic, or device.'' 15 U.S.C. 2602(2)(B)(vi). To the extent that bonding agents in the production of specialty batteries for medical applications qualify as a ''device'' as defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act, those particular uses that qualify as a ''device'' would be excluded from the ''chemical substance'' definition if ''manufactured, processed, or distributed in commerce for use as a . . . device,'' and would therefore not be subject to the rule if finalized). This stakeholder requested an exemption under TSCA section 6(g) for this use of methylene chloride. According to the requester, all major military and space applications, such as aircraft (F–35, B2), radios, and Mars mission equipment, require these batteries to function in very harsh conditions, including operation to −40 °C and storage at −54 °C.

Methylene chloride is used as a bonding agent for assembly of the plastic casings for these specialty batteries. The requester views the casing as a critical component of the battery because it houses and protects the cell anodes and cathodes. The requester explains that, during the solvent bonding process, methylene chloride dissolves the plastic slightly, allowing the polymers to form a physical bond comprised of the parent material. This results in a fully bonded battery casing which acts as a single Unit, rather than individual pieces integrated with layers of a different material. According to the requester, methylene chloride is a superior bonding agent for this process because of its unique evaporative qualities. In the requester's view, methylene chloride's low evaporation rate results in a higher degree of polymer bonding and a stronger casing, with less residue to inhibit the bonding process. The requester is not aware of any substance other than methylene chloride that would enable the production of battery casings of sufficient strength and durability for these specialty batteries. The requester further contends that the governmental and other entities for whom the requester produces these batteries prevent the substitution for methylene chloride in their contract specifications.

EPA's consideration of the lack of availability of technologically and economically feasible alternatives, pursuant to TSCA section 6(c)(2)(C), was one factor in the proposed determination not to prohibit manufacture, processing, distribution in commerce, and use of methylene chloride as a bonding agent for acrylic and polycarbonate in mission critical military and space vehicle applications, such as in the production of specialty batteries for use in such applications (Ref. 48) (discussed further in Unit V.B.). However, under TSCA section 6(a), EPA must still address identified risks such that they are no longer unreasonable. Based on information provided by NASA and the vendor, EPA determined that the production of these specialty batteries necessarily occurs in a highly industrialized and well-controlled environment, which EPA does not expect to be replicated for most uses of methylene chloride in general use adhesives. Such a highly industrialized and well-controlled environment would allow for establishment of a regulated area and effective monitoring. Additionally, EPA expects that, for this specific use, facilities would be able to successfully implement the WCPP, including exposure reduction to levels below which the unreasonable risk would not be present due primarily to the small quantities of methylene chloride used, as well as to the engineering and other controls in place. For example, in the vendor's process, ''methylene chloride is a component of the bonding cement that is moved through an entirely closed tubing system into a vented reservoir and vented enclosure for bonding and curing'' (Ref. 48). In this way, use of methylene chloride as a bonding agent in specialty batteries resembles other uses of methylene chloride for which the WCPP is being proposed such as laboratory use and paint and coating

removal by Federal agencies on safety-critical, corrosion-sensitive aircraft components. For this reason, EPA is proposing a WCPP for this particular subset of the methylene chloride commercial use in adhesives condition of use. EPA requests comment and further information regarding the Agency's expectations that the facilities in which this use is carried out are industrialized and highly controlled, and that existing or expected exposure reduction and workplace controls would be successful in achieving the requirements of the WCPP. EPA also notes that while the Agency is not aware of any similar use of methylene chloride as a bonding element for batteries for commercial spaceflight or other use, it requests comment and information on any such use.

For methylene chloride to be available for processing as a reactant and industrial and commercial use as a laboratory chemical, it must be manufactured (including imported), processed, and distributed in commerce. Likewise, as long as methylene chloride remains in use, it must also be disposed of. The manufacturing, processing, and disposal conditions of use for methylene chloride include, to some extent, the factors described earlier in this Unit favor the successful implementation of the WCPP (*e.g.,* they do not take place in the field (*i.e.,* they do not take place outside of a highly controlled environment) and are highly industrialized). Regulating upstream manufacturing and processing of methylene chloride is a key component of the supply-chain approach for risk management of commercial and consumer use of methylene chloride. Therefore, as discussed in Unit IV.A.1., EPA is proposing the WCPP for manufacture (including importing) and processing for certain uses, and disposal to ensure that workers are not subject to the unreasonable risk from methylene chloride as it moves throughout the supply chain.

Additionally, for methylene chloride, the strong precedent for dermal protection set by 29 CFR 1910.1052, in combination with the risk characterization in the 2020 Risk Evaluation for Methylene Chloride which indicated chemically resistant gloves, together with activity specific training are sufficient to address the unreasonable risk, led EPA to propose a dermal PPE requirement as part of the WCPP (Ref. 1).

As discussed in the Economic Analysis, there is some uncertainty relative to the burden of recycling and disposal facilities that would be required to implement a WCPP under this proposed regulation, particularly in implementing an air monitoring program. For example, disposal facilities may be receiving methylene chloride intermittently; however, facilities that currently receive methylene chloride-containing products or formulations for disposal may not receive methylene chloride in the future, as restrictions are finalized. As many of these facilities are small entities, EPA is requesting comment on what regulatory flexibilities (*e.g.,* extended compliance) may be afforded to entities that would continue to recycle and dispose of methylene chloride under the proposed regulation.

2. Prohibition

Because both EPA's 8-hour ECEL and 15-minute EPA STEL are significantly lower than the OSHA PEL and STEL, there is a high degree of uncertainty as to whether most industrial and commercial users will be able to comply with such a level and thus whether the unreasonable risk would be addressed. As discussed earlier in this Unit, this uncertainty, combined with the severity of the risks of methylene chloride and the prevalence of cost-effective alternative processes and products (Ref. 3), has led EPA to propose prohibitions, rather than compliance with the WCPP, for most industrial and commercial uses of methylene chloride, as outlined in Unit IV.A.2.

EPA also considered the potential for methylene chloride use to increase in particular sectors, such as vapor degreasing applications, where it has largely been phased out because of the well-established hazard (Refs. 3, 49). In order to prevent the potential for use of methylene chloride to increase in a sector that has already moved away from it, use of methylene chloride in vapor degreasing would be prohibited under the proposed regulatory and primary alternative regulatory action. The decline in use of methylene chloride was one of several considerations that led EPA to propose to prohibit use of methylene chloride in vapor degreasing.

Regarding industrial, commercial, and consumer uses of methylene chloride, TSCA section 6(a)(2) provides EPA with the authority to prohibit or otherwise restrict the manufacture (including import), processing, or distribution in commerce of a substance or mixture ''for a particular use'' to ensure that a chemical substance no longer presents unreasonable risk. For this rule, EPA proposes that ''for a particular use'' includes consumer use more broadly, as well as industrial and commercial use, which encompasses the individual industrial, commercial, and consumer uses evaluated in the 2020 Risk Evaluation for Methylene Chloride. Given the severity and ubiquitous nature of the risks identified in the 2020 Risk Evaluation for Methylene Chloride for all industrial, commercial, and consumer use, and noting that those conditions of use encompass all known, intended, and reasonably foreseen use of methylene chloride (other than use of methylene chloride in consumer paint and coating removers, which was subject to separate action under TSCA section 6 (84 FR 11420, March 27, 2019)), EPA proposes that prohibiting manufacture (including importing), processing, and distribution in commerce of methylene chloride for most industrial and commercial use and all consumer use is reasonable and necessary to eliminate the unreasonable risk of methylene chloride from industrial, commercial, and consumer use, including by precluding retailers from selling methylene chloride and methylene chloride-containing products to consumers for unspecified end-uses. (The proposed prohibitions would not extend to the use of methylene chloride in consumer paint and coating removers since manufacturing, processing, and distribution for that use are already prohibited.) EPA believes that any retailer selling methylene chloride-containing products to consumers for unspecified end-uses would be selling products for use by consumers for one of the consumer uses EPA evaluated in the 2020 Risk Evaluation for Methylene Chloride and found to drive the unreasonable risk for methylene chloride in the 2022 revised risk determination. EPA's proposed requirements to address unreasonable risk to consumers and bystanders to consumer use are described in Unit IV.A.

A key consideration regarding consumer uses is the role of retailers and other distributors. A retailer is defined in 40 CFR 751.103 as any entity that makes available a chemical substance or mixture to consumer end users, including through e-commerce internet sales or distribution, and is not specific to retailers of methylene chloride. Previously, in the 2019 methylene chloride TSCA section 6(a) risk management rulemaking addressing consumer use of methylene chloride in paint and coating removal (Ref. 37), EPA prohibited (*see* 40 CFR 751.105(c)) retailers from distributing in commerce paint and coating removers containing methylene chloride, as well as distribution to retailers under 40 CFR 751.105(b) (Ref. 37). To meet the same

goal of protecting consumers from accessing methylene chloride-containing products that could pose unreasonable risk, for a broader range of consumer use, EPA considered using a similar provision to ensure that retailers will not be able to purchase methylene chloride for sale or distribution to consumers, or to make available to consumers products containing methylene chloride. This provision aims to help prevent the use of methylene chloride in non-industrial settings or for off-label uses by consumers. For these reasons, as described in Unit IV.A.3., EPA's proposal to address unreasonable risk from methylene chloride includes prohibition on the distribution in commerce of methylene chloride to and by retailers.

3. Primary Alternative Regulatory Option

EPA acknowledges that for some of the occupational uses that it is proposing to prohibit, there may be some activities or facilities that could implement workplace protection requirements necessary to ensure that exposure remain below the ECEL and EPA STEL. In some cases, they may be able to undertake more extensive risk reduction measures than EPA currently anticipates. Therefore, for EPA's primary alternative regulatory action described in Unit IV.B., EPA is considering and requesting comment on a WCPP, including requirements to ensure exposures remain below an ECEL and EPA STEL, for some conditions of use of methylene chloride in addition to those conditions of use which are proposed to be subject to a WCPP under the proposed regulatory action (*i.e.,* those additional uses listed in Unit IV.B.). This includes conditions of use that have not resulted in documented acute fatalities, where reasonably available information suggests minimal ongoing use, where reasonably available information suggests use of methylene chloride may increase if other solvents are significantly restricted for that use such as for other solvents undergoing risk evaluation under TSCA section 6(b), and where the regulated entities may have fewer challenges implementing requirements to meet an ECEL and EPA STEL because work activities may occur in sophisticated facilities or take place in a closed system. The additional conditions of use which would be subject to WCPP under the primary alternative regulatory action described in this notice meet all of these criteria. However, EPA was not able to identify reasonably available information such as monitoring data or detailed activity descriptions to indicate with certainty that relevant regulated entities for these conditions of use could sufficiently mitigate identified unreasonable risk through a WCPP. Due to this uncertainty, EPA is requesting comment on the ways in which methylene chloride may be used in the additional conditions of use that would be subject to a WCPP under the primary alternative regulatory action, and the degree to which users of methylene chloride in these sectors could successfully implement the WCPP, including requirements to meet an ECEL and EPA STEL, as described in Unit IV.A.1., for the conditions of use listed for the primary alternative regulatory action in Unit IV.B.

Additionally, As discussed in Unit V.A.1. and 2., EPA acknowledges that for the occupational uses for which it is proposing the WCPP, there are varying degrees of uncertainty as to whether industrial and commercial owners and operators are able implement workplace protection requirements necessary to ensure that exposures remain below the ECEL and EPA STEL. For this reason, EPA's alternative regulatory action would prohibit two uses for which EPA is proposing the WCPP (industrial or commercial use for paint and coating removal from safety-critical, corrosion-sensitive components of aircraft and spacecraft by Federal agencies and their contractors; and industrial or commercial use as a bonding agent in the production of specialty batteries for military or space applications by Federal agencies and their contractors). Because of the importance of these uses for national security and critical infrastructure, EPA's alternative regulatory action would include a time-limited exemption under TSCA section 6(g) from the prohibition for these two uses, for a period of 10 years, during which time the regulated entity would comply with a WCPP to the extent practicable. The analyses for these exemptions are in Unit IV.B.

4. Risk Management Requirements Considered but Not Proposed

Since it is unlikely that all facilities with occupational exposures to methylene chloride would be able to implement a WCPP, including requirements to meet an ECEL and EPA STEL, EPA also examined the extent to which a certification and limited access program restricting methylene chloride use to trained and licensed users could ensure that only certain workers employed by a facility would be able to purchase and subsequently use methylene chloride. Under a limited access program, entities would submit a self-certification to the distributor at the point of purchasing the products. The self-certification could consist of a statement indicating that the facility is implementing a WCPP to control exposures to methylene chloride, as well as a connection between the purchaser and the facility (*e.g.,* a current employee). As discussed earlier in this Unit, because of the severity of acute risks from methylene chloride which could potentially lead to fatalities, and the high potential for diversion of commercial products of methylene chloride for non-commercial use, EPA has significant concerns regarding the appropriateness of a certification and limited access program for methylene chloride. These concerns are supported by previous comments received as part of public comments on the Advance Notice of Proposed Rulemaking for Methylene Chloride Commercial Paint and Coating Removal: Training, Certification and Limited Access Program expressing unease in implementing a training, certification and limited access program for methylene chloride (Ref. 50).

Several commenters on the Advance Notice of Proposed Rulemaking for Methylene Chloride Commercial Paint and Coating Removal: Training, Certification and Limited Access Program identified what they believe would be insufficiencies in training, certification, and limited access to methylene chloride (Ref. 50). Commenters expressed concerns that this type of program would not provide enough safeguards and would not eliminate unreasonable risk to workers. Commenters were skeptical of a training program's efficacy noting that deaths related to methylene chloride exposure still occurred with workers who were trained and wearing PPE (Ref. 50).

Several commenters believed that a training, certification, and limited access program would not be feasible. A commenter suggested that an effective training model to examine is the Alaska Hazardous Paint Certification program, which includes hands-on training and practice in local exhaust ventilation techniques and equipment and PPE gloves, clothing, and respirators. In the Alaskan program, a minimum of 16 hours for initial training, with at least 6 hours of hands-on training as well as 8-hour refresher class every 3 years, are necessary requirements. Moreover, commenters expressed that a robust training, certification, and limited access program would include multiple layers of training and certification and supporting documentation. A commenter also highlighted that ''small businesses do not have the same resources for implementing safety

programs as larger ones, yet they account for a very large percentage of [methylene chloride] users.'' In light of these comments, EPA decided to account for uncertainty related to ECEL implementation and compliance for certain uses by proposing prohibitions on those uses, rather than proposing a self-certification and limited access program. Nonetheless, EPA is requesting comment on the inclusion of a certification, training, and limited access program for any uses that would be subject to a WCPP, in addition to the requirements outlined in Unit IV.A.1.

Another option that EPA considered for occupational conditions of use was requiring specific, prescribed engineering controls, administrative controls, or PPE to reduce exposures to methylene chloride in occupational settings. These prescriptive requirements would be supported by information in the 2020 Risk Evaluation for Methylene Chloride. As described in Units III.A.1. and 2., EPA received input during required consultations and additional engagement that options that align with the hierarchy of controls (*i.e.,* elimination and substitution of hazards in the workplace), which could be accomplished through the implementation of a WCPP with a risk-based exposure limit, should be preferred over prescriptive controls (*Refs. 9, 51*). Inadequacy of engineering, administrative, and PPE control measures to lower exposure below the exposure limit would mean that elimination or substitution would be the only viable methods of addressing unreasonable risk, creating in effect a de-facto prohibition. Additionally, prescriptive controls present significant uncertainties related to their feasibility and consistency of proper use.

EPA determined that such prescriptive controls (*i.e.,* engineering or administrative controls, or PPE) may not be able to eliminate unreasonable risk for some conditions of use when used in isolation. In the 2020 Risk Evaluation for Methylene Chloride, many conditions of use still drive the unreasonable risk even with the application of air-supplied APF 50 respirators (Ref. 1). Additionally, where data were reasonably available, EPA modeled the change in air rates that would be needed to eliminate unreasonable risk and found that in some cases it was not possible to eliminate unreasonable risk with changes in airflow alone, while in other cases the change in airflow needed would not be feasible to achieve (Ref. 1). Because of the uncertainty regarding the feasibility of exposure reductions through prescriptive controls alone, EPA determined that a WCPP, including requirements to meet an ECEL and EPA STEL (which would be accompanied by monitoring requirements) in tandem with the implementation of engineering controls, administrative controls, and/or PPE as elements of the program, as appropriate, would more successfully reduce exposure so that the unreasonable risk is addressed. For occupational conditions of use where compliance with the WCPP is unlikely to eliminate the unreasonable risk driven by those conditions of use, prohibitions (rather than prescribed controls) would be more appropriate to ensure that methylene chloride does not present unreasonable risk under the conditions of use.

EPA also considered limiting the weight fraction of methylene chloride in consumer products and conducted an analysis using the Consumer Exposure Models for the 2020 Risk Evaluation for Methylene Chloride to estimate whether this would reduce risks from consumer conditions of use that drive the unreasonable risk for methylene chloride, such that they no longer drive the unreasonable risk (Ref. 52). For all consumer conditions of use, the weight fraction or concentration identified through this modeling that would address the unreasonable risk through inhalation or dermal pathways was so low that it was highly unlikely that methylene chloride would still serve its functional purpose in the formulation. EPA thus concluded that a weight fraction limit would essentially function as a prohibition yet with a greater amount of uncertainty regarding compliance and no increased benefit to consumer users; it was therefore not a preferred option for consumer uses. (Refs. 1, 52).

5. Additional Considerations

After considering the different regulatory options under TSCA section 6(a), alternatives (described in Unit III.B.4.), compliance dates, and other requirements under TSCA section 6(c), EPA developed the proposed regulatory action described in Unit IV.A. to address the unreasonable risk from methylene chloride. To ensure successful implementation of this proposed regulatory action, EPA considered other requirements to support compliance with the proposed regulations, such as requiring monitoring and recordkeeping to demonstrate compliance with the WCPP, or downstream notification regarding the prohibition on manufacturing, processing, and distribution in commerce of methylene chloride, and products containing methylene chloride, for consumer use. These proposed requirements are described in Unit IV.A.

Under TSCA section 6(g)(1)(B), EPA may grant an exemption from a requirement of a TSCA section 6(a) rule for a specific condition of use of a chemical substance or mixture if compliance with the requirement would significantly disrupt the national economy, national security, or critical infrastructure. Based on reasonably available information, EPA has found that a TSCA section 6(g) exemption is warranted for certain uses. Therefore, EPA is proposing to grant exemptions from the rule requirements under TSCA section 6(g), as detailed in Unit IV.A.5. Unit IV.A.5. also provides a description of the request for exemption from the rule requirements that EPA is not proposing to grant. TSCA section 6(g) assumes a particular use cannot continue such that the risks are no longer unreasonable. However, EPA notes that information may be provided during the public comment period indicating this may not be case. For example, new information may demonstrate compliance with a WCPP is possible.

As required under TSCA section 6(d), any rule under TSCA section 6(a) must specify mandatory compliance dates, which shall be as soon as practicable with a reasonable transition period, but no later than 5 years after the date of promulgation of the final rule (except in the case of a use exempted under TSCA section 6(g)). For ban or phase-out requirements, EPA must specify mandatory compliance dates for the start of ban or phase-out requirements, which must be as soon as practicable but no later than 5 years after the date of promulgation of the final rule (except in the case of a use exempted under TSCA section 6(g)), and for full implementation of ban or phase-out requirements, which must be as soon as practicable. These compliance dates are detailed in Unit IV.A. and IV.B.

B. Consideration of Alternatives in Deciding Whether To Prohibit or Substantially Restrict Methylene Chloride

Under TSCA section 6(c)(2)(C), in deciding whether to prohibit or restrict in a manner that substantially prevents a specific condition of use of a chemical substance or mixture, and in setting an appropriate transition period for such action, EPA must consider, to the extent practicable, whether technically and economically feasible alternatives that benefit human health or the environment, compared to the use so proposed to be prohibited or restricted,

will be reasonably available as a substitute when the proposed prohibition or other restriction takes effect. To that end, in addition to an Economic Analysis (Ref. 3), EPA conducted an Alternatives Assessment, using reasonably available information (Ref. 40).

For this assessment, EPA identified and analyzed alternatives to methylene chloride in products relevant to industrial, commercial, and consumer conditions of use proposed to be prohibited or restricted, even if such restrictions are not anticipated to substantially prevent the condition of use. EPA is aware of the lack of viable alternatives to methylene chloride for several conditions of use and considered that information to the extent practicable in the development of the regulatory options as described in Unit III.B.3.

As an example, EPA's consideration of the lack of viable alternatives to processing methylene chloride in the manufacture of HFC–32 taken in context with the risk estimates, monitoring data, and expected work practices informed EPA's proposed approach of WCPP for this condition of use. Similarly, when proposing WCPP for industrial or commercial use of methylene chloride for paint and coating removal from mission- and safety-critical, corrosion sensitive components of aircraft and spacecraft by Federal agencies or their contractors, EPA considered how the safety-critical, corrosion-sensitive components would be so negatively affected by the use of technically incompatible, substitute paint removal chemicals or methods that the safe performance of the aircraft could be compromised. There are no known substitutes for methylene chloride for this particular use. As discussed in the preamble to the 2017 NPRM, DOD has actively sought to reduce its use of methylene chloride in paint and coating removal since 1990. DOD has replaced most of its usage of methylene chloride for paint and coating removal with mechanical methods, benzyl alcohol products, other solvents, and laser ablation. In an effort to reduce the use of all hazardous air pollutants (HAPs) such as methylene chloride, the Army has conducted tests to identify and test the effectiveness of HAP-free paint and coating removers on military high-performance coatings (Ref. 53). In another example, the Air Force in December 2015 significantly reduced the use of methylene chloride for removing coatings on flight control parts and is now using substitute chemical products, primarily those with benzyl alcohol formulations (Ref. 48). Similarly, the Navy has transitioned substitutes to paint methylene chloride use when alternatives with equal performance are identified. For DOD, this evaluation of and transition to safer alternatives is ongoing and substitutions are approved where technically feasible and commensurate with performance and mission-readiness requirements.

DOD continues to pursue potential substitutes for methylene chloride. However, for safety-critical, corrosion-sensitive components on military aviation, including safety-critical components, DOD has found that currently available substitute chemicals for paint and coating removal have one or more technical limitations. These include the inability to effectively remove specific military high performance or chemical resistant coatings and incompatibility with underlying metallic, nonmetallic, and composite materials, resulting in material damage to critical components. In addition, substitute chemicals or methods currently available do not support DOD's need for coating removers that enable critical safety inspection, non-destructive inspection, material assessment, or field repair processes. For example, benzyl alcohol has replaced methylene chloride in many DOD paint and coating removal applications. However, acid benzyl alcohol formulations, which work more quickly than alkaline formulations, cannot be used on high-strength steel or magnesium metals because there is the potential for resulting hydrogen embrittlement (Ref. 54). In DOD's experience, the alkaline benzyl alcohol formulations require 25 to 50% more time than methylene chloride and are more labor-intensive, particularly on very thick coatings or polyurethane coatings with water-based primers (Ref. 54). In addition, the reaction rate for alkaline benzyl alcohol formulations is very slow when the temperature is below 65 degrees, so paint and coating removal in cold locations with this alternative must be performed in a heated area (Ref. 54). As described earlier in Unit V.A.1., aircraft and other assets operated by DHS, NASA, and the FAA also contain safety-critical, corrosion-sensitive components of the type described by DOD, and suitable alternatives to methylene chloride are similarly not available for all applications. Substitute chemicals for paint and coating removal for safety-critical, corrosion-sensitive components are not technically feasible as they have one or more technical limitations; are incompatible with underlying materials; and/or do not support the coating removal requirements of safety inspections, non-destructive inspection, material assessment, or field repair processes. Therefore, EPA has evaluated the effect that a significant restriction on the use of methylene chloride would have for industrial and commercial paint and coating removal by DOD, DHS, NASA, and FAA and concluded that under TSCA section 6(c)(2)(C) that technologically and economically feasible alternatives that benefit health or the environment would not be readily available as a substitute. Due to the essential nature of this subset of activities under industrial or commercial use of methylene chloride as a paint and coating remover, EPA's consideration of the availability of technologically and economically feasible alternative was one factor in the proposed determination not to prohibit manufacture, processing, distribution in commerce, and use of methylene chloride for paint and coating removal for safety-critical, corrosion sensitive components.

As an additional example, EPA considered the information provided regarding a lack of viable alternatives for the use of methylene chloride in chemical bonding of acrylic and polycarbonate, specifically for specialty batteries for use in military and space applications. As described earlier in Unit V.A., EPA received information from a stakeholder, as part of a request for an exemption under TSCA section 6(g), describing how methylene chloride is uniquely suited as a bonding agent for these specialty batteries. Upon receipt of the TSCA section 6(g) exemption request summarized in this unit, EPA consulted with NASA, and NASA provided information on its effort to screen alternative adhesives for the chemical bonding of acrylic and polycarbonate. Specifically, NASA identified ten materials and completed screening-level testing for six of those ten materials as of the publication of this proposed rule. Results submitted to EPA indicate that none of the materials tested met the technical requirements for chemical bonding applications (Ref. 47). While vendors submitting the TSCA section 6(g) exemption request predicted a timeline of at least one year to find a replacement for the bonding agent for specialty batteries, NASA noted that the projected substitution timeline applies only to the vendor's own battery production process. The total timeline, including qualification testing for human spaceflight, is a complex, multi-year process that could only begin after the vendor's substitution was completed.

NASA additionally emphasized that losing access to qualified high-performance substances such as specialty batteries would have immediate effects for currently ongoing space-flight programs, including the Artemis Program, with the potential to introduce an unacceptable level of risk to crew, vehicle, and viability of the program. Qualification of materials for human spaceflight can take years and significant resources to accomplish, while potentially impacting program production schedule and launch manifest.

NASA has emphasized that specific Artemis components have been designed to work with the identified specialty batteries with polycarbonate casing bonded using methylene chloride. The safety and reliability of these batteries has been established in uncrewed Artemis I test missions, and the next flights will take humans back to the Moon. A change of battery material would require recertification of multiple hardware pieces, retesting of crew and vehicle safety, and disrupt parts production and launch schedules that are already underway. NASA notes that stockpiling of batteries would not be an option, as batteries have a 2-year shelf life.

For this use, EPA has concluded under TSCA section 6(c)(2)(C) that technologically and economically feasible alternatives that benefit health or the environment would not be readily available as a substitute. Due to the essential nature of this subset of activities under industrial or commercial use of methylene chloride as an adhesive, a paint and coating remover, EPA's consideration of the availability of technologically and economically feasible alternative was one factor in the proposed determination not to prohibit manufacture, processing, distribution in commerce, and use of methylene chloride as a bonding agent in the production of specialty batteries for use in military and space applications.

EPA also notes that, for some conditions of use, EPA was unable to identify products currently available for sale that contain methylene chloride. EPA is soliciting comments on whether there are actually products in use or available for sale relevant to these conditions of use that contain methylene chloride at this time, so that EPA can ascertain whether there are alternatives that benefit human health or the environment. These conditions of use are detailed in the Alternatives Assessment (Ref. 40).

For conditions of use for which products currently containing methylene chloride were identified, EPA identified several hundred commercially available alternative products that do not contain methylene chloride, and listed in the Alternatives Assessment, to the extent practicable, their unique chemical components, or ingredients. For each of these chemical components or ingredients, EPA identified whether it functionally replaced methylene chloride for the product use and screened product ingredients for human health and environmental hazard, as well as identified flammability and global warming potential where information was reasonably available (Ref. 40). EPA then assigned a rating to the human health and environmental hazards, using a methodology described in the Alternatives Assessment document. EPA identified 65 total alternative products in the paint and coating remover category, of which furniture refinishing is a subcategory (Ref. 48). As described in the Economic Analysis, while not all of these alternative products may meet the specific use for some furniture refinishing uses, mechanical or thermal methods may be non-chemical alternatives to using products containing methylene chloride for paint and coating removal. EPA did not find barriers to pricing, customer satisfaction, coating removal performance, or content (specifically volatile organic compounds, or VOC) that may be caused by restricting the use of methylene chloride in this product category in general. For fire safety, the restriction of methylene chloride in this product category is met by products with very high flash points, or products with evaporation barriers that restrict vapor generation (Ref. 3). Therefore, EPA finds that there are technological and economically feasible alternatives in the marketplace.

In general, EPA identified products containing ingredients with a lower hazard screening rating than methylene chloride for certain endpoints, while some ingredients presented higher hazard screening ratings than methylene chloride (Ref. 40). These alternative hazard screening ratings are described in detail in the Alternatives Assessment grouped under common product use categories (Ref. 40). EPA has therefore, pursuant to TSCA section 6(c)(2)(C), considered, to the extent practicable, whether technically and economically feasible alternatives that benefit human health or the environment, compared to the use proposed to be prohibited or restricted, will be reasonably available as a substitute when the proposed prohibition or other restriction becomes effective. EPA is additionally requesting comment on the alternatives analysis as a whole.

VI. TSCA Section 6(c)(2) Considerations

A. Health Effects of Methylene Chloride and the Magnitude of Human Exposure to Methylene Chloride

EPA's analysis of the health effects of methylene chloride is in the 2020 Risk Evaluation for Methylene Chloride (Ref. 1). A summary is presented here.

The 2020 Risk Evaluation for Methylene Chloride identified six non-cancer adverse health effects: effects from acute/short-term exposure, liver effects, immune system effects, nervous system effects, reproductive/developmental effects, and irritation/burns (Ref. 1). The 2020 Risk Evaluation for Methylene Chloride also identified cancer hazards from carcinogenicity as well as genotoxicity, particularly for liver and lung tumors (Ref. 1).

Among the non-cancer adverse health effects, the 2020 Risk Evaluation for Methylene Chloride identified neurotoxicity indicative of central nervous system depression as a primary effect of methylene chloride in humans following acute inhalation exposures (Ref. 1). Identified central nervous system depressive symptoms include drowsiness, confusion, headache, dizziness, and neurobehavioral deficits when performing various tasks. Central nervous system depressant effects can result in loss of consciousness and respiratory depression, possibly resulting in irreversible coma, hypoxia, and eventual death (Ref. 1).

Additionally, the 2020 Risk Evaluation for Methylene Chloride identified the liver as a sensitive target organ for inhalation exposure (Ref. 1). For human health risks to workers and consumers, EPA identified cancer and non-cancer human health risks. Risks from acute exposures include central nervous system risks such as central nervous system depression and a decrease in peripheral vision, each of which can lead to workplace accidents and are precursors to more severe central nervous system effects such as incapacitation, loss of consciousness, coma, and death. For chronic exposures, EPA identified risks of non-cancer liver effects as well as liver and lung tumors (Ref. 1).

The 2020 Risk Evaluation for Methylene Chloride also identified several irritation hazards from methylene chloride exposure. Following exposures to methylene chloride vapors, irritation has been observed in the respiratory tract and eyes. Direct contact with liquid methylene chloride on the

skin has caused chemical burns in workers and gastrointestinal irritation in individuals who accidentally ingested methylene chloride (Ref. 1).

Regarding the magnitude of human exposure, one factor EPA considers for the conditions of use that drive unreasonable risk is the size of the exposed population, which, for methylene chloride, EPA estimates is 785,000 workers, 135,000 occupational non-users, and 15 million consumers (Ref. 1).

In addition to these estimates of numbers of workers, occupational non-users, consumers, and bystanders to consumer use directly exposed to methylene chloride, EPA recognizes there is exposure to the general population from air and water pathways for methylene chloride. (While bystanders are individuals in proximity to a consumer use of methylene chloride, fenceline communities are a subset of the general population who may be living in proximity to a facility where methylene chloride is being used in an occupational setting). As mentioned in Unit II.D., EPA has separately conducted a screening approach to assess whether there may be risks to the general population from these exposure pathways. While the use of this screening approach indicates some level of risk to fenceline communities, EPA cannot determine, without further data and quantitative analysis, whether the risk to these communities would be an unreasonable risk. This Unit summarizes the results of that fenceline analysis. Although EPA is not making a determination of unreasonable risk based on the fenceline screening analysis, the proposed regulatory action described in Unit IV. is expected to reduce the risks identified in the screening approach.

As described in Unit II.D., EPA's analysis was presented to the SACC peer review panel in March 2022, and EPA plans to consider SACC feedback (including the SACC recommendation to EPA to consider multiple years of release data to estimate exposures and associated risks) and make decisions regarding how to assess general population exposures in upcoming risk evaluations, such as for 1,4-dioxane and for the forthcoming 20 High Priority Substances. For methylene chloride, EPA recognizes that a key input into the fenceline assessment was data on releases from the most recent Toxics Release Inventory (TRI) reporting year and that the use of more than one year of data could result in different conclusions. Accordingly, in this Unit EPA presents the results of its analysis of the extent to which including more than one year of TRI data impacts EPA's conclusions regarding fenceline risks (Ref. 55).

EPA's fenceline analysis for the water pathway for methylene chloride, based on methods presented to the SACC, did not find risks from incidental oral and dermal exposure to surface water, and while EPA found one facility which indicated acute risk from drinking water, additional assessment of this location identified that there are no source drinking water intakes for public drinking water systems in proximity to the facility estimated to have risk, thereby making risks to the general population through the drinking water pathway unlikely.

Additionally, EPA's analysis, as presented to the SACC, identified 14 facilities, representing nine conditions of use, with some indication of expected exposure and associated cancer risk to receptors within select distances evaluated from 5 to 100 meters from the inhalation pathway. Those nine conditions of use are: industrial and commercial use in non-aerosol degreasers and cleaners; industrial and commercial use as a solvent for in-line vapor degreasing; industrial and commercial use as a solvent for cold cleaning; industrial and commercial use in aerosol spray degreasers and cleaners; industrial and commercial use in cellulose triacetate film production; industrial and commercial use in plastic and rubber product manufacturing; processing: incorporation into a formulation, mixture, or reaction product; industrial and commercial use as a propellant and blowing agent; and industrial and commercial use in paint and coating removers. Under the proposed regulatory action described in Unit IV.A., all of the conditions of use with an indication of risk from 5 to 100 meters would be prohibited, with the exception of processing: incorporation into a formulation, mixture, or reaction product.

Of those 14 facilities with indicated risk, only three had an indication of risk out to 100 meters from a releasing facility. Those three facilities represent three total conditions of use: industrial and commercial use in non-aerosol degreasers and cleaners; industrial and commercial use for plastic product manufacturing; and industrial and commercial use as a propellant and blowing agent. Under the proposed regulatory action described in Unit IV.A., these three conditions of use, as well as all of the conditions of use with an indication of risk at 5 to 100 meters would be prohibited, with the exception of processing: incorporation into a formulation, mixture, or reaction product.

Following SACC feedback, EPA applied a slightly modified pre-screening methodology to evaluate 6 years of methylene chloride release data (2015 through 2020 Toxic Release Inventory data as well as the 6-year average of that data) for those 14 facilities where there was an indication of exposure and associated risk via the ambient air pathway. The multi-year analysis further supported EPA's findings (indications of exposure and associated risks) from the original analysis for five of the 14 facilities, representing four conditions of use, which indicated exposure and associated risk at 100 meters from a releasing facility. Those four conditions of use are: processing: incorporation into a formulation, mixture, or reaction product; industrial and commercial use in non-aerosol degreasers and cleaners; industrial and commercial use for plastic product manufacturing; and industrial and commercial use as a propellant and blowing agent. For the additional nine facilities, the multi-year analysis did not indicate risks at 100 meters. The multi-year analysis incorporated 6 years of TRI data and found that while the annual releases may vary by as much as a factor of 10, the overall estimated exposure concentrations and associated risk calculations varied by no more than three times. Additionally, typical cancer benchmarks used by EPA and other regulatory agencies are an increased cancer risk above benchmarks ranging from 1 in 1,000,000 to 1 in 10,000 (*i.e.,* 1×10^{-6} to 1×10^{-4}), in some cases depending on the subpopulation exposed. (see, *e.g.,* EPA's interpretation set forth in 54 FR 38044, September 14, 1989) which discusses the use of benchmarks for purposes of section 112 of the Clean Air Act (CAA); see also EPA's interpretation of the upper bound of acceptable risk and the preferred benchmark described in the Letter of Concern regarding EPA Complaint Nos. 01R–22–R6, 02R–22–R6, and 04R–22–R6 see page 3 footnotes 5 and 6 and page 6 (Ref. 56)). In this fenceline analysis for the ambient air pathway for methylene chloride, estimates of risk to fenceline communities were calculated using 1×10^{-6} as the benchmark for cancer risk in fenceline communities. While EPA is unable to determine, based on the screening level fenceline analysis, whether risks to the general population drive the unreasonable risk, as a matter of risk management policy EPA considers the range of 1×10^{-6} to 1×10^{-4} as the appropriate benchmark

for increased cancer risk for the general population, including fenceline communities. It is preferable to have the air concentration of methylene chloride result in an increased cancer risk closer to the 1×10^{-6} benchmark, with the 1×10^{-4} benchmark generally representing the upper bound of acceptability for estimated excess cancer risk. The benchmark value is not a bright line, and the Agency considers a number of factors when determining unreasonable risk, such as the endpoint under consideration, the reversibility of effect, exposure-related considerations (*e.g.,* duration, magnitude, or frequency of exposure, or population exposed). Under the proposed regulatory action described in Unit IV.A., all of the conditions of use with an indication of risk at 100 meters would be prohibited, with the exception of processing: incorporation into a formulation, mixture, or reaction product.

Although the initial analysis presented to SACC and the multi-year analysis conducted in response to SACC feedback for methylene chloride indicated exposure and associated risks to select receptors within the general population at particular facilities, EPA is unable to formally determine with this analysis whether those risks drive the unreasonable risk. However, EPA believes that the prohibitions being proposed for manufacturing (including importing), processing, and distribution in commerce for 45 of 53 uses, including all consumer use and most commercial use, would address the majority of exposures to the general population. Of the 14 facilities which indicated some risk for methylene chloride, under the proposed regulatory option, only 3 could continue to use methylene chloride (all for processing: incorporation into formulation, mixture, or reaction product), and thus exposures to the fenceline at the remainder of those facilities would be addressed.

Under the proposed rule, only ten conditions of use would continue, namely domestic manufacturing (for downstream uses that would continue under the WCPP); import; processing as a reactant; processing: incorporation into a formulation, mixture, or reaction product; processing as repackaging; processing as recycling; industrial and commercial use as a laboratory chemical; industrial or commercial use in aerospace and military paint and coating removal from safety-critical, corrosion-sensitive components by Federal agencies and their contractors, industrial or commercial use as a bonding agent for acrylic and polycarbonate in mission-critical military and space vehicle applications, including in the production of specialty batteries for such by Federal agencies and their contractors, and disposal. Of those conditions of use, only processing: incorporation into formulation, mixture, or reaction product has risk indicated at the fenceline, and based on land use analysis, there do not appear to be communities currently located at the fencelines (Ref. 57). Additionally, over time this condition of use can reasonably be expected to decline because, while processing into a formulation, mixture, or reaction product would continue under a WCPP, all downstream distribution and use of formulations, mixtures, or reaction products (except for laboratory use and any time limited exemptions that could be established under TSCA section 6(g)) would be prohibited.

For all ten conditions of use that would remain ongoing, the proposed rule would require exposure controls via implementation of a WCPP as described in Unit IV.A.1. In the instances where efforts to reduce exposures in the workplace to levels below the ECEL and EPA STEL could lead to adoption of engineering controls that ventilate more methylene chloride outside, EPA believes this potential exposure would be limited as a result of the existing National Emission Standards for Hazardous Air Pollutants (NESHAPs) for methylene chloride for these conditions of use under the CAA (applicable NESHAPs: 40 CFR part 63 subpart F, Synthetic Organic Chemical Manufacturing Industry; 40 CFR part 63 subpart DD, Off-Site Waste and Recovery Operations; 40 CFR part 63 subpart VVV, Publicly Owned Treatment Works; and 40 CFR part 63 subpart VVVVVV, the NESHAP for Chemical Manufacturing Area Sources) and that any exceedances are an enforcement issue. Thus, EPA's proposal to prohibit manufacture, processing, and distribution in commerce of methylene chloride for all consumer use and most industrial and commercial use, and to prohibit most industrial and commercial use of methylene chloride, is expected to largely address the risks identified in the screening analysis to any general population or fenceline communities close to facilities engaging in methylene chloride use. EPA therefore does not intend to revisit the air pathway for methylene chloride as part of a supplemental risk evaluation.

B. Environmental Effects of Methylene Chloride and the Magnitude of Environmental Exposure to Methylene Chloride

EPA's analysis of the environmental effects of and the magnitude of exposure of the environment to methylene chloride is in the 2020 Risk Evaluation for Methylene Chloride (Ref. 1). The unreasonable risk determination for methylene chloride is based solely on risks to human health; based on the 2020 Risk Evaluation for Methylene Chloride, EPA determined that exposures to the environment did not drive the unreasonable risk.

For all conditions of use, the unreasonable risk determination is not driven by exposures via water for acute and chronic exposures to methylene chloride for amphibians, fish, and aquatic invertebrates. To characterize aquatic organisms' exposure to methylene chloride, modeled data were used to represent surface water concentrations near facilities actively releasing methylene chloride to surface water, and monitored concentrations were used to represent ambient water concentrations of methylene chloride. EPA considered the biological relevance of the species to determine the concentrations of concern for the location of surface water concentration data to produce risk quotients, as well as frequency and duration of the exposure. While some site-specific risk quotients, calculated from modeled release data from facilities conducting recycling, disposal, and wastewater treatment plant activities, indicated risk, uncertainties in the analysis were considered. These uncertainties include limitations in data, since monitoring data were not available near facilities where methylene chloride is released, and data incorporated from the Toxics Release Inventory, which does not include release data for facilities with fewer than ten employees. As an additional uncertainty, the model does not consider chemical fate or hydrologic transport properties and may not consider dilution in static water bodies. Additional analysis indicated that model outputs, rather than monitoring estimates, may best represent concentrations found at the point of discharge from the facilities (Ref. 1).

The toxicity of methylene chloride to sediment-dwelling invertebrates is similar to its toxicity to aquatic invertebrates. Methylene chloride is most likely present in the pore waters and not absorbed to the sediment organic matter because methylene chloride has low partitioning to organic matter. The concentrations in sediment

pore water are similar to or less than the concentrations in the overlying water, and concentrations in the deeper part of sediment are lower than the concentrations in the overlying water. Therefore, the risk estimates, based on the highest ambient surface water concentration, do not support an unreasonable risk determination to sediment-dwelling organisms from acute or chronic exposures. There is uncertainty due to the lack of ecotoxicity studies specifically for sediment-dwelling organisms and limited sediment monitoring data (Ref. 1).

Based on its physical-chemical properties, methylene chloride does not partition to or accumulate in soil. Therefore, the physical chemical properties of methylene chloride do not support an unreasonable risk determination to terrestrial organisms.

C. Benefits of Methylene Chloride for Various Uses

Methylene chloride is a solvent used in a variety of industrial, commercial, and consumer use applications, including adhesives, pharmaceuticals, metal cleaning, chemical processing, and feedstock in the production of refrigerant hydrofluorocarbon-32 (HFC–32) (82 FR 7467). Specifically, methylene chloride use in commercial paint and coating removal provides benefits for some users because it is readily available and works quickly and effectively on nearly all coatings without damaging most substrates. For a variety of additional uses (*e.g.,* adhesives, adhesive removers, cold pipe insulation, welding anti-spatter spray) methylene chloride is relatively inexpensive, highly effective, evaporates quickly, and is not flammable, making it a popular and effective solvent for many years. As of 2016, the leading applications for methylene chloride are as a solvent in the production of pharmaceuticals and polymers and paint removers, although recent regulations and voluntary industry actions are expected to decrease the chemical's use in the paint remover sector (40 CFR part 751, subpart B). The total aggregate production volume ranged from 100 to 500 million pounds between 2016 and 2019 according to CDR (Ref. 8).

D. Reasonably Ascertainable Economic Consequences of the Proposed Rule

1. Likely Effect of the Rule on the National Economy, Small Business, Technological Innovation, the Environment, and Public Health.

The reasonably ascertainable economic consequences of this proposed rule include several components, all of which are described in the Economic Analysis for this proposed rule (Ref. 3). With respect to the anticipated effects of this proposed rule on the national economy, EPA considered the number of businesses and workers that would be affected and the costs and benefits to those businesses and workers and did not find that there would be an impact on the national economy (Ref. 3). The economic impact of a regulation on the national economy becomes measurable only if the economic impact of the regulation reaches 0.25% to 0.5% of Gross Domestic Product (GDP) (Ref. 58). Given the current GDP, this is equivalent to a cost of $40 billion to $80 billion. Therefore, because EPA has estimated that the non-closure-related cost of the proposed rule would range from $13.2 million annualized over 20 years at a 3% discount rate and $14.5 million annualized over 20 years at a 7% discount rate, EPA has concluded that this rule is highly unlikely to have any measurable effect on the national economy (Ref. 3). In addition, EPA considered the employment impacts of this proposed rule, and found that the direction of change in employment is uncertain, but EPA expects the short-term and longer-term employment effects to be small. To that end, EPA is requesting public comment on short term and longer-term employment effects from this proposal.

Of the small businesses potentially impacted by this proposed rule, 98% (225,248 firms) are expected to have impacts of less than 1% to their firm revenues (rounded metric), 0.1% (118 firms) are expected to have impacts between 1 and 3% to their firm revenues (rounded metric), and 0.03212.1% (4,905 firms) are expected to have impacts greater than 3% to their firm revenues (rounded metric). Excluding end-users, total estimated impacts on small businesses are $9.3 million (annualized using a 7 percent discount rate). End users with economic and technologically feasible alternatives available do not have economic impacts that are estimated beyond rule familiarization costs ($1.8 million in total costs, annualized using a 7 percent discount rate). Thus, the estimated total impact of the rule on small businesses ranges from $11.1 to $73.6 million (see section 7.11 of the Economic Analysis). Commercial paint and coating removers are one product type where for which methylene chloride is likely the most effective product for many applications. In particular, alternatives to methylene chloride paint and coating removers in commercial furniture refinishing may not be as cost-effective for this use because they may take more time to achieve the desired outcome or require alternate processes affecting operations that present challenges for certain businesses. The impact of a prohibition of methylene chloride for furniture refinishing could result in the closure of an unknown number of affected entities or business lines. As discussed in Unit I.E., closure of affected furniture refinishing firms using methylene chloride following this rulemaking has an upper bound for economic impacts of $1.8 billion in total revenue, and $67 million in terms of the total profit, under the assumption that all affected firms fully close due to the restrictions on methylene chloride. A detailed discussion of potential economic impacts as a result of varying percentages of furniture refinishing firms closing is provided in the Economic Analysis in section 7.11 (Ref. 3).

With respect to this proposed rule's effect on technological innovation, EPA expects this rule to spur more innovation than it will hinder. A prohibition or significant restriction on the manufacture, processing, and distribution in commerce of methylene chloride for uses covered in this proposed rule may increase demand for existing, as well as development of additional, safer chemical substitutes. This proposed rule is not likely to have significant effects on the environment because, as discussed in Unit VI.B., methylene chloride does not present an unreasonable risk to the environment, though this proposed rule does present the potential for small reductions in air emissions and soil contamination associated with improper disposal of products containing methylene chloride. The effects of this proposed rule on public health are estimated to be positive, due to the potential prevention of deaths from acute exposure and reduced risk of cancer from chronic exposure to methylene chloride.

2. Costs and Benefits of the Proposed Regulatory Action and of the One or More Primary Alternative Regulatory Actions Considered by the Administrator

The costs and benefits that can be monetized for this proposed rule are

described at length in in the Economic Analysis (Ref. 3). The non-closure-related costs for this proposed rule are estimated to be $13.2 million annualized over 20 years at a 3% discount rate and $14.5 million annualized over 20 years at a 7% discount rate. The monetized benefits are estimated to be $17.7 to $18.5 million annualized over 20 years at a 3% discount rate and $13.4 to $13.9 million annualized over 20 years at a 7% discount rate.

EPA considered the estimated costs to regulated entities as well as the cost to administer and enforce alternative regulatory actions. The primary alternative regulatory action is described in detail in Unit IV.B. The estimated annualized, non-closure-related costs of the primary alternative regulatory action are $12.4 million at a 3% discount rate and $13.3 million at a 7% discount rate over 20 years (Ref. 3). The estimated annualized benefits of this primary alternative regulatory action are $17.7 to $18.5 million at a 3% discount rate and $13.4 to $13.9 million at a 7% discount rate over 20 years (Ref. 3).

This proposal is expected to achieve health benefits for the American public, some of which can be monetized and others that, while tangible and significant, cannot be monetized. EPA believes that the balance of costs and benefits of this proposal cannot be fairly described without considering the additional, non-monetized benefits of mitigating the non-cancer adverse effects. The multitude of adverse effects from methylene chloride exposure can profoundly impact an individual's quality of life, as discussed in Units II.A. (overview), III.B.2. (description of the unreasonable risk), V.A. (discussion of the health effects), and the Risk Evaluation. Some of the adverse effects can be immediately experienced and can result in sudden death; others can have impacts that are experienced for a shorter portion of life but are nevertheless significant in nature. The incremental improvements in health outcomes achieved by given reductions in exposure cannot be quantified for non-cancer health effects associated with methylene chloride exposure, and therefore cannot be converted into monetized benefits. The qualitative discussion throughout this rulemaking and in the Economic Analysis highlights the importance of these non-cancer effects, which are not able to be monetized in the way that EPA is able to for cancer and death. These effects include not only cost of illness but also personal costs such as emotional and mental stress that are hard to measure appropriately. Considering only monetized benefits significantly underestimates the impacts of methylene chloride adverse outcomes and underestimates the benefits of this proposed rule. As the proposed option is more restrictive and therefore more protective than the primary alternative option, the value of unquantified benefits may be higher for the proposed option. This implies that the difference between the proposed and primary alternative options is larger than it appears, in favor of the proposed option, based on monetized benefits alone.

The 2020 Risk Evaluation for Methylene Chloride identified two non-cancer health effects in reviewed scientific literature relevant to children, namely reproductive and developmental hazards. The 2020 Risk Evaluation for Methylene Chloride summarizes human health hazards identified in the review of scientific literature, including studies investigating methylene chloride exposure and reproductive and developmental effects as well as developmental neurotoxicity. Some epidemiological studies identified effects that include reduced fertility, spontaneous abortions, oral cleft defects, heart defects, and autism spectrum disorder (ASD). For ASD, due to methodological reasons including confounding by other chemicals and lack of temporal specificity, the 2020 Risk Evaluation for Methylene Chloride did not advance this hazard to a dose response calculation. Additionally, EPA did not carry reproductive/developmental effects forward for dose-response, because epidemiological studies lacked controls for co-exposures, animal studies observed effects mostly at higher methylene chloride concentrations, and EPA identified no relevant mechanistic information (Ref. 1). Nonetheless, additional health benefits may be achieved by reducing the incidence of reproductive effects for workers in commercial facilities or companies that use methylene chloride for the commercial uses proposed to be regulated (Ref. 3).

EPA was unable to estimate either the precise reduction in individual risk of these reproductive and developmental effects from reducing exposure to methylene chloride or the total number of cases avoided can be estimated due to a lack of necessary data. Nevertheless, reproductive hazards such as reduced fertility are important considerations. These health effects are serious and can have impacts throughout a lifetime; for example, infertility and fertility treatment can have deleterious social and psychological consequences such as mental distress (Ref. 59).

The potential impacts of these effects include monetary impacts from associated healthcare costs such as fertility treatments, as well as complications from fertility treatments (*e.g.,* higher multiple birth rates), mental stress and emotional suffering, which cannot be quantified or monetized but should not be ignored.

3. Cost Effectiveness of the Proposed Regulatory Action and of One or More Primary Alternative Regulatory Actions Considered by the Administrator

Cost effectiveness is a method of comparing certain actions in terms of the expense per item of interest or goal. A goal of this proposed regulatory action is to prevent user deaths resulting from exposure to methylene chloride. The proposed regulatory action would cost, excluding closure-related costs, $9.9 million per potential prevented death while the primary alternative regulatory action would cost, excluding closure-related costs, $9.3 million per potential prevented death (using the 3% discount rate). While the primary alternative regulatory action would be lower in cost compared to the proposed action, the difference is small and both options are considered to have similar levels of cost effectiveness in decreasing the potential for death from exposure to methylene chloride (Ref. 3). See Chapter 9 of the Economic Analysis for greater detail on the cost effectiveness of the proposed and primary regulatory actions.

4. Requests for Comment on Economic Analysis

As described in the Economic Analysis, two conditions of use, Processing: Recycling and Disposal, are responsible for the majority (~60%) of the estimated total $13 million non-closure-related costs of the rule. Given the prevalence of small entities in this sector, EPA requests comment on what regulatory flexibilities, within the scope of TSCA and mitigating unreasonable risk, may be afforded to these conditions of use to reduce burden of complying with the WCPP.

As described in the Economic Analysis and the Alternatives Assessment, alternatives for methylene chloride as a processing aid were not identified. EPA requests information on potential alternative processing aids to methylene chloride as it relates to the proposed regulatory option for this COU. The Economic Analysis includes a qualitative discussion of uncertainty in cost estimates, including uncertainties related to the cost of reformulating products that currently contain methylene chloride, which

could be underestimated, or overestimated. EPA requests comment on additional aspects of reformulation, including any costs that may be associated with mitigating countervailing risks of alternative formulations. Additionally, EPA requests comment on the degree to which qualities or properties of methylene chloride, beyond those discussed in the Economic Analysis and summarized in Unit VI.C. may make methylene chloride a preferable choice when compared to alternatives with similar costs and effectiveness. EPA also requests comment regarding information to estimate transition costs to suitable alternatives, including how often these costs might be incurred or what the specific costs would be per-user or per-firm when they are incurred. Similarly, EPA requests comment on how costs and economic impacts from firm closures may be reduced with longer compliance timeframes. Finally, EPA requests comment on how better to monetize the benefits of each alternative in the Economic Analysis and whether EPA should consider any other categories of benefits.

VII. TSCA Section 9 Analysis and Section 14 and 26 Considerations

A. TSCA Section 9(a) Analysis

TSCA section 9(a) provides that, if the Administrator determines, in the Administrator's discretion, that an unreasonable risk may be prevented or reduced to a sufficient extent by an action taken under a Federal law not administered by EPA, the Administrator must submit a report to the agency administering that other law that describes the risk and the activities that present such risk. TSCA section 9(a) describes additional procedures and requirements to be followed by EPA and the other Federal agency after submission of the report. As discussed in this Unit, for this proposed rule, the Administrator does not determine that unreasonable risk from methylene chloride under the conditions of use may be prevented or reduced to a sufficient extent by an action taken under a Federal law not administered by EPA.

TSCA section 9(d) instructs the Administrator to consult and coordinate TSCA activities with other Federal agencies for the purpose of achieving the maximum enforcement of TSCA while imposing the least burden of duplicative requirements. For this proposed rule, EPA has coordinated with appropriate Federal executive departments and agencies including OSHA and the Consumer Product Safety Commission (CPSC) to identify their respective authorities, jurisdictions, and existing laws with regard to risk evaluation and risk management of methylene chloride, which are summarized in this Unit.

As discussed in more detail in Unit II.C., OSHA requires that employers provide safe and healthful working conditions by setting and enforcing standards and by providing training, outreach, education, and assistance. OSHA has established health standards for methylene chloride covering employers in General Industry, Shipyards, and Construction (29 CFR 1910.1052(a)). Gaps exist between OSHA's authority to set workplace standards under the OSH Act and EPA's obligations under TSCA section 6 to eliminate unreasonable risk presented by chemical substances under the conditions of use. As noted previously, to set PELs for chemical exposure, OSHA must first establish that the new standards are economically and technologically feasible (79 FR 61384, 61387, Oct. 10, 2014). When setting the 8-hour TWA PEL for methylene chloride in 1997, OSHA concluded that ''at the 25 ppm PEL the residual risk still greatly exceeds any significant risk threshold,'' but set the PEL at that level because it was the lowest level for which OSHA could document technological and economic feasibility across the affected industries at that time (62 FR 1494, 1575 January 10, 1997; 63 FR 50172, 50713, September 22, 1998). Thus, if OSHA were to initiate a new action to lower its PEL, the difference in requirements between the OSH Act and TSCA could result in the OSHA PEL still being set at a higher level than the risk-based exposure limit for methylene chloride determined by EPA to be necessary to address the unreasonable risk identified under TSCA. However, EPA believes that the feasibility of technology has advanced over the last 25 years such that for certain conditions of use, based on monitoring data received during the risk evaluation and feedback during SBAR, EPA's risk-based level of 2 ppm is achievable, and indeed, is already being achieved. For most industrial and commercial conditions of use, EPA has determined it is not feasible to meet the ECEL and is thus proposing to prohibit those uses. In addition, OSHA may set exposure limits for workers, but its authority is limited to the workplace and does not extend to consumer uses of hazardous chemicals, and thus OSHA cannot address the unreasonable risk from methylene chloride under all of its conditions of use, which include consumer uses. OSHA also does not have direct authority over State and local employees, and it has no authority over the working conditions of State and local employees in States that have no OSHA-approved State Plan under 29 U.S.C. 667.

CPSC, under authority provided to it by Congress in the CPSA, protects the public from unreasonable risk of injury or death associated with consumer products. Under the CPSA, CPSC has the authority to regulate methylene chloride in consumer products, but not in other sectors such as automobiles, some industrial and commercial products, or aircraft for example. CPSC issued its methylene chloride guidance under the FHSA, which does not include the same jurisdictional exceptions as the CPSA. Recently, CPSC revised its labeling guidance for methylene chloride under the FHSA to provide more immediate guidance and clarity to consumers and industry regarding the acute hazards associated with using methylene chloride-based paint removers while they remain on the market (83 FR 12254, March 21, 2018). However, while EPA believes that the updated CPSC labeling guidance, if properly implemented by industry, would prevent some users from using methylene chloride paint and coating removal products in an unsafe manner, for the reasons described in the proposal, it is unlikely to address the unreasonable risks to consumers under a 9(a) determination by the Administrator. Furthermore, in a letter to EPA regarding paint and coating removers, CPSC stated ''because TSCA gives EPA the ability to reach both occupational and consumer uses, we recognize that EPA may address risks associated with these chemicals in a more cohesive and coordinated manner given that CPSC lacks authority to address occupational hazards.'' (EPA–HQ–OPPT–2016–0231–0154).

Therefore, EPA maintains that TSCA is the appropriate vehicle to deliver broad protections to consumers who may use formulations that contain methylene chloride and whose use drives the unreasonable risk of injury to health from methylene chloride. An action under TSCA also would be able to address occupational unreasonable risk and would reach entities that are not subject to OSHA. The timeframe and any exposure reduction as a result of updating OSHA or CPSC regulations for methylene chloride cannot be estimated, while TSCA imposes a much more accelerated 2-year statutory timeframe for proposing and finalizing requirements to address unreasonable risk. Regulating methylene chloride's

unreasonable risk utilizing TSCA authority will also avoid the situation where a patchwork of regulations amongst several Agencies using multiple laws and differing legal standards would occur and is therefore a more efficient and effective means of addressing the unreasonable risk of methylene chloride.

Moreover, the 2016 amendments to TSCA altered both the manner of identifying unreasonable risk and EPA's authority to address unreasonable risk, such that risk management is increasingly distinct from provisions of the CPSA, FHSA, or, OSH Act., In a TSCA section 6 risk management rule, following an unreasonable risk determination, EPA must apply risk management requirements to the extent necessary so that the chemical no longer presents unreasonable risk and only consider costs and benefits of the regulatory action to the extent practicable, 15 U.S.C. 2605(a) and (c)(2). By contrast, a consumer product safety rule under the CPSA must include a finding that ''the benefits expected from the rule bear a reasonable relationship to its costs.'' 15 U.S.C. 2058(f)(3)(E). Additionally, the 2016 amendments to TSCA reflect Congressional intent to ''delete the paralyzing 'least burdensome' requirement,'' 162 Cong. Rec. S3517 (June 7, 2016), a reference to TSCA section 6(a) as originally enacted in 1976, which required EPA to use ''the least burdensome requirements'' that protect ''adequately'' against unreasonable risk, 15 U.S.C. 2605(a) (1976). However, a consumer product safety rule under the CPSA must impose ''the least burdensome requirement which prevents or adequately reduces the risk of injury for which the rule is being promulgated.'' 15 U.S.C. 2058(f)(3)(F) Analogous requirements, also at variance with recent revisions to TSCA, affect the availability of action CPSC may take under the FHSA relative to action EPA may take under TSCA. 15 U.S.C. 1262. But EPA's substantive burden under TSCA section 6(a) is to apply requirements to the extent necessary so that the chemical substance no longer presents the unreasonable risk that was determined in accordance with TSCA section 6(b)(4)(A) without consideration of cost or other non-risk factors.

EPA therefore concludes that TSCA is the most appropriate regulatory authority able to prevent or reduce unreasonable risk of methylene chloride to a sufficient extent across the range of conditions of use, exposures, and populations of concern. This unreasonable risk can be addressed in a more coordinated, efficient, and effective manner under TSCA than under different laws implemented by different agencies. Further, there are key differences between the finding requirements of TSCA and those of the OSH Act, CPSA, and FHSA. For these reasons, in the Administrator's discretion, the Administrator has analyzed this issue and does not determine that unreasonable risk from methylene chloride may be prevented or reduced to a sufficient extent by an action taken under a Federal law not administered by EPA.

B. TSCA Section 9(b) Analysis

If EPA determines that actions under other Federal laws administered in whole or in part by EPA could eliminate or sufficiently reduce a risk to health or the environment, TSCA section 9(b) instructs EPA to use these other authorities to protect against that risk unless the Administrator determines in the Administrator's ''discretion that it is in the public interest to protect against such risk'' under TSCA. In making such a public interest finding, TSCA section 9(b)(2) states: ''the Administrator shall consider, based on information reasonably available to the Administrator, all relevant aspects of the risk . . . and a comparison of the estimated costs and efficiencies of the action to be taken under this title and an action to be taken under such other law to protect against such risk.''

Although several EPA statutes have been used to limit methylene chloride exposure (Refs. 3, 7), regulations under those EPA statutes largely regulate releases to the environment, rather than occupational or consumer exposures. While these limits on releases to the environment are protective in the context of their respective statutory authorities, regulation under TSCA is also appropriate for occupational and consumer exposures and in some cases can provide upstream protections that would prevent the need for release restrictions required by other EPA statutes (*e.g.,* RCRA, CAA, CWA).

The primary exposures and unreasonable risk to consumers, bystanders, workers, and occupational non-users would be addressed by EPA's proposed prohibitions and restrictions under TSCA section 6(a). In contrast, the timeframe and any exposure reduction as a result of updating regulations for methylene chloride under RCRA, CAA, or CWA cannot be estimated, nor would they address the direct human exposure to consumers, bystanders, workers, and occupational non-users from the conditions of use evaluated in the 2020 Risk Evaluation for Methylene Chloride. More specifically, none of EPA's other statutes (*e.g.,* RCRA, CAA, and CWA) can address exposures to workers and occupational non-users related to the specific activities that result in occupational exposures associated with disposal activities. EPA therefore concludes that TSCA is the most appropriate regulatory authority able to prevent or reduce risks of methylene chloride to a sufficient extent across the range of conditions of use, exposures, and populations of concern.

For these reasons, the Administrator does not determine that unreasonable risk from methylene chloride under its conditions of use, as evaluated in the 2020 Risk Evaluation for Methylene Chloride, could be eliminated or reduced to a sufficient extent by actions taken under other Federal laws administered in whole or in part by EPA.

C. TSCA Section 14 Requirements

EPA is also providing notice to manufacturers, processors, and other interested parties about potential impacts to confidential business information that may occur if this rule is finalized as proposed. Under TSCA sections 14(a) and 14(b)(4), if EPA promulgates a rule pursuant to TSCA section 6(a) that establishes a ban or phase-out of a chemical substance, the protection from disclosure of any confidential business information regarding that chemical substance and submitted pursuant to TSCA will be ''presumed to no longer apply,'' subject to the limitations identified in TSCA section 14(b)(4)(B)(i) through (iii). If this rule is finalized as proposed, then pursuant to TSCA section 14(b)(4)(B)(iii), the presumption against protection from disclosure would apply only to information about the specific conditions of use that this rule would prohibit or phase out. Similarly, if this rule is finalized as proposed, the presumption against protection from disclosure would not apply to certain uses that this rule proposes to exempt from the ban or phase-out pursuant to TSCA section 6(g). Per TSCA section 14(b)(4)(B)(i), the presumption against protection would not apply to information about these conditions of use. However, the presumption against protection would apply to information about conditions of use that are not exempt from the ban or phase-out, pursuant to TSCA section 6(g). Manufacturers or processors seeking to protect such information would be able to submit a request for nondisclosure as provided by TSCA sections 14(b)(4)(C) and 14(g)(1)(E). Any request for nondisclosure would need to be

submitted within 30 days after receipt of notice from EPA under TSCA section 14(g)(2)(A). EPA anticipates providing such notice via the Central Data Exchange (CDX).

D. TSCA Section 26 Considerations

In accordance with TSCA section 26(h), EPA has used scientific information, technical procedures, measures, methods, protocols, methodologies, and models consistent with the best available science. As in the case of the unreasonable risk determination, risk management decisions for this proposed rule, as discussed in Unit III.B.3. and Unit V., were based on a risk evaluation that was subject to public comment and independent, expert peer review, and developed in a manner consistent with the best available science and based on the weight of the scientific evidence as required by TSCA sections 26(h) and (i) and 40 CFR 702.43 and 702.45. In particular, the ECEL and EPA STEL values incorporated into the WCPP are derived from the analysis in the 2020 Risk Evaluation for Methylene Chloride; they likewise represent decisions based on the best available science and the weight of the scientific evidence (Ref. 11). The ECEL value of 2 ppm as an 8-hour TWA is based on the chronic non-cancer human equivalent concentration (HEC) for liver toxicity identified in the 2020 Risk Evaluation for Methylene Chloride, which is the concentration at which an adult human would be unlikely to suffer adverse effects if exposed for a working lifetime, including susceptible subpopulations. The EPA STEL of 16 ppm as a 15-minute TWA is derived from the non-cancer endpoint of central nervous system depression resulting from acute exposures that was identified in the 2020 Risk Evaluation for Methylene Chloride.

The extent to which the various information, procedures, measures, methods, protocols, methodologies, or models, as applicable, used in EPA's decisions have been subject to independent verification or peer review is adequate to justify their use, collectively, in the record for this rule. Additional information on the peer review and public comment process, such as the peer review plan, the peer review report, and the Agency's response to public comments, can be found at EPA's risk evaluation docket at EPA–HQ–OPPT–2020–0465.

VIII. Requests for Comment

EPA is requesting public comment on all aspects of this proposal, including the proposed and primary alternative regulatory actions and all supporting analysis. Additionally, within this proposal, the Agency is soliciting feedback from the public on specific issues throughout this proposed rule. For ease of review, this section summarizes those specific requests for comment.

1. EPA is requesting public comment on the proposed regulatory action and primary alternative regulatory action. (Unit III.A.).

2. EPA is requesting comment on the proposed rule's TSCA section 6(g) exemptions' provisions and rationales. (Unit III.A.).

3. Following Panel recommendations in the Panel report (Ref. 6) and in response to SERs recommendations, EPA is requesting comment on the following topics as outlined in the SBAR Panel Report:

a. EPA requests comment on the extent to which a regulation under TSCA section 6(a) could minimize requirements, such as testing and monitoring protocols, recordkeeping, and reporting requirements, which may exceed those already required under OSHA's regulations for methylene chloride.

b. EPA requests comment on the feasibility of complying with and monitoring for an Existing Chemical Exposure Limit (ECEL) of 2 ppm. In particular, EPA requests comment on changes that may be needed to meet such a standard, for example changes related to elimination of methylene chloride or substitution, engineering controls, process changes, and monitoring frequency.

c. EPA requests comment on workplace monitoring for implementation of an ECEL. EPA is soliciting information related to the frequency of monitoring, initial monitoring, and periodic monitoring for workplace exposure levels and how a lower exposure level from the OSHA PEL may impact the frequency of periodic monitoring. Specifically, EPA requests comment about when this may impact the frequency of periodic monitoring where initial monitoring shows that employee exposures are above the level that would initiate requirements for compliance with the ECEL or an OSHA STEL.

d. EPA requests comment on reasonable compliance timeframes for small businesses, including timeframes for reformulation of products or processes containing methylene chloride; implementation of new engineering or administrative controls; changes to labels, SDSs, and packaging; implementation of new PPE, including training and monitoring practices; and supply chain management challenges. EPA also requests comment on establishing differing compliance or reporting requirements or timetables that take into account the limited resources available to small entities.

e. EPA requests comment on the feasibility and availability of various prescriptive engineering controls to reduce exposure levels, and information on any technologies or prescriptive control options used in combination for addressing the unreasonable risk.

f. EPA requests comment on providing an option of either complying with the ECEL or implementing various administrative and engineering controls, such as those employed in a closed-loop system, including information on how a small business can demonstrate that such controls eliminate the unreasonable risk for that use.

g. EPA requests comment on establishing a certification program for the use of methylene chloride by the furniture refinishing industry as well as measures to address the unreasonable risk for commercial use of methylene chloride in paint and coating removal for furniture refinishing.

h. EPA requests comment on means by which small businesses can maintain access to methylene chloride for industrial and commercial uses including establishing training, certification, and limited access programs.

i. EPA requests comment on TSCA section 6(g)(1) exemptions for any MIL–SPEC programs where methylene chloride is specified or required for a specific end-use application.

j. EPA requests comment on temporary work practices to allow for limited circumstances, including but not limited to equipment failure or maintenance activity, where monitoring may not be feasible to comply with an ECEL.

k. EPA requests comment on the extent to which methylene chloride may be used in the same facility for TSCA and non-TSCA uses.

4. EPA requests comment on whether a definition should be promulgated for each condition of use of methylene chloride and, if so, whether the descriptions in Unit III.B.1.f. are consistent with the conditions of use evaluated in the 2020 Risk Evaluation for Methylene Chloride and whether they provide a sufficient level of detail such that they would improve the clarity and readability of the regulation if promulgated. (Unit III.B.1.f.).

5. EPA is requesting comment on the proposed implementation timeframe for the WCPP requirements; EPA proposes that they would take effect 180 days

after publication of the final rule, at which point entities would be required to conduct initial monitoring (as described in Unit IV.A.1.c.) and develop an exposure control plan within 1 year of publication of the final rule (Unit IV.A.1.a. and d.). (Unit IV.A.1.a.).

6. EPA acknowledges that new monitoring methods or technologies may have been developed since 1997 that would allow for greater accuracy, and thus a smaller range for monitoring results, and EPA requests comment on the exposure monitoring accuracy requirements. (Unit IV.A.1.c.i.).

7. EPA acknowledges that the 25% buffer for the 8-hour and 15-minute TWA potentially could allow some exposures above the exposure limits proposed here. EPA requests comment on these buffers' effects and any alternatives to account for measurement variance or uncertainty. (Unit IV.A.1.c.i.).

8. EPA is soliciting comments regarding how owners and operators could conduct initial exposure monitoring to ensure that it is representative of all tasks likely to be conducted by potentially exposed persons. (Unit IV.A.1.c.ii.).

9. EPA is soliciting comments regarding the proposed requirement for recurring 5-year initial exposure monitoring. (Unit IV.A.1.c.ii.).

10. EPA requests comment on the timeframes for periodic monitoring outlined in Unit IV.A.1.c.iii, particularly whether more frequent monitoring may be possible or recommended. (Unit IV.A.1.c.iii.).

11. EPA is requesting public comments on the proposed conditions for periodic monitoring for methylene chloride as part of implementation of the WCPP that differ from OSHA's existing monitoring requirements under 29 CFR 1910.1052. (Unit IV.A.1.c.iv.).

12. EPA requests comment on the degree to which additional guidance related to use of gloves might be necessary. Additionally, EPA requests comment on whether EPA should specifically incorporate dermal protection into the exposure control plan and require consideration of the hierarchy of controls for dermal exposures. (Unit IV.A.1.e.i.).

13. EPA requests comment on the 15-day timeframe for notification of potentially exposed persons of monitoring results and the possibility for a shorter timeframe, such as 5 days. (Unit IV.A.1.f.ii.).

14. EPA requests comment relative to the ability of owners or operators to conduct initial monitoring by 180 days after publication of the final rule, and anticipated timelines for any procedural adjustments needed to comply with the requirements outlined in Unit IV.A.1. (Unit IV.A.1.g.).

15. EPA requests comment on the impacts, if any, the proposed prohibition described in Unit IV.A.2., or other aspects of this proposal, may have on the production and availability of any food, food additive, drug, cosmetic, device, or other substance excluded from the definition of ''chemical substance'' under TSCA section 3(2)(B)(ii) through (vi). (Unit IV.A.2.).

16. EPA requests comment regarding the number of entities that could potentially close as well as associated costs with a prohibition of methylene chloride for certain industrial and commercial conditions of use identified in Unit IV.A.2. (Unit IV.A.2.).

17. EPA would like comment on whether it should consider a *de minimis* level of methylene chloride in formulations for certain continuing industrial and commercial uses to account for impurities (*e.g.,* 0.1% or 0.5%) when finalizing the prohibitions described in Unit IV.A., and, if so, what level should be considered *de minimis* (Units IV.A.2., and IV.A.3.).

18. EPA is proposing that the prohibition of certain industrial and commercial conditions of use described in Unit IV.A.2 would occur 90 days after the publication date of the final rule for manufacturers, 180 days for processors, 270 days for distributing to retailers, 360 days for all other distributors and retailers, and 450 days for industrial and commercial uses. EPA requests comment on whether additional time is needed, for example, for products affected by proposed restrictions to clear the channels of trade. (Unit IV.A.2.).

19. EPA requests comments on an appropriate, predictable process that could expedite reconsideration for uses that Federal agencies or their contractors become aware of after the final rule is issued using the tools available under TSCA, aligning with the requirements of TSCA section 6(g). EPA requests comment on the appropriate types of information for use in evaluating this type of category of use, and other considerations that should apply. (Unit IV.A.2).

20. EPA would like comment on whether distributors that are not retailers should be required to use tax IDs or other verification methods prior to selling methylene chloride or products containing methylene chloride to ensure consumers are not purchasing methylene chloride or commercial or industrial products containing methylene chloride. (Unit IV.A.3.).

21. During litigation (see *Lab. Council for Latin Am. Advancement* v. *United States Env't Prot. Agency,* 12 F.4th 234 (2d Cir. 2021)) on a previous rulemaking (84 FR 11420, March 27, 2019) petitioners argued that EPA's definition of ''retailer'' was so broad as to cover all commercial entities, creating supply chain issues for commercial users seeking to attain and use the chemical for commercial activities. EPA has not found this to be the case; small businesses that are non-retail distributors exist and even participated as small entity representatives consulted as part of the SBAR process for this rulemaking. Nonetheless, EPA is soliciting comment on whether similar supply chain issues for uses that are permitted under the WCPP are anticipated. (Unit IV.A.3.).

22. EPA is proposing that the prohibition of manufacturing, processing, and distribution for consumer use described in Unit IV.A.3. would occur 90 days after the publication date of the final rule for manufacturers, 180 days for processers, 270 days for distributing to retailers, and 360 days for all other distributors and retailers after the publication date of the final rule. EPA requests comment on whether additional time is needed, for example, for products affected by proposed restrictions to clear the channels of trade. (Unit IV.A.3.).

23. EPA requests comments on the appropriateness of identified compliance timeframes for recordkeeping and downstream notification requirements described in Unit IV.A.4. (Unit IV.A.4.b.).

24. EPA recognizes that in some situations, certain facilities may do both Federal contractor and commercial aviation work and may use methylene chloride for paint and coating removal from safety-critical, corrosion-sensitive components on military, Federal, or commercial aviation. EPA requests comment on whether such co-located activities in a facility should be subject to the WCPP, rather than the exemption under TSCA section 6(g). Additionally, EPA seeks additional information and requests comment on whether it is possible to distinguish between commercial aviation facilities that would be able to meet the WCPP and those that would not, including what criteria should be used for such distinctions (*e.g.,* size of facility, volume or type of work performed, record of exposure reduction practices). EPA also requests comment on the extent to which specific commercial aviation and aerospace uses or types of facilities could fully comply with the WCPP to address identified unreasonable risk. (Unit IV.A.5.a.i.).

25. EPA requests comments on all aspects of the proposed TSCA section 6(g) exemption from the proposed prohibition on use of methylene chloride in commercial paint and coating removal for paint and coating removal essential for critical infrastructure by certificated commercial air carriers, commercial operators, or repair stations, or by manufacturers of aircraft or aerospace vehicles and hardware, noting that the proposed exemptions would be limited to the safety-critical, corrosion-sensitive components on aircraft and aerospace vehicles, including safety-critical components. (Unit IV.A.5.a.ii.).

26. EPA requests comment on this TSCA section 6(g) exemption for continued emergency use of methylene chloride in the furtherance of NASA's mission as described in this unit, and whether any additional conditions of use should be included, in particular for any uses qualified for space flight for which no technically or economically feasible safer alternative is available. Additionally, EPA requests comment on what would constitute sufficient justification of an emergency. (Unit IV.A.5.b.ii.).

27. EPA requests comments on all aspects of the preliminary determination that a TSCA section 6(g) exemption is not warranted for the use of methylene chloride in furniture refinishing, including information on the availability of alternatives and the time needed to implement alternatives. EPA emphasizes that the Agency is seeking input regarding whether an exemption is needed and welcomes information related to this condition of use during the public comment period. (Unit IV.A.5.c.).

28. Primary alternative regulatory action: EPA requests comment on the ways in which methylene chloride may be used in the additional conditions of use that would be subject to a WCPP under the primary alternative regulatory action, and the degree to which users of methylene chloride in these sectors could successfully implement the WCPP, including requirements to meet an ECEL and EPA STEL, as described in Unit IV.A.1., for the conditions of use listed for the primary alternative regulatory action in Unit IV.B. EPA is also requesting comment on whether to consider a regulatory alternative that would subject more conditions of use to a WCPP, instead of prohibition, than those currently contemplated in the primary alternative regulatory action. EPA also requests monitoring data and detailed descriptions of methylene chloride involving activities for these conditions of use to determine whether these additional conditions of use could comply with the WCPP such that risks are no longer unreasonable. (Unit IV.B.).

29. Primary alternative regulatory action: EPA requests comment on the degree to which entities using methylene chloride as a processing aid may comply with the proposed WCPP requirements for methylene chloride. EPA requests comment on the degree to which alternatives may or may not be available for use of methylene chloride as a heat transfer fluid and in other processing aid applications. (Unit IV.B.).

30. Primary alternative regulatory action: EPA requests comment on the ability of regulated entities engaged in the additional conditions of use that would be subject to a WCPP under the primary alternative regulatory action to conduct initial monitoring within 12 months, anticipated timelines for any procedural adjustments needed to comply with the requirements, and the extent to which this option could result in additional exposure, compared the proposed regulatory option as described in Unit IV.A. Overall, EPA requests comment on any advantages or drawbacks for the timelines outlined in Unit IV.B., compared to the timelines identified for the proposed regulatory action in Unit IV.A. (Unit IV.B.)

31. EPA requests comment and further information regarding the Agency's expectations that Federal and Federal contractor facilities would be subject to a higher level of oversight than non-Federal or contractor facilities, and that existing or expected controls would be successful in achieving the requirements of the WCPP. (Unit V.A.1.).

32. EPA requests comment and further information regarding the Agency's expectations that the facilities in which use of methylene chloride as a bonding agent in specialty batteries is carried out are industrialized and highly controlled, and that existing or expected exposure reduction and workplace controls would be successful in achieving the requirements of the WCPP. EPA also notes that while the Agency is not aware of any similar use of methylene chloride as a bonding element for batteries for commercial spaceflight or other use, it requests comment and information on any such use. (Unit V.A.1.).

33. EPA is requesting comment on what regulatory flexibilities may be afforded to entities that will continue to recycle and dispose of methylene chloride under the proposed regulation. (Unit V.A.1.).

34. EPA is requesting comment on the inclusion of a certification, training, and limited access program for any uses that would be subject to a WCPP, in addition to the requirements outlined in Unit IV.A.1. (Unit V.A.4.).

35. For some conditions of use, EPA was unable to identify products currently available for sale that contain methylene chloride. EPA is soliciting comments on whether there are actually products in use or available for sale relevant to these conditions of use that contain methylene chloride at this time, so that EPA can ascertain whether there are alternatives that benefit human health or the environment. (Unit V.B.).

36. EPA is requesting comment on the alternatives analysis as a whole. (Unit V.B.).

37. EPA considered the employment impacts of this proposed rule, and found that the direction of change in employment is uncertain, but EPA expects the short-term and longer-term employment effects to be small. To that end, EPA is requesting public comment on short term and longer-term employment effects from this proposal. (Unit VI.D.1.).

38. As described in the Economic Analysis, two conditions of use, Processing: Recycling and Disposal, are responsible for the majority (~60%) of the estimated total $12 million in non-closure-related costs of the rule. Given the prevalence of small entities in this sector, EPA requests comment on what regulatory flexibilities, within the scope of TSCA and mitigating unreasonable risk, may be afforded to these conditions of use to reduce burden of complying with the WCPP. (Unit VI.D.4.).

39. As described in the Economic Analysis and the Alternatives Analysis, alternatives for methylene chloride as a processing aid were not identified. EPA requests information on potential alternative processing aids to methylene chloride as it relates to the proposed regulatory option for this COU. (Unit VI.D.4.).

40. The Economic Analysis includes a qualitative discussion of uncertainty in cost estimates, including uncertainties related to the cost of reformulating products that currently contain methylene chloride, which could be underestimated, or overestimated. EPA requests comment on additional aspects of reformulation, including any costs that may be associated with mitigating countervailing risks of alternative formulations. (Unit VI.D.4.)

41. EPA requests comment on the degree to which qualities or properties of methylene chloride, beyond those discussed in the Economic Analysis and summarized in Unit VI.C., may make methylene chloride a preferable choice when compared to alternatives with

similar costs and effectiveness. (Unit VI.D.4.)

42. EPA requests comment regarding information to estimate transition costs to suitable alternatives, including how often these costs might be incurred or what the specific costs would be per-user or per-firm when they are incurred. (Unit VI.D.4.)

43. EPA requests comment on how costs and economic impacts from firm closures may be reduced with longer compliance timeframe. (Unit VI.D.4.)

44. EPA requests comment on how better to monetize the benefits of each alternative in the Economic Analysis and whether EPA should consider any other categories of benefits. (Unit VI.D.4.)

IX. References

The following is a listing of the documents that are specifically referenced in this document. The docket includes these documents and other information considered by EPA, including documents that are referenced within the documents that are included in the docket, even if the referenced document is not itself physically located in the docket. For assistance in locating these other documents, please consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

1. EPA. Risk Evaluation for Methylene Chloride (MC). EPA Document #740–R1–8010
2. EPA. Final Revised Unreasonable Risk Determination for Methylene Chloride. November 2022.
3. EPA. Economic Analysis of the Proposed Regulation of Methylene Chloride. RIN 2070–AK70. August 2022.
4. Public Workshop on Use of Methylene Chloride in Furniture Refinishing in collaboration with the Small Business Administration Office of Advocacy. September 12, 2017.
5. EPA Workshop on Furniture Refinishing and Methylene Chloride. September 12, 2017.
6. EPA. Final Report of the Small Business Advocacy Review Panel on EPA's Planned Proposed Rule Toxic Substances Control Act (TSCA) Section 6(a) Methylene Chloride. October 28, 2021.
7. EPA. Regulatory Actions Pertaining to Methylene Chloride. January 24, 2023.
8. EPA. Access CDR Data: 2020 CDR Data. Last Updated on May 16, 2022.
9. NIOSH. Hierarchy of Controls. Accessed October 6, 2022
10. EPA. Methylene Chloride; Revision to Toxic Substances Control Act (TSCA) Risk Determination; Notice of Availability. **Federal Register** (87 FR 67901, November 10, 2022
11. EPA. Existing Chemical Exposure Limit (ECEL) for Occupational Use of Methylene Chloride. December 10, 2020.
12. OSHA. Standard Interpretations: 8-hr total weight average (TWA) permissible exposure limit (PEL). Accessed October 6, 2022.
13. Putz *et al.* A comparative study of the effects of carbon monoxide and methylene chloride on human performance. J Environ Pathol Toxicol 2: 97–112. 1979.
14. NTP. NTP Toxicology and Carcinogenesis Studies of Dichloromethane (Methylene Chloride) (CAS No. 75–09–2) in F344/N Rats and B6C3F1 Mice (Inhalation Studies). National Toxicology Program technical report series vol. 306. 1986.
15. K.D. Nitschke; *et al.* Methylene Chloride: A 2-Year Inhalation Toxicity and Oncogenicity Study in Rats. Fundam Appl Toxicol 11: 48–59. 1988.
16. K.D. Nitschke; *et al.* Methylene Chloride: Two-Generation Inhalation Reproductive Study in Rats. Fundam Appl Toxicol 11: 60–67. 1988.
17. Executive Order 13990. Protecting Public Health and the Environment and Restoring Science to Tackle the Climate Crisis. **Federal Register** (86 FR 7037, January 25, 2021).
18. Executive Order 13985. Advancing Racial Equity and Support for Underserved Communities Through the Federal Government. **Federal Register** (86 FR 7009, January 25, 2021).
19. Executive Order 14008. Tackling the Climate Crisis at Home and Abroad. **Federal Register** (86 FR 7619, February 1, 2021).
20. EPA Press Release. EPA Announces Path Forward for TSCA Chemical Risk Evaluations. June 2021.
21. SACC. Science Advisory Committee on Chemicals Meeting Minutes and Final Report No. 2022–01. March 15–17, 2022.
22. EPA. Notes from Federalism Consultation on Forthcoming Proposed Rulemakings for Methylene Chloride and 1-Bromopropane under TSCA Section 6(a). Office of Pollution Prevention and Toxics. October 22, 2023.
23. EPA. Notes from Tribal Consultations on Forthcoming Proposed Rulemakings for Methylene Chloride and 1-Bromopropane under TSCA Section 6(a). Office of Pollution Prevention and Toxics. November 12–17, 2020.
24. Liz Hitchcock; Safer Chemicals Healthy Families. 11/20 Environmental Justice Consultations for 1-Bromopropane and Methylene Chloride. November 20, 2020.
25. California Communities Against Toxics *et al.* Comment letter re TSCA environmental justice consultations. November 13, 2020.
26. Swati Rayasam; Program on Reproductive Health and the Environment (PRHE). PRHE follow up documents from EJ consultation meeting. November 30, 2020.
27. EPA. Initial Regulatory Flexibility Analysis for Methylene Chloride; Regulation of Methylene Chloride under TSCA § 6(a) Proposed Rule; RIN 2070–AK70. November 22, 2022.
28. EPA. Methylene Chloride: Risk Evaluation and Risk Management under TSCA Section 6. SBA Small Business Roundtable. September 11, 2020.
29. EPA. Stakeholder Meeting List for Proposed Rulemaking for Methylene Chloride under TSCA Section 6(a). October 27, 2022.
30. EPA. 2021 Policy on Children's Health. October 5, 2021.
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32. Anh Hoang; Kathleen Fagan; Dawn L. Cannon; *et al.* Assessment of Methylene Chloride–Related Fatalities in the United States, 1980–2018. JAMA Intern Med. 2021.
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35. OSHA; NIOSH. Hazard Alert: Methylene Chloride Hazards for Bathtub Refinishers. January 2013.
36. OSHA. 1910.1052 App A—Substance Safety Data Sheet and Technical Guidelines for Methylene Chloride. Accessed October 6, 2022.
37. EPA. Final Rule. Methylene Chloride; Regulation of Paint and Coating Removal for Consumer Use Under TSCA Section 6(a). **Federal Register** (84 FR 11420, March 27, 2019
38. Leslie Riegle. Re: Regulation of Certain Uses Under Toxic Substances Control Act: Methylene Chloride and N-methylpyrrolidone. Aerospace Industries Association (AIA). May 19, 2017.
39. Miria M. Finckenor; NASA. Materials for Spacecraft. 2016.
40. EPA. An Alternatives Assessment for Use of Methylene Chloride. August 2022.
41. White House. United States Space Priorities Framework. December 2021.
42. Federal Aviation Administration (FAA). Flight Program Operations. Last updated: April 13, 2022.
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45. Halogenated Solvents Industry Alliance Inc. (HSIA). Docket No. EPA–HQ–OPPT–2016–0742. August 16, 2018.
46. EPA. Final Report of the Small Business Advocacy Review Panel on EPA's Planned Proposed Rule Toxic Substances Control Act (TSCA) Section 6(a) Methylene Chloride. Appendix B: Written Comments Submitted by Small Entity Representatives. October 28, 2021.
47. EPA. Proposed Rule. Methylene Chloride and N-Methylpyrrolidone; Regulation of Certain Uses Under TSCA Section 6(a). **Federal Register** (82 FR 7464, January 19, 2017
48. Kenneth M. Walter and Val C. Sackmann. Material Substitution of Methylene Chloride (MeCl)/Phenol Paint Stripper. AIHce 2016. May 21–26, 2016.

49. EPA. Meeting with Baron-Blakeslee on Risk Management under TSCA Section 6 for Trichloroethylene, Perchloroethylene, 1-Bromopropane, and Methylene Chloride. April 1, 2021
50. EPA. ANPRM. Methylene Chloride; Commercial Paint and Coating Removal Training, Certification and Limited Access Program. **Federal Register** (84 FR 11466, March 27, 2019
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52. EPA. Risk Calculator for Consumer Inhalation and Dermal Exposures. June 2020.
53. John Kelley and Thomas Considine. Performance Evaluation of Hap-Free Paint Strippers vs. Methylene-Chloride-Based Strippers for Removing Army Chemical Agent Resistant Coatings (CARC). Army Research Laboratory. June 2006.
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56. OEJECR EPA Complaint Nos. 01R–22–R6–, 02R–22–R6, and 04R–22–R6. October 12, 2022.
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61. EPA. TSCA Work Plan Chemical Risk Assessment; Methylene Chloride: Paint Stripping Use. EPA Document #740–R1–4003. August 2014. *https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/tsca-work-plan-chemical-risk-assessment-methylene.*
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X. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders can be found at *https://www.epa.gov/laws-regulations/laws-and-executive-orders.*

A. Executive Orders 12866: Regulatory Planning and Review and 13563: Improving Regulation and Regulatory Review

This action is an economically significant regulatory action that was submitted to the Office of Management and Budget (OMB) for review under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011). Any changes made in response to OMB recommendations during that review have been documented in the docket. EPA prepared an Economic Analysis of the potential costs and benefits associated with this action, which is available in the docket and is summarized in Units I.E. and VI.D. (Ref. 3).

B. Paperwork Reduction Act (PRA)

The information collection activities in this proposed rule have been submitted to OMB for review and comment under the PRA, 44 U.S.C. 3501 *et seq.* The Information Collection Request (ICR) document that EPA prepared has been assigned EPA ICR No. 2735.01 (Ref. 60). You can find a copy of the ICR in the docket for this rule, and it is briefly summarized here.

There are two primary provisions of the proposed rule that may increase burden under the PRA.

The first is downstream notification, which would be carried out by updates to the relevant SDS and which would be required for manufacturers, processors, and distributors in commerce of methylene chloride, who would provide notice to companies downstream upon shipment of methylene chloride about the prohibitions. The information submitted to downstream companies through the SDS would provide knowledge and awareness of the restrictions to these companies.

The second primary provision of the proposed rule that may increase burden under the PRA is WCPP-related information generation, recordkeeping, and notification requirements (including development of exposure control plans; exposure level monitoring and related recordkeeping; development of documentation for a PPE program and related recordkeeping; development of documentation for a respiratory protection program and related recordkeeping; development and notification to potentially exposed persons (employees and others in the workplace) about how they can access the exposure control plans, exposure monitoring records, PPE program implementation documentation, and respirator program documentation; and development of documentation demonstrating eligibility for an exemption from the proposed prohibitions, and related recordkeeping).

Respondents/affected entities: Persons that manufacture, process, use, distribute in commerce, or dispose of methylene chloride or products containing methylene chloride. See also Unit I.A.

Respondent's obligation to respond: Mandatory (TSCA section 6(a) and 40 CFR part 751).

Frequency of response: On occasion.

Estimated number of respondents: 237,929.

Total estimated burden: 129,772 hours (per year). Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: $10,385,871 (per year), includes $2,809,809 annualized capital or operation and maintenance costs.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. After display in the **Federal Register** when approved, the OMB control numbers for EPA regulations in 40 CFR are listed in 40 CFR part 9 and displayed on the form and instructions or collection portal, as applicable.

Submit your comments on the Agency's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden to the EPA using the docket identified at the beginning of this proposed rule. You may also send your ICR-related comments to OMB's Office of Information and Regulatory Affairs using the interface at *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. OMB must receive comments no later than July 3, 2023. EPA will respond to any ICR-related comments in the final rule.

C. Regulatory Flexibility Act (RFA)

Pursuant to section 603 of the RFA, 5 U.S.C. 601 *et seq.,* EPA prepared an initial regulatory flexibility analysis (IRFA) that examines the impact of the proposed rule on small entities along with regulatory alternatives that could minimize that impact (Ref. 27). The complete IRFA is available for review in the docket and is summarized here.

1. Need for the Rule

Under TSCA section 6(a) (15 U.S.C. 2605(a)), if EPA determines after a TSCA section 6(b) risk evaluation that a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to

the risk evaluation, under the conditions of use, EPA must by rule apply one or more requirements listed in TSCA section 6(a) to the extent necessary so that the chemical substance or mixture no longer presents such risk. Methylene chloride was the subject of a risk evaluation under TSCA section 6(b)(4)(A) that was issued in June 2020. In addition, in 2022, EPA issued a revised unreasonable risk determination that methylene chloride as a whole chemical substance presents an unreasonable risk of injury to health under the conditions of use. As a result, EPA is proposing to take action to the extent necessary so that methylene chloride no longer presents such risk.

2. Objectives and Legal Basis for the Rule

Under TSCA section 6(a) (15 U.S.C. 2605(a)), if EPA determines through a TSCA section 6(b) risk evaluation that a chemical substance presents an unreasonable risk of injury to health or the environment, EPA must by rule apply one or more requirements listed in TSCA section 6(a) to the extent necessary so that the chemical substance or mixture no longer presents such risk. EPA has determined through a TSCA section 6(b) risk evaluation that methylene chloride presents an unreasonable risk under the conditions of use.

3. Description and Number of Small Entities to Which the Rule Will Apply

The proposed rule potentially affects small manufacturers (including importers), processors, distributors, retailers, users of methylene chloride or of products containing methylene chloride, and entities engaging in disposal. EPA estimates that the proposed rule would affect approximately 237,930 firms using methylene chloride, of which 230,266 are estimated to be small entities. End users with economic and technologically feasible alternatives available do not have estimated cost impacts beyond rule familiarization costs. Alternative products that are drop-in substitutes (*i.e.,* requiring no changes by the user in how the product is used) are available for most uses including adhesives, various degreasers, or lubricants and greases. However, in some cases some effort might be required by firms using methylene chloride products to identify suitable alternatives, test them for their desired applications, learn how to use them safely and effectively, and implement new processes for using the alternative products. The information to estimate how often these costs might be incurred or what the specific costs would be per-user or per-firm when they are incurred is not available. Therefore, EPA is unable to consider these costs quantitatively in the IRFA or Economic Analysis.

4. Projected Compliance Requirements

To address the unreasonable risk EPA has identified, EPA is proposing to: (i) Prohibit the manufacture (including import), processing, and distribution in commerce of methylene chloride for all consumer use (other than the use of methylene chloride in consumer paint and coating removers, which was subject to separate action under TSCA section 6 (84 FR 11420, March 27, 2019); (ii) prohibit most industrial and commercial uses of methylene chloride; (iii) require a WCPP for certain industrial and commercial conditions of use, including inhalation exposure concentration limits; (iv) require recordkeeping and downstream notification requirements for several conditions of use; and (v) provide time-limited exemptions under TSCA section 6(g) for military and civilian aviation from the prohibition addressing the use of methylene chloride for paint and coating removal to avoid significant disruptions to national security and critical infrastructure.

EPA is proposing to prohibit most conditions of use. For other conditions of use that drive the unreasonable risk determination for methylene chloride, EPA proposes a WCPP to address the unreasonable risk. A WCPP would encompass inhalation exposure thresholds, includes monitoring and recordkeeping requirements to verify that those thresholds are not exceeded, and other components, such as dermal protection, to ensure that the chemical substance no longer presents unreasonable risk. Under a WCPP, owners or operators would have some flexibility, within the parameters outlined in Unit IV.A.1., regarding the manner in which they prevent exceedances of the identified exposure thresholds. Therefore, EPA generally refers to the WCPP approach as a non-prescriptive approach. In the case of methylene chloride, meeting the exposure thresholds proposed by EPA for certain occupational conditions of use would address unreasonable risk driven by inhalation exposure from those conditions of use for potentially exposed persons.

EPA's proposed requirements include the specific exposure limits that would be required to meet the TSCA section 6(a) standard to apply one or more requirements to the substance so that it no longer presents unreasonable risk, and also include ancillary requirements necessary for the ECEL's successful implementation as part of a WCPP.

EPA is not proposing reporting requirements beyond downstream notification (third-party notifications). Regarding recordkeeping requirements, three primary provisions of the proposed rule relate to recordkeeping. The first is recordkeeping for PPE: under the proposed regulatory action, facilities complying with the rule through WCPP would be required to develop and maintain records associated with a dermal and inhalation protection and in accordance with an exposure control plan. Additionally, under the proposed regulatory action, facilities complying with the rule through a WCPP would be required to monitor exposure levels and maintain records of this monitoring. Last, under the proposed regulatory action, facilities complying with the rule through a WCPP would be required to notify potentially exposed persons of monitoring results.

a. Classes of Small Entities Subject to the Compliance Requirements

The small entities that would be potentially directly regulated by this rule are small businesses that manufacture (including import), process, distribute in commerce, use, or dispose of methylene chloride, including retailers of methylene chloride for end-consumer uses.

b. Professional Skills Needed To Comply

Entities that would be subject to this proposal that manufacture (including import), process, or distribute methylene chloride in commerce for consumer use would be required to cease under the proposed rule. The entity would be required to modify their Safety Data Sheet or develop another way to inform their customers of the prohibition on manufacture, processing, and distribution of methylene chloride for consumer use. They would also be required to keep records of how much methylene chloride they sold, and to whom, and maintain a copy of the method they use for notifying their customers. None of these activities require any special skills.

Entities that use methylene chloride in any of the industrial and commercial conditions of use that are prohibited would be required to cease under the proposed rule. Restriction or prohibition of these uses will likely require the implementation of an alternative chemical or the cessation of use of methylene chloride in a process or equipment that may require persons

with specialized skills, such as engineers or other technical experts. Instead of developing an alternative method themselves, commercial users of methylene chloride may choose to contract with another entity to do so.

Entities that would be permitted to continue to manufacture, process, distribute, use, or dispose of methylene chloride would be required to implement a WCPP and would have to meet the provisions of the program for continued use of methylene chloride. Adaption to a WCPP may require persons with specialized skills such as an engineer or health and safety professional. Instead of implementing the WCPP themselves, entities that use methylene chloride may choose to contract with another entity to do so. Records would have to be maintained for compliance with a WCPP. While this recording activity itself may not require a special skill, the information to be measured and recorded may require persons with specialized skills such as an industrial hygienist.

5. Relevant Federal Rules

Because of its health effects, methylene chloride is subject to numerous State, Federal, and international regulations restricting and regulating its use. The following is a summary of the regulatory actions pertaining to methylene chloride; for a full description see appendix A of the 2020 Risk Evaluation for Methylene Chloride.

EPA has issued numerous rules and notices pertaining to methylene chloride under its various authorities. Methylene chloride is a hazardous air pollutant (HAP) under the CAA (42 U.S.C. 7412(b)(1)). EPA promulgated National Emission Standards for Hazardous Air Pollutants (NESHAPs) for methylene chloride for several industrial source categories.

With this proposed rule under TSCA section 6, certain uses identified under these NESHAPs would be prohibited while other uses would be subject to a WCPP. Moreover, the proposed rule would allow methylene chloride's continued use in processing as a reactant for the manufacture of HFC–32 and subject to compliance as part of a WCPP.

Programs within EPA implementing other environmental statutes, including, but not limited to, the RCRA, the Comprehensive Environmental Response, the Compensation, and Liability Act (CERCLA), the SDWA, and the CWA, classify methylene chloride as a hazardous waste, a hazardous substance, a volatile organic contaminant, and a toxic pollutant, respectively. Releases into the environment of methylene chloride in excess of 1,000 pounds must be reported under CERCLA (40 CFR 302.4). While TSCA shares equity in the regulation of methylene chloride, EPA does not anticipate this rule to duplicate nor conflict with the aforementioned programs' classifications and associated rules.

In addition to regulations administered by the EPA, methylene chloride is also subject to regulations by other Federal agencies.

In 2005, the Secretary of Transportation listed methylene chloride as a hazardous material with regard to transportation that is subject to regulations prescribing requirements applicable to the shipment and transportation of listed hazardous materials under the Hazardous Materials Transportation Act (70 FR 34381, June 14, 2005).

OSHA has a standard for regulating methylene chloride under 29 CFR 1910.1052. The OSHA PEL, action level, STEL, and ancillary requirements have established a strong precedent for exposure threshold requirements within the regulated community. However, EPA recognizes that the existing PEL and STEL do not eliminate the unreasonable risk identified by EPA under TSCA, and EPA is therefore proposing to apply new, lower exposure thresholds, derived from the 2020 Risk Evaluation for Methylene Chloride, while aligning with existing requirements wherever possible. For methylene chloride, this approach would eliminate the unreasonable risk driven by certain conditions of use, reduce burden for complying with the regulations, and provide the familiarity of a pre-existing framework for the regulated community.

Under the FHSA enforced by CPSC, household products are required to have hazardous substance labels for products that contain methylene chloride. In 1987, CPSC issued a decision to require labeling of household products that contain methylene chloride under the FHSA (52 FR 34698, September 14, 1987). Labels indicated that inhalation of methylene chloride vapor has caused cancer in certain laboratory animals, and the labels specified precautions to be taken during use by consumers. In 2018, in response to a petition, CPSC updated the labeling policy for paint strippers containing methylene chloride to include a warning of the acute hazards from inhalation of methylene chloride vapors in addition to the chronic hazards (83 FR 12254, March 21, 2018, and 83 FR 18219, April 26, 2018). With the proposed prohibition on the manufacture, processing, and distribution in commerce of methylene chloride for paint and coating removal under TSCA, EPA anticipates that CPSC may require labeling for any products that fall outside of the scope of TSCA and would not present conflict.

In pesticides, methylene chloride was registered as an antimicrobial pesticide in 1974 pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (7 U.S.C. 136 *et seq.*). Methylene chloride was also a pesticide product inert ingredient used as a solvent and co-solvent, and as a dispersing and wetting agent. In June 1998, EPA published a **Federal Register** document that designated methylene chloride as a List 1 inert ingredient due to its toxicological and other concerning effects (63 FR 34384, June 24, 1998) (FRL–5792–3). In 2002, EPA revoked pesticide tolerance exemptions for methylene chloride as an extraction solvent and as a post-harvest fumigant for crops established under the Federal Food, Drug, and Cosmetic Act (FFDCA) (67 FR 16027, April 4, 2002) (FRL–6833–3).

In 1989, the Food and Drug Administration (FDA) banned methylene chloride as an ingredient in all cosmetic products because of its animal carcinogenicity and likely hazard to human health under the FFDCA (54 FR 27328, June 29, 1989). Before 1989, methylene chloride had been used in aerosol cosmetic products, such as hairspray (Ref. 61).

6. Significant Alternatives to the Proposed Rule

As discussed further in Unit V.A.4. and the IRFA, EPA considered—in addition to the prohibition and WCPP that are proposed—a wide variety of control measures to address the unreasonable risk from methylene chloride such as weight fractions, prescriptive controls, and a certification and limited access program. The Agency determined that some methods either did not effectively address the unreasonable risk presented by methylene chloride or there was uncertainty in conditions of use that would be less able to comply with a comprehensive WCPP to adequately protect potentially exposed persons. The primary alternative regulatory action was considered and found to provide greater uncertainty in addressing the unreasonable risk from methylene chloride under the conditions of use.

As required by the RFA section 609(b), EPA also convened a SBAR Panel to obtain advice and recommendations from small entity

representatives that potentially would be subject to the rule's requirements. The SBAR Panel evaluated the assembled materials and small-entity comments on issues related to elements of an IRFA. The panel recommended EPA include certain requests for comment, which can be found in Unit VIII. (number 3.a through 3.k) and summarized in the Initial Regulatory Flexibility Assessment (Ref. 27). The full SBAR Panel Report is in the rulemaking docket (Ref. 6).

D. Unfunded Mandates Reform Act (UMRA)

This action contains a Federal mandate under UMRA, 2 U.S.C. 1531–1538, that may result in expenditures of $100 million or more for State, local and Tribal governments, in the aggregate, or the private sector in any one year. Accordingly, the EPA has prepared a written statement required under UMRA section 202. The statement is included in the docket for this action and briefly summarized here.

EPA estimates the compliance costs of the proposed rule to the private sector to be approximately to be $13.2 million annualized over 20 years at a 3% discount rate and $14.5 million annualized over 20 years at a 7% discount rate. However, the costs of the rule to the private sector are difficult to completely quantify. EPA's upper-bound estimate for the potential economic impact of the proposed rule on firms subject to the proposed prohibition on the use of methylene chloride in commercial furniture refinishing involves a worst-case assumption that all of as many as 5,000 furniture refinishing firms will fully close due to the proposed prohibition.

As described in more detail in Units I.E. VI.D.2. and Tables 3–1 and 6–12 of the Economic Analysis (Ref. 3), EPA estimates the upper-bound economic impact of potential closures of affected furniture refinishing firms using methylene chloride following this rulemaking to be $1.8 billion in total lost revenue, and $67 million in terms of the total lost profit, under the assumption that all affected firms fully close due to the proposed restrictions on methylene chloride. Thus, the Agency concludes that cost of the rule to the private sector may exceed the inflation-adjusted UMRA threshold of $100 million in any one year.

Nevertheless, the economic impact of a regulation on the national economy is generally considered to be measurable only if the economic impact of the regulation reaches 0.25 percent to 0.5 percent of GDP (Ref. 58). Given the current GDP of $23.17 trillion, this is equivalent to a cost of $58 billion to $116 billion. Therefore, EPA has concluded that this rule is highly unlikely to have any measurable effect on the national economy. Additional information on EPA's estimates of the benefits and costs of this action are provided in Units I.E. and VI.D.2., and in the Economic Analysis for this action (Ref. 3). Information on the authorizing legislation is provided in Unit I.B. Information on prior consultations with affected State, local, and Tribal governments is provided in Unit III.A.1.

This action is not subject to the requirements of UMRA section 203 because it contains no regulatory requirements that might significantly or uniquely affect small governments.

E. Executive Order 13132: Federalism

EPA has concluded that this action has federalism implications, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999), because regulation under TSCA section 6(a) may preempt State law. As set forth in TSCA section 18(a)(1)(B), the issuance of rules under TSCA section 6(a) to address the unreasonable risks presented by a chemical substance has the potential to trigger preemption of laws, criminal penalties, or administrative actions by a State or political subdivision of a State that are: (1) Applicable to the same chemical substance as the rule under TSCA section 6(a); and (2) Designed to prohibit or otherwise restrict the manufacture, processing, or distribution in commerce or use of that same chemical. TSCA section 18(c)(3) applies that preemption only to the ''hazards, exposures, risks, and uses or conditions of use'' of such chemical included in the final TSCA section 6(a) rule.

EPA provides the following preliminary federalism summary impact statement. The Agency consulted with State and local officials early in the process of developing the proposed action to permit them to have meaningful and timely input into its development. This included a consultation meeting on October 22, 2020, and a background presentation on September 9, 2020. EPA invited the following national organizations representing State and local elected officials to these meetings: Association of State Drinking Water Administrators, National Association of Clean Water Agencies, Western States Water Council, National Water Resources Association, American Water Works Association, Association of Metropolitan Water Agencies, Association of Clean Water Administrators, Environmental Council of the States, National Association of Counties, National League of Cities, County Executives of America, U.S. Conference of Mayors, and National Association of Attorneys General. A summary of the meeting with these organizations, including the views that they expressed, is available in the docket (Ref. 22). As discussed in Unit III.A.1., during Federal consultation meetings EPA provided information on TSCA section 6 regulations and participants discussed preemption as well as the relationship between TSCA and existing statutes such as the CWA and SDWA. (Ref. 22). EPA provided an opportunity for these organizations to provide follow-up comments in writing but did not receive any such comments.

F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This action does not have Tribal implications as specified in Executive Order 13175 (65 FR 67249, November 9, 2000) because it will not have substantial direct effects on Tribal governments, on the relationship between the Federal Government and the Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes. Methylene chloride is not manufactured, processed, or distributed in commerce by Tribes and, therefore, this rulemaking would not impose substantial direct compliance costs on Tribal governments. Thus, Executive Order 13175 does not apply to this action.

Consistent with the EPA Policy on Consultation and Coordination with Indian Tribes, EPA consulted with Tribal officials during the development of this action. The Agency held a Tribal consultation from October 7, 2020, to January 8, 2021, with meetings on November 12 and 13, 2020. Tribal officials were given the opportunity to meaningfully interact with EPA concerning the current status of risk management. During the consultation, EPA discussed risk management under TSCA section 6(a), findings from the 2020 Risk Evaluation for Methylene Chloride, types of information to inform risk management, principles for transparency during risk management, and types of information EPA sought from Tribal officials (Ref. 23). EPA briefed Tribal officials on the Agency's risk management considerations and Tribal officials raised no related issues or concerns to EPA during or in follow-up to those meetings (Ref. 23). EPA received no written comments as part of this consultation.

G. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

This action is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997) because EPA does not believe the environmental health or safety risks addressed by this action present a disproportionate risk to children as reflected by the conclusions of the methylene chloride risk evaluation. Accordingly, this action's health and risk assessments are contained in Units III.A.3., III.B.2., and V.A., as well as in the 2020 Risk Evaluation for Methylene Chloride, and the Economic Analysis for this proposed rulemaking (Refs. 1, 3).

H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution or Use

This action is not a ''significant energy action'' under Executive Order 13211 (66 FR 28355, May 22, 2001) because it is not likely to have a significant adverse effect on the supply, distribution or use of energy.

I. National Technology Transfer and Advancement Act (NTTAA)

Pursuant to the NTTAA section 12(d), 15 U.S.C. 272, the Agency has determined that this rulemaking involves environmental monitoring or measurement, specifically for occupational inhalation exposures to methylene chloride. Consistent with the Agency's Performance Based Measurement System (PBMS), EPA proposes not to require the use of specific, prescribed analytic methods. Rather, the Agency plans to allow the use of any method that meets the prescribed performance criteria. The PBMS approach is intended to be more flexible and cost-effective for the regulated community; it is also intended to encourage innovation in analytical technology and improved data quality. EPA is not precluding the use of any method, whether it constitutes a voluntary consensus standard or not, as long as it meets the performance criteria specified.

For this rulemaking, the key consideration for the PBMS approach is the ability to accurately detect and measure airborne concentrations of methylene chloride at the ECEL, the ECEL action level, and the EPA STEL. Some examples of methods which meet the criteria are included in appendix A of the ECEL memo (Ref. 11). EPA recognizes that there may be voluntary consensus standards that meet the proposed criteria (Ref. 62). EPA requests comments on whether it should incorporate such voluntary consensus standards in the rule and seeks information in support of such comments regarding the availability and applicability of voluntary consensus standards that may achieve the sampling and analytical requirements of the rule in lieu of the PBMS approach.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

Executive Order 12898 (59 FR 7629, February 16, 1994) directs Federal agencies, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on minority populations (people of color and/or Indigenous peoples) and low-income populations.

EPA believes that the human health and environmental conditions that exist prior to this action do not result in disproportionate and adverse effects on people of color, low-income populations, and/or Indigenous peoples. The documentation for this decision is contained in the Economic Analysis (Ref. 3), which is in the public docket for this action. As part of the Economic Analysis for this rulemaking, EPA conducted an environmental justice analysis using information about the facilities, workforce, and communities potentially affected by the regulatory options under current conditions, before the proposed regulation would goes into effect. The analysis drew on publicly available data provided by EPA, U.S. Census Bureau, and Centers for Disease Control and Prevention (CDC), including data from TRI, EPA Enforcement and Compliance History Online (ECHO), National Air Toxics Assessment (NATA), the American Community Survey, and the Behavioral Risk Factor Surveillance System. The intent of the analysis was to characterize the baseline conditions faced by communities and workers to identify the potential for disproportionate impacts on minority and low-income populations.

EPA believes that this action is not likely to result in new disproportionate and adverse effects on people of color, low-income populations and/or Indigenous peoples. However, while this regulatory action would apply requirements to the extent necessary so that methylene chloride no longer presents an unreasonable risk, EPA is not able to quantify the distribution of the change in risk across affected workers, communities, or demographic groups due to data limitations that prevented EPA from conducting a more comprehensive analysis of such a change.

EPA additionally identified and addressed environmental justice concerns by conducting outreach to advocates of communities that might be subject to disproportionate exposure to methylene chloride, such as minority populations, low-income populations, and Indigenous peoples.

On November 16 and 19, 2020, EPA held public meetings as part of this consultation. (Ref. 51). See also Unit III.A.1. These meetings were held pursuant to and in compliance with Executive Order 12898 and Executive Order 14008, Tackling the Climate Crisis at Home and Abroad (86 FR 7619, February 1, 2021). EPA received three written comments following the EJ meetings, in addition to oral comments provided during the consultations (Refs. 24, 25, 26). In general, commenters supported strong regulation of methylene chloride to protect lower-income communities and workers. Commenters supported strong outreach to affected communities, encouraged EPA to follow the hierarchy of controls, favored prohibitions, and noted the uncertainty of use—and in some cases inadequacy—of PPE.

The information supporting this Executive Order review is contained in Units II.D., III.A.1., and VI.A., and well as in the Economic Analysis (Ref. 3, 51). EPA's presentations, a summary of EPA's presentation and public comments made, and fact sheets for the environmental justice consultations related to this rulemaking are available at *https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/environmental-justice-consultations-methylene-chloride.* These materials are also available in the public docket for this rulemaking.

List of Subjects in 40 CFR Part 751

Environmental protection, Chemicals, Export notification, Hazardous substances, Import certification, Reporting and recordkeeping.

Michael S. Regan,

Administrator.

Therefore, for the reasons stated in the preamble, EPA proposes to amend 40 CFR chapter I as follows:

PART 751—REGULATION OF CERTAIN CHEMICAL SUBSTANCES AND MIXTURES UNDER SECTION 6 OF THE TOXIC SUBSTANCES CONTROL ACT

■ 1. The authority citation for part 751 continues to read as follows:

Authority: 15 U.S.C. 2605.

■ 2. Amend § 751.5 by adding in alphabetical order definitions for ''authorized person'', ''ECEL'', ''EPA STEL'', ''owner or operator'', ''potentially exposed person'', ''regulated area'', and ''retailer'' to read as follows:

§ 751.5 Definitions

* * * * *

Authorized person means any person specifically authorized by the owner or operator to enter, and whose duties require the person to enter, a regulated area.

* * * * *

ECEL is an Existing Chemical Exposure Limit, which is an EPA regulatory limit on workplace exposure to an airborne concentration of a chemical substance, generally based on an eight (8)-hour time-weighted average (TWA).

* * * * *

EPA STEL is a Short-Term Exposure Limit, which is an EPA regulatory limit on workplace exposure to an airborne concentration of a chemical substance, based on an exposure of less than eight hours.

Owner or operator means any person who owns, leases, operates, controls, or supervises a workplace covered by this part.

* * * * *

Potentially exposed person means any person who may be occupationally exposed to a chemical substance or mixture in a workplace as a result of a condition of use of that chemical substance or mixture.

Regulated area means an area established by the regulated entity to demarcate areas where airborne concentrations of a specific chemical substance exceed, or there is a reasonable possibility they may exceed, the ECEL or the EPA STEL.

Retailer means a person who distributes in commerce or makes available a chemical substance or mixture to consumer end users, including e-commerce internet sales or distribution. Any distributor with at least one consumer end user customer is considered a retailer. A person who distributes in commerce or makes available a chemical substance or mixture solely to commercial or industrial end users or solely to commercial or industrial businesses is not considered a retailer.

■ 3. Revise § 751.101 to read as follows:

§ 751.101 General.

This subpart sets certain restrictions on the manufacture (including import), processing, distribution in commerce, use, and disposal of methylene chloride (CASRN 75–09–2) to prevent unreasonable risks of injury to health.

■ 4. Amend § 751.103 by adding in alphabetical order a definition for ''ECEL'' to read as follows:

§ 751.103 Definitions.

* * * * *

ECEL action level means a concentration of airborne methylene chloride of 1 part per million (1 ppm) calculated as an 8-hour time weighted average (TWA).

* * * * *

■ 5. Amend § 751.105 by revising the section heading to read as follows:

§ 751.105 Prohibition of manufacturing (including import), processing, and distribution in commerce related to consumer paint and coating removal.

* * * * *

§ 751.107 [Redesignated as § 751.111]

■ 6. Redesignate § 751.107 as § 751.111 in subpart B and add new § 751.107 in subpart B to read as follows:

§ 751.107 Other prohibitions of manufacturing (including import), processing, distribution in commerce, and use.

(a) *Applicability.* (1) The provisions of this section apply to all manufacturing (including import)),), processing, and distribution in commerce of methylene chloride for consumer use other than for the paint and coating removal use addressed under § 751.105.

(2) The provisions of this section apply to all manufacturing (including import), processing, and distribution in commerce of methylene chloride for industrial or commercial use, and to all commercial or industrial use of methylene chloride, other than the conditions of use addressed under § 751.109(a).

(b) *Prohibitions.* (1) After [DATE 90 DAYS AFTER DATE OF PUBLICATION OF FINAL RULE IN THE **FEDERAL REGISTER**], all persons are prohibited from manufacturing (including import) methylene chloride, for the uses listed in paragraphs (a)(1) and (2) of this section except for those uses specified in paragraph (b)(7) of this section.

(2) After [DATE 180 DAYS AFTER DATE OF PUBLICATION OF FINAL RULE IN THE **FEDERAL REGISTER**], all persons are prohibited from processing methylene chloride, including any methylene chloride-containing products for the uses listed in paragraphs (a)(1) and (2) of this section except for those uses specified in paragraph (b)(7) of this section.

(3) After [DATE 270 DAYS AFTER DATE OF PUBLICATION OF FINAL RULE IN THE **FEDERAL REGISTER**], all persons are prohibited from distributing in commerce methylene chloride, including any methylene chloride-containing products, to retailers for any use.

(4) After [DATE 360 DAYS AFTER DATE OF PUBLICATION OF FINAL RULE IN THE **FEDERAL REGISTER**], all retailers are prohibited from distributing in commerce (including making available) methylene chloride, including any methylene chloride-containing products, for any use.

(5) After [DATE 360 DAYS AFTER DATE OF PUBLICATION OF FINAL RULE IN THE **FEDERAL REGISTER**], all persons are prohibited from distributing in commerce (including making available) methylene chloride, including any methylene chloride-containing products for any use described in paragraphs (a)(1) and (2) of this section except for those uses specified in paragraph (b)(7) of this section.

(6) After [DATE 450 DAYS AFTER DATE OF PUBLICATION OF FINAL RULE IN THE **FEDERAL REGISTER**], all persons are prohibited from industrial or commercial use of methylene chloride, including any methylene chloride containing products for the uses listed in paragraph (a)(2) of this section except for those uses specified in paragraph (b)(7) of this section.

(7) After [DATE 10 YEARS AFTER DATE OF PUBLICATION OF FINAL RULE IN THE **FEDERAL REGISTER**], all persons are prohibited from manufacturing (including import), processing, distribution in commerce, or use of methylene chloride, including any methylene chloride containing products, for industrial or commercial use for paint or coating removal from safety critical, corrosion-sensitive components of aircraft or spacecraft as described in § 751.115(b)(1) through (3).

§ 751.109 [Redesignated as § 751.113]

■ 7. Redesignate § 751.109 as new § 751.113 in subpart B and add new § 751.109 in subpart B to read as follows:

§ 751.109 Workplace Chemical Protection Program.

(a) *Applicability.* The provisions of this section apply to the following

conditions of use of methylene chloride, except to the extent the conditions of use are prohibited by §§ 751.105 and 751.107:

(1) Manufacturing (domestic manufacture);

(2) Manufacturing (import);

(3) Processing: as a reactant;

(4) Processing: incorporation into a formulation, mixture, or reaction product;

(5) Processing: repackaging;

(6) Processing: recycling;

(7) Industrial and commercial use as a laboratory chemical;

(8) Industrial or commercial use for paint and coating removal from safety-critical, corrosion-sensitive components of aircraft and spacecraft that are owned or operated by the U.S. Department of Defense, the National Aeronautics and Space Administration, the U.S. Department of Homeland Security, and the Federal Aviation Administration that is performed by the agency or the agency's contractor at locations controlled by the agency or the agency's contractor.

(9) Industrial or commercial use as a bonding agent for acrylic and polycarbonate in mission-critical military and space vehicle applications, including in the production of specialty batteries for applications that are performed by the U.S. Department of Defense, the National Aeronautics and Space Administration, or the U.S. Department of Homeland Security or their contractors at locations controlled by the agency or the agency's contractor; and

(10) Disposal;

(b) *Relationship to 29 CFR part 1910.* For purposes of this section:

(1) Any provisions applying to ''employee'' in 29 CFR 1910.1020, 29 CFR 1910.132, 29 CFR 1910.134, and 29 CFR 1910.1052 also apply equally to potentially exposed persons; and

(2) Any provisions applying to ''employer'' in 29 CFR 1910.1020, 29 CFR 1910.132, 29 CFR 1910.134, and 29 CFR 1910.1052 also apply equally to any owner or operator for the regulated area.

(c) *Exposure limits.* The owner or operator must ensure the following:

(1) *Existing Chemical Exposure Limit (ECEL).* No person is exposed to an airborne concentration of methylene chloride in excess of 2 parts of methylene chloride per million parts of air (2 ppm) as an 8-hour TWA.

(2) *EPA short-term exposure limit (EPA STEL).* No person is exposed to an airborne concentration of methylene chloride in excess of 16 parts of methylene chloride per million parts of air (16 ppm) as determined over a sampling period of 15 minutes.

(3) *Regulated areas.* Owners or operators must establish and maintain regulated areas in accordance with 29 CFR 1910.1052(e)(2), (4), (5), (6), and (7), within 3 months after receipt of the results of any monitoring data as outlined in paragraph (d) of this section. Owners or operators must establish a regulated area wherever a potentially exposed person's exposure to airborne concentrations of methylene chloride exceeds or can reasonably be expected to exceed either the ECEL or EPA STEL.

(d) *Exposure monitoring*—(1) *In general*—(i) *Characterization of exposures.* Owners or operators must determine each potentially exposed person's exposure by either:

(A) Taking a personal breathing zone air sample of each potentially exposed person's exposure; or

(B) Taking personal breathing zone air samples that are representative of each potentially exposed person's exposure.

(ii) *Representative samples.* Owners or operators are permitted to consider personal breathing zone air samples to be representative of each potentially exposed person's exposure when they are taken as follows:

(A) *ECEL.* The owner or operator has taken one or more personal breathing zone air samples for at least one potentially exposed person in each job classification in a work area during every work shift, and the person sampled is expected to have the highest methylene chloride exposure.

(B) *EPA STEL.* The owner or operator has taken one or more personal breathing zone air samples which indicate the highest likely 15-minute exposures during such operations for at least one potentially exposed person in each job classification in the work area during every work shift, and the person sampled is expected to have the highest methylene chloride exposure.

(C) *Exception.* Personal breathing zone air samples taken during one work shift may be used to represent potentially exposed person exposures on other work shifts where the owner or operator can document that the tasks performed and conditions in the workplace are similar across shifts.

(iii) *Accuracy of monitoring.* Owners or operators must ensure that the methods used to perform exposure monitoring produce results that are accurate to a confidence level of 95%, and are:

(A) Within plus or minus 25% for airborne concentrations of methylene chloride above the ECEL or the EPA STEL; or

(B) Within plus or minus 35% for airborne concentrations of methylene chloride at or above the ECEL action level but at or below the ECEL.

(iv) *Currency of monitoring data.* Owners or operators are not permitted to rely on monitoring data that is more than 5 years old to demonstrate compliance with initial or periodic monitoring requirements for either the ECEL or the EPA STEL.

(2) *Initial monitoring.* (i) After [DATE 180 DAYS AFTER DATE OF PUBLICATION OF FINAL RULE IN THE **FEDERAL REGISTER**] each owner or operator of a workplace where methylene chloride is present must perform an initial exposure monitoring to determine each potentially exposed person's exposure, except under the following temporary conditions:

(A) An owner or operator can provide EPA with objective data generated during the last 5 years that demonstrates to EPA that methylene chloride cannot be released in the workplace in airborne concentrations at or above the ECEL action level (1-ppm 8-hour TWA) or above the EPA STEL (16 ppm 15-minute TWA) and that the data represents the highest methylene chloride exposures likely to occur under conditions of use described in paragraph (a) of this section; or

(B) Where potentially exposed persons are exposed to methylene chloride for fewer than 30 days per year, and the owner or operator has measurements by direct-metering devices which give immediate results and which provide sufficient information regarding exposures to determine and implement the control measures that are necessary to reduce exposures to below the ECEL action level and EPA STEL.

(ii) An owner or operator must re-conduct an initial exposure monitoring at least once every 5 years if methylene chloride is present in the workplace.

(3) *Periodic monitoring.* Where the initial exposure monitoring shows exposure at or above the ECEL action level at or above the EPA STEL, the owner or operator must establish an exposure monitoring program for periodic monitoring of exposure to methylene chloride in accordance with table 1 to this paragraph (d)(3).

TABLE 1 TO § 751.109(d)(3)—PERIODIC MONITORING REQUIREMENTS BASED ON INITIAL EXPOSURE MONITORING RESULTS

Air concentration condition observed during initial exposure monitoring	Periodic monitoring requirement
If the initial exposure monitoring concentration is below the ECEL action level and at or below the EPA STEL.	ECEL and EPA STEL monitoring not required.
If the initial exposure monitoring concentration is below the ECEL action level and above the EPA STEL.	ECEL monitoring not required, and EPA STEL monitoring required every 3 months.
If the initial exposure monitoring concentration is at or above the ECEL action level and at or below the ECEL; and at or below the EPA STEL.	ECEL monitoring every 6 months.
If the initial exposure monitoring concentration is at or above the ECEL action level and at or below the ECEL; and above the EPA STEL.	ECEL monitoring every 6 months and EPA STEL monitoring every 3 months.
If the initial exposure monitoring concentration is above the ECEL and below, at, or above the EPA STEL.	ECEL monitoring every 3 months and EPA STEL monitoring every 3 months.
Two consecutive monitoring events have taken place 7 days apart that indicate that potential exposure has decreased from above the ECEL to at or below the ECEL, but at or above the ECEL action level.	Reduce ECEL periodic monitoring frequency from every 3 months to every 6 months.
Two consecutive monitoring events have taken place 7 days apart that indicate that potential exposure has decreased to below the ECEL action level and at or below the EPA STEL.	Transition from ECEL periodic monitoring frequency from of every 6 months to initial monitoring once every 5 years. The second consecutive monitoring event will delineate the new date from which the next 5-year initial exposure monitoring must occur.
If the owner or operator engages in any conditions of use described in paragraph (a) of this section and is required to monitor either the ECEL or EPA STEL in a 3-month interval, but does not engage in any of those uses for the entirety of the 3-month interval.	The owner or operator may forgo the upcoming periodic monitoring event. However, documentation of cessation of use of methylene chloride must be maintained, and initial monitoring is required when the owner or operator resumes or starts any of the conditions of use described in paragraph (a) of this section.
Owner or operator engages in any conditions of use described in paragraph (a) of this section and is required to monitor the ECEL in a 6-month interval, but does not engage in any of those uses for the entirety of the 6-month interval..	The owner or operator may forgo the upcoming periodic monitoring event. However, documentation of cessation of the condition(s) of use must be maintained until periodic monitoring resumes, and initial monitoring is required when the owner or operator resumes or starts any of the conditions of use described in paragraph (a) of this section.

Note: Additional scenarios in which monitoring may be required are discussed paragraph (d)(4).

(4) *Additional monitoring.* The owner or operator must conduct an additional initial exposure monitoring immediately after any change that may reasonably be expected to introduce additional sources of exposure to methylene chloride, or otherwise result in increased exposure to methylene chloride compared to the most recent monitoring event.

(5) *Notification of monitoring results.* (i) The owner or operator must inform potentially exposed persons of monitoring results within 15 working days.

(ii) This notification must include the following:

(A) Exposure monitoring results;

(B) Identification and explanation of the ECEL, ECEL Action Level, and EPA STEL in plain language;

(C) Explanation of any corresponding required respiratory protection as described in paragraph (f);

(D) Descriptions of actions taken by the owner or operator to reduce exposure;

(E) Quantity of methylene chloride in use;

(F) Location of methylene chloride use;

(G) Manner of methylene chloride use;

(H) Identified releases of methylene chloride; and

(I) Whether the airborne concentration of methylene chloride exceeds the ECEL or the EPA STEL.

(iii) Notice must be provided in plain language writing, in a language that the person understands, to each potentially exposed person or posted in an appropriate and accessible location outside the regulated area with an English-language version and a non-English language version representing the language of the largest group of workers who do not read English.

(e) *ECEL control procedures and plan*—(1) *Method of compliance.* After [DATE 360 DAYS AFTER DATE OF PUBLICATION OF FINAL RULE IN THE **FEDERAL REGISTER**], the owner or operator must institute and maintain the effectiveness of engineering controls and work practices to reduce exposure to or below the ECEL and EPA STEL except to the extent that the owner or operator can demonstrate that such controls are not feasible. Wherever the feasible engineering controls and work practices which can be instituted are not sufficient to reduce exposures for potentially exposed person to or below the ECEL or EPA STEL, the owner or operator must use them to reduce exposure to the lowest levels achievable by these controls and must supplement them by the use of respiratory protection that complies with the requirements of paragraph (f) of this section to reduce exposures to or below the ECEL or EPA STEL. Wherever engineering controls and work practices are not feasible, the owner or operator must use respiratory protection that complies with the requirements of paragraph (f) of this section to reduce exposures for potentially exposed persons to or below the ECEL or EPA STEL. Where an owner or operator cannot demonstrate the use of engineering controls or work practices that result in exposure below the ECEL or EPA STEL, and has not demonstrated that it has supplemented the risk of exposure with respiratory protection, this will constitute a failure to comply with the ECEL. Additionally, the owner or operator must not implement a schedule of personnel rotation as a means of compliance with the ECEL.

(2) *Exposure control plan requirements.* After [DATE 360 DAYS AFTER DATE OF PUBLICATION OF FINAL RULE IN THE **FEDERAL REGISTER**], the owner or operator must include and document in an exposure control plan the following:

(i) Identification of exposure controls and rationale for using or not using exposure controls in the following sequence—elimination, substitution,

engineering controls, and administrative controls—to reduce exposures in the workplace to either at or below the ECEL or EPA STEL or to the lowest level achievable, and the exposure controls selected based on feasibility, effectiveness, and other relevant considerations;

(ii) If exposure controls were not selected, document the efforts identifying why these are not feasible, not effective, or otherwise not implemented;

(iii) Actions taken to implement exposure controls selected, including proper installation, maintenance, training or other steps taken;

(iv) Regular inspections, evaluations, and updating of the exposure controls to ensure effectiveness and confirmation that all persons are using them accordingly;

(v) Occurrence and duration of any start-up, shutdown, or malfunction of exposure controls or of facility equipment that causes air concentrations to be above the ECEL or EPA STEL and subsequent corrective actions taken during start-up, shutdown, or malfunctions to mitigate exposures to methylene chloride; and

(vi) Objective data generated during the previous 5 years, when used to forgo the initial exposure monitoring, must include: the use of methylene chloride being evaluated, the source of objective data, measurement methods, measurement results, and measurement analysis of the use of methylene chloride, and any other relevant data to the operations, processes, or person's exposure.

(3) *Respirator requirements.* The owner or operator must supply a respirator, selected in accordance with paragraph (f) of this section, to each potentially exposed person who enters a regulated area and must ensure each potentially exposed person uses that respirator whenever methylene chloride exposures may exceed the ECEL or EPA STEL.

(f) *Respiratory protection*—(1) *Respirator conditions.* After [DATE 270 DAYS AFTER DATE OF PUBLICATION OF FINAL RULE IN THE **FEDERAL REGISTER**] or within 3 months after receipt of the results of any exposure monitoring as described in paragraph (d) of this section, owners or operators must provide respiratory protection to all potentially exposed persons in the regulated area as outlined in paragraph (c)(3) of this section, and according to the provisions outlined in 29 CFR 1910.134(a) through (l) (except paragraph (d)(1)(iii)) and as specified in this paragraph for potentially exposed persons exposed to methylene chloride in concentrations above the ECEL or the EPA STEL. For the purpose of this paragraph (f), the maximum use concentration (MUC) as used in 29 CFR 1910.134 must be calculated by multiplying the assigned protection factor (APF) specified for a respirator by the ECEL or EPA STEL.

(2) *Respirator selection criteria.* The type of respiratory protection that regulated entities must select and provide to potentially exposed persons in accordance with 29 CFR 1910.1052(g)(3)(i), is directly related to the monitoring results, as follows:

(i) If the measured exposure concentration is at or below the ECEL or EPA STEL: no respiratory protection is required.

(ii) If the measured exposure concentration is above 2 ppm and less than or equal to 50 ppm: the respirator protection required is any NIOSH-certified supplied-air respirator (SAR) or airline respirator in a continuous-flow mode equipped with a loose-fitting facepiece or helmet/hood (APF 25).

(iii) If the measured exposure concentration is above 50 ppm and less than or equal to 100 ppm the respirator protection required is:

(A) Any NIOSH-certified Supplied-Air Respirator (SAR) or airline respirator in a demand mode equipped with a full facepiece (APF 50); or

(B) Any NIOSH-certified Self-Contained Breathing Apparatus (SCBA) in demand-mode equipped with a full facepiece or helmet/hood (APF 50).

(iv) If the measured exposure concentration is unknown or at any value above 100 ppm and up to 2,000 ppm the respirator protection required is:

(A) Any NIOSH-certified Supplied-Air Respirator (SAR) or airline respirator in a continuous-flow mode equipped with a full facepiece or certified helmet/hood (APF 1,000); or

(B) Any NIOSH-certified Supplied-Air Respirator (SAR) or airline respirator in pressure-demand or other positive-pressure mode equipped with a full facepiece (APF 1,000); or

(C) Any NIOSH-certified Self-Contained Breathing Apparatus (SCBA) in a pressure-demand or other positive-pressure mode equipped with a full facepiece or certified helmet/hood (APF 10,000).

(3) *Minimal respiratory protection.* Requirements outlined in paragraph (e)(2) of this section represent the minimum respiratory protection requirements, such that any respirator affording a higher degree of protection than the required respirator may be used.

(4) *Workplace participation.* Owners or operators must document the notice to and ability of any potentially exposed person to access the exposure control plan and other associated records.

(g) *Dermal protection.* (1) Owners or operators must require the donning of gloves that are chemically resistant to methylene chloride with activity-specific training where dermal contact with methylene chloride is possible, after application of the requirements in paragraph (e), in accordance with the NIOSH hierarchy of controls.

(2) Owners or operators must minimize and protect potentially exposed persons from dermal exposure in accordance with 29 CFR 1910.1052(h) and (i).

(h) *Training.* Owners or operators must provide training in accordance with 29 CFR 1910.1052(l)(1) through (6) to potentially exposed persons prior to or at the time of initial assignment to a job involving potential exposure to methylene chloride. In addition, if respiratory protection or PPE must be worn within a regulated area, owners or operators must provide training in accordance with 29 CFR 1910.132(f) to potentially exposed persons within that regulated area.

■ 8. Revise newly redesignated § 751.111 to read as follows:

§ 751.111 Downstream notification.

(a) After August 26, 2019, and before [DATE 150 DAYS AFTER DATE OF PUBLICATION OF FINAL RULE IN THE **FEDERAL REGISTER**] for each person who manufactures (including imports), and before [DATE 210 DAYS AFTER DATE OF PUBLICATION OF FINAL RULE IN THE **FEDERAL REGISTER**] for each person who processes or distributes in commerce, methylene chloride for any use must, prior to or concurrent with the shipment, notify companies to whom methylene chloride is shipped, in writing, of the restrictions described in § 751.105. Notification must occur by inserting the following text in section 1(c) and section 15 of the SDS provided with the methylene chloride or with any methylene chloride containing product:

> This chemical/product is not and cannot be distributed in commerce (as defined in TSCA section 3(5)) or processed (as defined in TSCA section 3(13)) for consumer paint or coating removal.

(b) Beginning on [DATE 150 DAYS AFTER DATE OF PUBLICATION OF FINAL RULE IN THE **FEDERAL REGISTER**], each person who manufactures (including import) methylene chloride for any use must, prior to or concurrent with the shipment, notify companies to whom

methylene chloride is shipped, in writing, of the restrictions described in this subpart in accordance with paragraph (d) of this section.

(c) Beginning on [DATE 210 DAYS AFTER DATE OF PUBLICATION OF FINAL RULE IN THE **FEDERAL REGISTER**], each person who processes or distributes in commerce methylene chloride or methylene chloride-containing products for any use must, prior to or concurrent with the shipment, notify companies to whom methylene chloride is shipped, in writing, of the restrictions described in this subpart in accordance with paragraph (d) of this section.

(d) The notification required under paragraphs (b) and (c) of this section must occur by inserting the following text in section 1(c) and section 15 of the SDS provided with the methylene chloride or with any methylene chloride containing product:

After August 26, 2019, this chemical/product is not and cannot be distributed in commerce or processed for consumer paint or coating removal. After [DATE 270 DAYS AFTER DATE OF PUBLICATION OF FINAL RULE IN THE **FEDERAL REGISTER**] this chemical/product cannot be distributed in commerce to retailers for any use. After [DATE 360 DAYS AFTER DATE OF PUBLICATION OF FINAL RULE IN THE **FEDERAL REGISTER**], this chemical/product is and can only be processed or distributed in commerce for the following purposes: (1) Processing as a reactant; (2) Processing for incorporation into a formulation, mixture, or reaction product; (3) Processing for repackaging; (4) Processing for recycling; (5) Industrial or commercial use as a laboratory chemical; (6) Industrial or commercial use as a bonding agent for acrylic and polycarbonate in mission-critical military and space vehicle applications, including in the production of specialty batteries for such applications that are performed by the U.S. Department of Defense, the National Aeronautics and Space Administration, or the Department of Homeland Security or their contractors at locations controlled by the agency or the agency's contractor; (7) Industrial or commercial use for paint and coating removal from safety-critical, corrosion-sensitive components of aircraft and spacecraft that are owned or operated by the U.S. Department of Defense, the National Aeronautics and Space Administration, the U.S. Department of Homeland Security, and the Federal Aviation Administration that is performed by the agency or the agency's contractor at locations controlled by the agency or the agency's contractor; (8) Industrial or commercial use for paint and coating removal from safety critical, corrosion-sensitive components of other aircraft or spacecraft until [DATE 10 YEARS AFTER DATE OF PUBLICATION OF FINAL RULE IN THE **FEDERAL REGISTER**]; and (9) Disposal.

■ 9. Revise newly redesignated § 751.113 to read as follows:

§ 751.113 Recordkeeping Requirements.

(a) *General records.* Each person who manufactures (including imports), processes, or distributes in commerce any methylene chloride after August 26, 2019, must retain in one location at the headquarters of the company, or at the facility for which the records were generated, documentation showing:

(1) The name, address, contact, and telephone number of companies to whom methylene chloride was shipped;

(2) A copy of the notification provided under § 751.111; and

(3) The amount of methylene chloride shipped.

(b) *Exposure monitoring records.* Owners or operators are required to retain monitoring records in accordance with 29 CFR 1910.1052(m)(2) Additionally, for each monitoring event of methylene chloride required under this subpart, owners or operators must document the following:

(1) All measurements that may be necessary to determine the conditions that may affect the monitoring results;

(2) The identity of all other potentially exposed persons whose exposure was not measured but whose exposure is intended to be represented by the area or representative sampling monitoring;

(3) Use of established analytical methods;

(4) Compliance with the Good Laboratory Practice Standards in accordance with 40 CFR part 792; and

(5) Information regarding air monitoring equipment including: type, maintenance, calibrations, performance tests, limits of detection, and any malfunctions.

(c) *Exposure control records.* Owners or operators must retain records of:

(i) Exposure control plan as described in § 751.109(e)(2);

(ii) Regulated areas and authorized personnel;

(iii) Facility exposure monitoring records;

(iv) Notifications of exposure monitoring results;

(v) Personal protective equipment (PPE) and respiratory protection used by potentially exposed persons and program implementation, including fit-testing; and

(vi) Information and training provided pursuant to subsection (i) of this section.

(d) *Records related to § 751.115 exemptions.* To maintain eligibility for an exemption described in § 751.115, the records maintained by the owners or operators must demonstrate compliance with the specific conditions of the exemption.

(e) *Minimum record retention period.* The records required under paragraphs (a) through (c) of this section must be retained for at least 5 years from the date that such records were generated.

■ 10. Add § 751.115 to subpart B to read as follows:

§ 751.115 Exemptions.

(a) *In general.* (1) Time-limited exemptions as described in paragraphs (b)(1) through (3) of this section provided for through § 751.107(b)(7) are established in this section in accordance with 15 U.S.C. 2605(g)(1)(B).

(2) Time-limited exemptions as described in paragraph (b)(4) of this section are established in this section in accordance with 15 U.S.C. 2605(g)(1)(A).

(3) In order to be eligible for the exemptions established in this section, regulated parties must comply with all conditions established for such exemptions in accordance with 15 U.S.C. 2605(g)(4).

(b) *Time-limited exemptions.* (1) Paint or coating removal from safety-critical, corrosion-sensitive components of aircraft owned or operated by air carriers or commercial operators certificated under 14 CFR part 119 until [DATE 10 YEARS AFTER DATE OF PUBLICATION OF FINAL RULE IN THE **FEDERAL REGISTER**]. The following are specific conditions of this exemption:

(i) The paint or coating removal must be performed on the premises of maintenance or repair facilities operated by air carriers or commercial operators certificated under 14 CFR part 119 or at repair stations certificated under 14 CFR part 145, if their primary business is performing maintenance, preventive maintenance, rebuilding, or alteration of aircraft operated by air carriers and commercial operators certificated under 14 CFR part 119.

(ii) The owner or operator of the location where the paint or coating removal is being performed must comply with the Workplace Chemical Protection Program provisions in § 751.109.

(iii) The owner or operator of the location where the paint or coating removal is being performed must comply with the recordkeeping requirements in § 751.113.

(2) Paint and coating removal from safety-critical, corrosion-sensitive components of aircraft intended for, or suitable for operation by, air carriers and commercial operators certificated under 14 CFR part 119 until [DATE 10 YEARS AFTER DATE OF

PUBLICATION OF FINAL RULE IN THE **FEDERAL REGISTER**]. The following are specific conditions of this exemption:

(i) The paint or coating removal must be performed at locations owned or operated by the manufacturer of the aircraft.

(ii) The owner or operator of the location where the paint or coating removal is being performed must comply with the Workplace Chemical Protection Program provisions in § 751.109.

(iii) The owner or operator of the location where the paint or coating removal is being performed must comply with the recordkeeping requirements in § 751.113.

(3) Paint and coating removal from safety-critical, corrosion-sensitive components of spacecraft used in, or intended for use in, commercial space transportation operations subject to 14 CFR chapter III, including payloads such as satellites and similar hardware, until [DATE 10 YEARS AFTER DATE OF PUBLICATION OF FINAL RULE IN THE **FEDERAL REGISTER**]. The following are specific conditions of this exemption:

(i) The paint or coating removal must be performed at locations owned or operated by the manufacturer of the spacecraft or payload or similar hardware.

(ii) The owner or operator of the location where the paint or coating removal is being performed must comply with the Workplace Chemical Protection Program provisions in § 751.109.

(iii) The owner or operator of the location where the paint or coating removal is being performed must comply with the recordkeeping requirements in § 751.113.

(4) Use of methylene chloride or methylene chloride-containing products identified in paragraph (b)(4)(i) of this section in an emergency by the National Aeronautics and Space Administration and its contractors operating within the scope of their contracted work until [DATE 10 YEARS AFTER DATE OF PUBLICATION OF FINAL RULE IN THE **FEDERAL REGISTER**].

(i) *Applicability.* The emergency use exemption described in this paragraph (b)(4) shall apply to the following specific conditions of use as described in paragraphs (b)(4)(i)(A)(*1*) through (*7*) of this section.

(A) Conditions of use subject to this exemption:

(*1*) Industrial and commercial use as solvent for cold cleaning

(*2*) Industrial and commercial use as a solvent for aerosol spray degreaser/cleaner

(*3*) Industrial and commercial use in adhesives, sealants and caulks

(*4*) Industrial and commercial use in adhesive and caulk removers

(*5*) Industrial and commercial use in metal non-aerosol degreasers

(*6*) Industrial and commercial use in non-aerosol degreasers and cleaners

(*7*) Industrial and commercial use as solvent that becomes part of a formulation or mixture

(B) Emergency use:

(*1*) *In general.* An emergency is a serious and sudden situation requiring immediate action, within 15 days or less, necessary to protect:

(*i*) Safety of National Aeronautics and Space Administration's or their contractors' personnel;

(*ii*) National Aeronautics and Space Administration's missions;

(*iii*) Human health, safety, or property, including that of adjacent communities; or

(*iv*) The environment.

(*2*) *Duration.* Each emergency is a separate situation; if use of methylene chloride exceeds 15 days, then justification must be documented.

(*3*) *Eligibility.* To be eligible for the exemption, the National Aeronautics and Space Administration and its contractors must:

(*i*) Select methylene chloride because there are no technically and economically feasible safer alternatives available during the emergency.

(*ii*) Perform the emergency use of methylene chloride at locations controlled by National Aeronautics and Space Administration or its contractors.

(ii) *Requirements.* To be eligible for the emergency use exemption described in this paragraph (b)(4), National Aeronautics and Space Administration and its contractors must comply with the following conditions:

(A) *Notification.* Within 15 days of the emergency use by National Aeronautics and Space Administration and its contractors, National Aeronautics and Space Administration must provide notice to EPA that includes the following:

(*1*) Identification of the conditions of use detailed in paragraph (b)(4)(i)(A) of this section that the emergency use fell under;

(*2*) An explanation for why the emergency use met the definition of emergency in paragraph (b)(4)(i)(B) of this section; and

(*3*) An explanation of why methylene chloride was selected, including why there were no technically and economically feasible safer alternatives available in the particular emergency.

(B) *Exposure.* The owner or operator must comply with the Workplace Chemical Protection Program provisions in § 751.109, to the extent technically feasible in light of the particular emergency.

(C) *Recordkeeping.* The owner or operator of the location where the use takes place must comply with the recordkeeping requirements in § 751.113.

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Part VI

Department of Energy

Federal Energy Regulatory Commission
18 CFR Part 35
Incentives for Advanced Cybersecurity Investment; Final Rule

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

18 CFR Part 35

[Docket No. RM22–19–000; Order No. 893]

Incentives for Advanced Cybersecurity Investment

AGENCY: Federal Energy Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Federal Energy Regulatory Commission is revising its regulations to provide incentive-based rate treatment for the transmission of electric energy in interstate commerce and the sale of electric energy at wholesale in interstate commerce by utilities for the purpose of benefitting consumers by encouraging investments by utilities in Advanced Cybersecurity Technology and participation by utilities in cybersecurity threat information sharing programs, as directed by the Infrastructure Investment and Jobs Act of 2021.

DATES: This rule is effective July 3, 2023.

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SUPPLEMENTARY INFORMATION:

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I. Introduction

1. In this final rule, the Federal Energy Regulatory Commission revises its regulations pursuant to section 219A of the Federal Power Act (FPA) [1] to add subpart K, consisting of § 35.48, to our regulations to establish rules for incentive-based rate treatment for certain voluntary cybersecurity investments [2] by utilities [3] as described in this final rule. These rules make incentive-based rate treatment available to utilities that make voluntary cybersecurity investments in Advanced Cybersecurity Technology [4] that

[1] Infrastructure Investment and Jobs Act of 2021, Public Law 117–58, section 40123, 135 Stat. 429, 951 (to be codified at 16 U.S.C. 824s–1) (IIJA).

[2] In this final rule, the term investments includes expenditures that can be either capitalized costs or expenses.

[3] Notwithstanding that FPA section 219A requires the Commission to offer incentives to public utilities, as discussed in section III.A.1. of this final rule, we make rate incentives also available to non-public utilities that have or will have a rate on file with the Commission, similar to Commission precedent under FPA section 219, 16 U.S.C. 824s. We intend that all references in this final rule to utilities include both public utilities and non-public utilities that have or will have a rate on file with the Commission.

[4] FPA section 219A(a)(1) defines the term Advanced Cybersecurity Technology to mean any technology, operational capability, or service, including computer hardware, software, or a related

enhance their security posture by improving their ability to protect against, detect, respond to, or recover from a cybersecurity threat and to utilities that participate in cybersecurity threat information sharing programs. The Commission is issuing this final rule to comply with FPA section 219A(c).[5] This voluntary cybersecurity incentive-based rate treatment is for the purpose of benefitting consumers by encouraging cybersecurity investments in Advanced Cybersecurity Technology and in participation in cybersecurity threat information sharing programs.[6]

2. We establish a regulatory framework for utilities to request incentive-based rate treatment for certain voluntary cybersecurity investments.[7] Under this framework, we: (1) identify the utilities permitted to request incentive-based rate treatment for cybersecurity investments; (2) establish the criteria that the Commission will use to determine whether a cybersecurity investment is eligible to receive an incentive-based rate treatment; (3) discuss the approaches that a utility may use to demonstrate that a cybersecurity investment satisfies the eligibility criteria; (4) explain the types of incentive-based rate treatments available for qualifying cybersecurity investments; (5) set limits on the duration of the incentive-based rate treatment; (6) describe what utilities must include in their applications for incentive-based rate treatment for cybersecurity investments; and (7) establish the annual reporting requirements for utilities that receive incentive-based rate treatment for their cybersecurity investments.

II. Background

A. Infrastructure Investment and Jobs Act of 2021

3. On November 15, 2021, the IIJA was signed into law.[8] Section 40123 of the IIJA added section 219A to the FPA, which directs the Commission to revise its regulations to establish, by rule, incentive-based, including performance-based, rate treatments for the transmission of electric energy in interstate commerce and the sale of electric energy at wholesale in interstate commerce by public utilities for the purpose of benefitting consumers by encouraging investments by public utilities in Advanced Cybersecurity Technology and participation by public utilities in cybersecurity threat information sharing programs.

1. Advanced Cybersecurity Technology

4. Under FPA section 219A(a), an Advanced Cybersecurity Technology can be a product and/or a service.[9] Cybersecurity products are generally hardware, software, and cybersecurity services that can be used for information technology (IT) systems and/or operational technology (OT) systems.[10] Cybersecurity products can include, but are not limited to, security information and event management systems, intrusion detection systems, anomaly detection systems, encryption tools, data loss prevention systems, forensic toolkits, incident response tools, imaging tools, network behavior analysis tools, access management systems, configuration management systems, anti-malware tools, user behavior analytic software, event logging systems, and any system for access control, identification, authentication, and/or authorization control.

5. Cybersecurity services may be either automated or manual and can include, but are not limited to, system installation and maintenance, network administration, asset management, threat and vulnerability management, training, incident response, forensic investigation, network monitoring, data sharing, data recovery, disaster recovery, network restoration, log analytics, cloud network storage, and any general cybersecurity consulting service.

6. Under FPA section 219A(a), Advanced Cybersecurity Technology Information may include, but is not limited to, plans, policies, procedures, specifications, implementation, configuration, manuals, instructions, accounting, financials, logs, records, and physical or electronic access lists related to or regarding the Advanced Cybersecurity Technology. FPA section 219A(g) states that Advanced Cybersecurity Technology Information that is provided to, generated by, or collected by the Federal Government under FPA section 219A subsections (b), (c), or (f) shall be considered to be critical electric infrastructure information under FPA section 215A.[11] Utilities submitting to the Commission Advanced Cybersecurity Technology Information or other information they believe to be Critical Energy/Electric Infrastructure Information (CEII) must clearly indicate which portions of their filing contains CEII and provide public and non-public versions of the information pursuant to the Commission's regulations.[12]

2. Cybersecurity Threat Information Sharing Programs

7. FPA section 219A(c) directs the Commission to identify incentive-based rate treatments that could support participation by public utilities in cybersecurity threat information sharing programs. Utilities face barriers to participating in cybersecurity information sharing programs, such as the high costs associated with implementing monitoring technology and maintenance of sensor technology, the amount of time and effort required to share information, incurring fees to participate in cybersecurity threat information sharing programs, and concerns regarding the confidentiality of the information once shared.

B. Study and Report to Congress

8. As an initial step in the process of revising the Commission's regulations, FPA section 219A(b) requires the Commission to conduct a study, in consultation with certain entities,[13] to identify incentive-based rate treatments, including performance-based rates, for the jurisdictional transmission and sale of electric energy that could support investments in Advanced Cybersecurity Technology and participation by public utilities in cybersecurity threat

asset, that enhances the security posture of public utilities through improvements in the ability to protect against, detect, respond to, or recover from a cybersecurity threat. IIJA, Public Law 117–58, section 40123, 135 Stat. at 951 (to be codified at 16 U.S.C. 824s–1(a)(1)). FPA section 219A(a)(2) defines the term Advanced Cybersecurity Technology Information to mean information relating to advanced cybersecurity technology or proposed advanced cybersecurity technology that is generated by or provided to the Commission or another Federal agency. *Id.* at 952 (to be codified at 16 U.S.C. 824s–1(a)(2)).

[5] IIJA, Public Law 117–58, section 40123, 135 Stat. at 952 (to be codified at 16 U.S.C. 824s–1(c)).

[6] *Id.*

[7] *Incentives for Advanced Cybersecurity Investment,* Notice of Proposed Rulemaking, 87 FR 60567 (Oct. 6, 2022), 180 FERC ¶ 61,189 (2022) (NOPR).

[8] IIJA, Public Law 117–58, 135 Stat. 429.

[9] *Id.* at 952 (to be codified at 16 U.S.C. 824s–1(c)).

[10] The National Institute of Standards and Technology (NIST) glossary defines OT to mean programmable systems or devices that interact with the physical environment (or manage devices that interact with the physical environment). These systems/devices detect or cause a direct change through the monitoring and/or control of devices, processes, and events. Examples include industrial control systems, building management systems, fire control systems, and physical access control mechanisms. NIST, *Computer Security Resource Center, Glossary* (Mar. 10, 2022), *https://csrc.nist.gov/glossary.*

[11] IIJA, Public Law 117–58, section 40123, 135 Stat. at 952 (to be codified at 16 U.S.C. 824s–1(g)) (citing 16 U.S.C. 824o–1).

[12] *See* 18 CFR 388.113(d)(1)(i)–(ii).

[13] FPA section 219A(b) identifies the following entities: the Secretary of Energy; North American Electric Reliability Corporation (NERC); Electricity Subsector Coordinating Council (ESCC); and National Association of Regulatory Utility Commissioners (NARUC).

information sharing programs.[14] As directed, Commission staff consulted with the specified entities to help identify incentive-based rate treatments that could enhance the security posture of the Bulk-Power System.[15]

9. In addition to conducting the study, FPA section 219A(b) requires the Commission to submit a report to Congress (Report) detailing the results of the study. On May 13, 2022, the Report was submitted to Congress.[16] The Report, among other things, outlined prior Commission efforts to address incentives for cybersecurity initiatives. The Report provided information regarding potential incentive-based rate treatments and the Commission's general ratemaking authority, including the prior adoption of rate incentives and performance-based ratemaking in other contexts. In addition, the Report discussed challenges associated with adopting an incentive-based rate structure to enhance the security posture of the Bulk-Power System.

C. NOPR

10. On September 22, 2022, the Commission issued the NOPR in this proceeding, proposing under FPA section 219A to establish rules for incentive-based rate treatments for certain voluntary cybersecurity investments by utilities.[17] The Commission proposed that these rules would make incentives available to utilities that make certain cybersecurity investments that enhance their security posture by improving their ability to protect against, detect, respond to, or recover from a cybersecurity threat, or that participate in cybersecurity threat information sharing programs to the benefit of ratepayers and national security.

11. First, the Commission proposed a regulatory framework for how a utility could qualify for incentives for eligible cybersecurity investments.[18] Under this framework, the Commission proposed that eligible cybersecurity investments must: (1) materially improve cybersecurity through either an investment in Advanced Cybersecurity Technology or participation in a cybersecurity threat information sharing program; [19] and (2) not already be mandated by Critical Infrastructure Protection (CIP) Reliability Standards, or local, State, or Federal law.[20] The Commission proposed that a utility would seek incentive-based rate treatment for a cybersecurity investment in a filing pursuant to FPA section 205,[21] and that the incentive would be effective no earlier than the date of the Commission order approving the incentive request.[22]

12. Second, the Commission proposed to evaluate cybersecurity investments using a list of pre-qualified expenditures that are determined by the Commission to be eligible for incentives, which would be posted on the Commission's public website (PQ List).[23] The Commission proposed that any cybersecurity investment that is on the PQ List would be entitled to a rebuttable presumption of eligibility for an incentive.[24] With the Commission having evaluated cybersecurity investments to include on the PQ List in advance of the application for incentive-based rate treatment, along with the rebuttable presumption, the Commission postulated that the PQ List approach would provide an efficient and transparent mechanism for determining appropriate cybersecurity investments that are eligible for incentives.[25] The Commission also discussed and sought comment on a potential alternative approach, whereby a utility's cybersecurity investment would be evaluated on a case-by-case basis to determine if it is eligible for an incentive.[26]

13. Third, the Commission proposed two potential cybersecurity incentives: (1) a return on equity (ROE) adder of 200 basis points (Cybersecurity ROE Incentive); [27] and (2) deferred cost recovery for certain cybersecurity investments that enables the utility to defer expenses and include the unamortized portion in its rate base (Cybersecurity Regulatory Asset Incentive).[28]

14. Fourth, the Commission proposed that any approved incentive(s) would remain in effect for five years from the date on which the cybersecurity investment(s) enters service or the expenses are incurred, or expire earlier if certain other conditions discussed in the NOPR are met before the end of that five year period, *e.g.,* the cybersecurity investment becomes mandatory.[29] For continued voluntary participation in a cybersecurity threat information sharing program, however, the Commission proposed that utilities be able to continue deferring these expenses and including them in their rate base for each annual tranche of expenses, for as long as: (1) the utility continues incurring costs for its participation in the program; and (2) the program remains eligible for incentives.[30] The Commission sought comment on the proposed duration and expiration conditions for incentives granted under this proposal.

15. Finally, the Commission proposed that a utility receiving a cybersecurity incentive pursuant to the proposed rule must make an annual informational filing by June 1 of each year following the receipt of incentive for as long as the utility receives the incentive.[31] The Commission proposed that the annual filing should detail the specific cybersecurity investments that were made pursuant to the Commission's approval and the corresponding FERC account used.[32]

16. The initial comment period for the NOPR ended on November 7, 2022, and the Commission received 27 initial comments. The reply comment period for the NOPR ended on November 21, 2022, and the Commission received six reply comments.

III. Discussion

17. To implement the statutory directive in FPA section 219A, we add subpart K to our regulations, consisting of § 35.48, to establish the rules for incentive-based rate treatment for utilities that voluntarily make cybersecurity investments as described in this final rule. For this final rule, a

[14] IIJA, Public Law 117–58, section 40123, 135 Stat. at 952 (to be codified at 16 U.S.C. 824s–1(b)).

[15] The term Bulk-Power System is defined in FPA section 215 and refers to: (1) facilities and control systems necessary for operating an interconnected electric energy transmission network (or any portion thereof); and (2) electric energy from generation facilities needed to maintain transmission system reliability. 16 U.S.C. 824o(a)(1). In the context of developing and determining the applicability of mandatory Reliability Standards, NERC uses the term bulk electric system, which NERC defines to generally include the transmission facilities that are operated at 100 kV or higher and real power or reactive power resources connected at 100 kV or higher. *See* NERC, Glossary of Terms Used in NERC Reliability Standards (Mar. 8, 2023), *https://www.nerc.com/pa/Stand/Glossary%20of%20Terms/Glossary_of_Terms.pdf* (NERC Glossary).

[16] FERC, *Incentives for Advanced Cybersecurity Technology Investment* (May 2022).

[17] NOPR, 180 FERC ¶ 61,189 at P 1.

[18] *Id.* P 2.

[19] *Id.* PP 20–22.

[20] *Id.*

[21] 16 U.S.C. 824d. The Commission noted that a utility would be permitted to first file a petition for declaratory order to seek a Commission determination on its eligibility for an incentive, but the utility would still need to make a filing with the Commission pursuant to FPA section 205 before adding the incentive-based rate treatment to its rate on file with the Commission.

[22] NOPR, 180 FERC ¶ 61,189 at P 24.

[23] *Id.* P 25.

[24] *Id.* P 26.

[25] *Id.* P 27.

[26] *Id.* P 32.

[27] *Id.* P 36.

[28] *Id.* P 39.

[29] *Id.* PP 46–49.

[30] *Id.* P 49.

[31] *Id.* PP 54–56.

[32] *See* 18 CFR pt. 141.

cybersecurity investment includes both expenses and capitalized costs associated with Advanced Cybersecurity Technology and participation in a cybersecurity threat information sharing program. In this final rule we: (1) identify the utilities permitted to request incentive-based rate treatment for cybersecurity investments; (2) establish the criteria that the Commission will use to determine whether a cybersecurity investment is eligible to receive an incentive-based rate treatment; (3) discuss the approaches that a utility may use to demonstrate that a cybersecurity investment satisfies the eligibility criteria; (4) explain the type of incentive-based rate treatment available for qualifying cybersecurity investments; (5) set limits on the duration of the incentive-based rate treatment; (6) describe what utilities must include in their applications for incentive-based rate treatment for cybersecurity investments; and (7) establish the annual reporting requirements for utilities that receive incentive-based rate treatment for their cybersecurity investments.

A. Cybersecurity Investments

18. We establish a structure that allows certain entities to request rate incentives for cybersecurity investments that satisfy the eligibility criteria. First, we determine which utilities may request the cybersecurity incentives. Next, we add definitions that identify the types of investments for which those utilities could seek incentive-based rate treatment. Finally, we establish the eligibility criteria that the Commission will use to determine whether a cybersecurity investment is eligible for an incentive.

1. Utilities Eligible To Request Rate Incentives for Cybersecurity Investments

19. FPA section 219A(c) directs the Commission to establish, by rule, incentive-based rate treatment for the transmission of electric energy in interstate commerce and the sale of electric energy at wholesale in interstate commerce by public utilities for the purpose of benefiting consumers by encouraging cybersecurity investments.[33]

a. NOPR Proposal

20. In the NOPR, the Commission proposed to make rate incentives available to both public utilities as well as non-public utilities that have or will have a rate on file with the Commission, similar to Commission precedent regarding transmission incentives under FPA section 219.[34] The Commission explained that it intended that all references to utilities in the NOPR would include both public utilities and non-public utilities that have or will have a rate on file with the Commission.

b. Comments

21. Some commenters discuss the utilities that should or should not be eligible for cybersecurity incentives. American Public Power Association (APPA) agrees with the NOPR proposal that non-public utilities with rates on file with the Commission should be eligible to receive incentives for qualifying investments.[35] Electric Power Supply Association (EPSA) also supports the proposal and argues that the statutory language in FPA section 219A requires the Commission to extend the proposed incentives to all utilities whose rates are regulated by the Commission, including those utilities who recover their costs through competitive markets.[36]

22. EPSA contends that Congress did not intend to limit cybersecurity incentives to utilities with cost-of-service rates on file with the Commission, but rather intended to make incentive-based rates available to all utilities, including those with market-based rates.[37] EPSA specifically suggests that the Commission establish formula rates for costs associated with identified incented cybersecurity investments. Alternatively, EPSA suggests allowing market-based rate entities to make FPA section 205 filings to recover the costs of eligible cybersecurity investments.[38] In contrast, California Public Utilities Commission and the California Department of Water Resources State Water Project (California Parties) suggest that market-based rate sellers or generators should not be eligible for incentives, so as to avoid interference with competitive markets.[39] Transmission Access Policy Study Group (TAPS) states that the Commission should explicitly exclude generators with market-based rates from incentive eligibility.[40] APPA urges the Commission to clarify in the final rule that its proposed incentives are limited to cost-based rates and not available for wholesale sales made under market-based rate authority.[41]

c. Commission Determination

23. We adopt the NOPR proposal to permit public utilities and non-public utilities that have or will have a rate on file with the Commission to seek incentive-based rate treatment for their eligible cybersecurity investments.[42]

24. We add § 35.48(a) to our regulations, which declares that the purpose of this section is to establish rules for incentive-based rate treatment for utilities with rates on file with the Commission that voluntarily make cybersecurity investments. In doing so, we adopt the NOPR proposal to allow utilities described in FPA section 201(f)[43] that have or will have a rate on file with the Commission to be eligible to receive incentives for cybersecurity investments in the same manner as public utilities. Accordingly, we add § 35.48(c) to our regulations, which states that the Commission will authorize incentive-based rate treatment to public and non-public utilities that have or will have a rate on file with the Commission for their voluntary cybersecurity investments, provided that the resulting rate is just and reasonable and not unduly discriminatory or preferential.

25. In FPA section 219A(c), Congress directs the Commission to offer incentive-based rate treatment for both the transmission of electric energy in interstate commerce and the sale of electric energy at wholesale in interstate commerce. This rulemaking satisfies the statutory requirement of providing the opportunity for public and non-public utilities to file to seek authorization to recover the cost of and receive incentive-based rate treatment on eligible cybersecurity investments.

26. We disagree with EPSA's contentions that utilities that make sales of energy, capacity, or ancillary services at market-based rates should be able to continue to make those sales and also separately recover the costs of, and receive incentive-based rate treatment on, eligible cybersecurity investments. The Incentive permitted in this final rule may only be recovered through a cost-of-service rate. As noted above, the ability to seek incentive-based rate treatment under this final rule meets the requirements of FPA section 219A.[44] All

[33] IIJA, Public Law 117–58, section 40123, 135 Stat. at 952 (to be codified at 16 U.S.C. 824s–1(c)).

[34] NOPR, 180 FERC ¶ 61,189 at P 1 n.3 (citing 16 U.S.C. 824s).

[35] APPA Initial Comments at 6.

[36] EPSA Initial Comments at 6–7.

[37] *Id.* at 6.

[38] *Id.* at 8.

[39] California Parties Reply Comments at 13.

[40] TAPS Initial Comments at 26–27.

[41] APPA Initial Comments at 22.

[42] NOPR, 180 FERC ¶ 61,189 at P 1 n.3.

[43] 16 U.S.C. 824(f).

[44] The dissent's criticism correctly notes that FPA section 219A is designed to provide incentives for certain cybersecurity investments. However, FPA section 219A also requires the Commission to

Continued

sellers of energy, capacity, and ancillary services are free to file cost-of-service rates under FPA section 205. Thus, we note that utilities currently making sales of energy, capacity, and ancillary services under market-based rate authority may make a filing to recover their entire cost of service, including costs of and an incentive on, eligible cybersecurity investments and proceed to make sales exclusively under that cost-based rate.[45]

2. Cybersecurity Investment Definitions

27. The cybersecurity investments eligible for incentives could include investments in Advanced Cybersecurity Technology, voluntary participation in a cybersecurity threat information sharing program, or both. Accordingly, we add § 35.48(b) to our regulations to define these and other terms used in that section. We incorporate the definitions of Advanced Cybersecurity Technology and Advanced Cybersecurity Technology Information in FPA section 219A(a).[46] Therefore, we define Advanced Cybersecurity Technology as any technology, operational capability, or service, including computer hardware, software, or a related asset, that enhances the security posture of public utilities through improvements in the ability to protect against, detect, respond to, or recover from a cybersecurity threat (as defined in section 102 of the Cybersecurity Act of 2015 (6 U.S.C. 1501)).[47] We define Advanced Cybersecurity Technology Information as information relating to Advanced Cybersecurity Technology or proposed Advanced Cybersecurity Technology that is generated by or provided to the Commission or another Federal agency.[48] In accordance with FPA section 219A(g), Advanced Cybersecurity Technology Information is considered to be Critical Electric Infrastructure Information as that term is defined in FPA section 215A(a)(3) and § 388.113(c)(1) of the Commission's regulations.[49] We also define CEII in new subpart K as having the same meaning as that term is defined in § 388.113 of the Commission's regulations. In addition, we define Electric Reliability Organization and Reliability Standard as having the same meanings as those terms are defined in § 39.1 of the Commission's regulations.[50]

3. Cybersecurity Investment Eligibility Criteria

a. NOPR Proposal

28. In the NOPR, the Commission proposed that a cybersecurity investment must satisfy two eligibility criteria to be considered for a cybersecurity incentive.[51] First, the cybersecurity investment would need to materially improve cybersecurity through either an investment in Advanced Cybersecurity Technology or participation in a cybersecurity threat information sharing program. Second, the cybersecurity investment could not already be mandated by CIP Reliability Standards, or otherwise mandated by local, State, or Federal law. Additionally, the Commission sought comment on whether, and if so how, the Commission should evaluate and ensure that the benefits of the cybersecurity investment exceed the combined costs of the cybersecurity investment and incentive, to ensure that the proposed rates are just and reasonable. The Commission also sought comment on whether these would be the appropriate criteria and whether there are additional criteria or limitations that the Commission should consider (*e.g.,* whether the Commission should consider an obligation imposed by a State commission as a condition for a merger to be ineligible for an incentive).

29. The Commission proposed that, in determining which cybersecurity investments will materially improve a utility's security posture, the Commission will consider the following sources: (1) security controls enumerated in the NIST Special Publication (SP) 800–53 ''Security and Privacy Controls for Information Systems and Organizations'' catalog; [52] (2) security controls satisfying an objective found in the NIST Cybersecurity Framework; [53] (3) a specific recommendation from the Department of Homeland Security's (DHS) Cybersecurity and Infrastructure Security Agency (CISA) or from the Department of Energy (DOE); [54] (4) a specific recommendation from the CISA Shields Up Campaign; [55] (5) participation in the Cybersecurity Risk Information Sharing Program (CRISP) or similar cybersecurity threat information sharing program; and/or (6) the Cybersecurity Capability Maturity Model (C2M2) Domains [56] at the highest Maturity Indicator Level.[57] The Commission proposed that using these sources from other agencies responsible for addressing sophisticated and rapidly evolving cyber threats as qualifiers for the consideration of incentives would allow the Commission to benefit from the expertise of other Federal agencies and help ensure that the cybersecurity investments will be targeted and effective.

b. Comments

30. Microsoft Corporation (Microsoft) and the Michigan Public Service Commission (Michigan Commission) support the proposed eligibility criteria.[58] The Office of the Ohio Consumers' Counsel (Ohio Consumers' Counsel) also supports the proposed eligibility criteria and recommends that the Commission require utilities to demonstrate that their eligible expenditures provide quantifiable, incremental benefits to rate payers that will exceed expenditure cost.[59]

31. Alliant Energy Corporate Services, Inc. (Alliant), the Interstate Natural Gas Association of America (INGAA), the National Rural Electric Cooperative (NRECA), and APPA support the proposed eligibility criterion that a utility must show that a cybersecurity investment materially improves its cybersecurity posture for its investment to be eligible for an incentive.[60] While NRECA supports the proposed eligibility criterion, it is concerned that ''materially improves cybersecurity''

determine that any rate approved under this rule be just and reasonable, not unduly discriminatory or preferential. IIJA, Public Law 117–58, section 40123, 135 Stat. at 952 (to be codified at 16 U.S.C. 824s–1(e)). We agree with TAPS that the recovery of costs and an incentive as set forth in this final rule is not compatible with making sales at market-based rates. Therefore, our decision on this issue seeks to give meaning to all of the provisions of FPA section 219A.

[45] *Cf. PJM Interconnection, L.L.C.,* 178 FERC ¶ 61,121, at P 115 (2022) (noting generators' ability to choose between selling capacity at cost-based or market-based rates).

[46] IIJA, Public Law 117–58, section 40123, 135 Stat. 429, 951 (to be codified at 16 U.S.C. 824s–1(a)(1), (2)).

[47] *Id.* (to be codified at 16 U.S.C. 824s–1(a)(1)).

[48] *Id.* (to be codified at 16 U.S.C. 824s–1(a)(2)).

[49] 16 U.S.C. 824o–1(a)(3); 18 CFR 388.113(c)(1).

[50] 18 CFR 39.1.

[51] NOPR, 180 FERC ¶ 61,189 at P 20.

[52] NIST, Special Publication 800–53, Revision 5, *Security and Privacy Controls for Information Systems and Organizations,* (Dec. 12, 2020), *https://www.nist.gov/privacy-framework/nist-privacy-framework-and-cybersecurity-framework-nist-special-publication-800-53.*

[53] *See* NIST, *Cybersecurity Framework, https://www.nist.gov/cyberframework.*

[54] S*ee, e.g.,* CISA, *National Cyber Awareness System Alerts, https://www.cisa.gov/uscert/ncas/alerts.*

[55] *See* CISA, *Shields Up, https://www.cisa.gov/shields-up.*

[56] *See* DOE, *Cybersecurity Capability Maturity Model, https://www.energy.gov/ceser/cybersecurity-capability-maturity-model-c2m2.*

[57] NOPR, 180 FERC ¶ 61,189 at P 21.

[58] Microsoft Initial Comments at 1; Michigan Commission Initial Comments at 5–6.

[59] Ohio Consumers' Counsel Initial Comments at 4–5.

[60] Alliant Initial Comments at 3–4; INGAA Initial Comments at 3; NRECA Initial Comments at 4–5; APPA Initial Comments at 3.

may be too subjective to ensure that cybersecurity investments provide adequate benefits to customers.[61] NRECA recommends that the Commission specify additional criteria or establish a minimum level of benefit or value a cybersecurity investment would provide to be eligible.[62]

32. The Public Utilities Commission of Ohio's Office of the Federal Energy Advocate (Ohio FEA) and Edison Electric Institute (EEI) do not support the proposed eligibility criterion that a cybersecurity investment must materially improve cybersecurity.[63] Ohio FEA asserts that the term ''materially improves'' may be ambiguous and suggests that the Commission should provide additional detail regarding this criterion in order to achieve its objective and streamline review of cybersecurity incentives.[64] EEI argues that applying a ''materially improve'' test will lead to subjective and inconsistent results because it is unclear what additional insights the Commission would reference beyond the six sources from other agencies to satisfy the criterion.[65] EEI argues that the materiality test is not part of the statutory language and will not necessarily improve the cybersecurity posture of the filing utility.[66] EEI recommends that, instead, the Commission give utilities the flexibility to propose other sources than the six listed in the NOPR and provide context for why a cybersecurity investment supports a targeted level of cyber maturity within a broader cybersecurity risk management and control framework.[67]

33. Ohio FEA supports the Commission referencing other Federal agencies and activities to determine whether a cybersecurity investment materially improves cybersecurity but asserts that the final determination should be based on the specific circumstances of the filing utility.[68] INGAA recommends that the Federal Bureau of Investigation (FBI) and the National Security Agency (NSA) be added to the sources used to inform the Commission's determination of whether a particular cybersecurity investment satisfies the first eligibility criterion.[69] DOE states that, while the six sources listed in the NOPR are beneficial and valuable, they are not a comprehensive list of ways that cybersecurity can be measured.[70] SecurityScorecard recommends that international standards such as ISO/IEC 27000 and Information Systems Audit and Control Association's Control Objectives for Information and Related Technologies also be considered when assessing the materiality criteria.[71]

34. DOE and EEI recommend that the Commission adjust the eligibility criteria referencing the C2M2 Domains from the highest Maturity Indicator Level to lower, incremental levels.[72] DOE and EEI argue that investments made to reach lower, incremental maturity levels would be more valuable than overinvestment in unnecessary controls to reach the highest Maturity Indicator Level.[73]

35. Most commenters support the idea that expenditures already mandated by local, State, or Federal law or an enforceable CIP Reliability Standard should not be eligible for an incentive. EEI, NRECA, and INGAA support this eligibility criterion as proposed in the NOPR. Other commenters argue that the proposed criterion should be expanded to include other types of legally binding agreements or Reliability Standards.[74] TAPS, APPA, Ohio FEA, California Parties, and the Maryland Public Service Commission and Pennsylvania Public Utility Commission (Maryland and Pennsylvania Commissions) argue that investments made to satisfy any type of legal obligation should be ineligible for an incentive, including, for example, remedial measures as a settlement of NERC compliance violations, a condition of a State or Federal license, a condition of a merger proceeding, and an obligation under a cybersecurity insurance policy.[75] APPA further recommends that the Commission clarify whether investments are ineligible if mandated by only CIP Reliability Standards or also by any other mandatory Reliability Standard.[76] In addition to an expanded definition of ''mandated,'' TAPS recommends that the Commission require a filing utility to attest that a cybersecurity investment for which it seeks incentives is not being made to satisfy any legal obligation.[77]

36. The North American Electric Reliability Corporation and the six Regional Entities[78] (NERC) states that any voluntary incentives should build upon and complement existing cybersecurity CIP Reliability Standards.[79] NERC recommends that the Commission consider the relationship between voluntary cybersecurity investments and mandatory CIP Reliability Standards and cautions that it may be a challenge for the Commission to determine whether a particular investment is mandated by the CIP Reliability Standards.[80] NERC explains that, because the CIP Reliability Standards are outcome oriented and do not prescribe specific technologies, a utility may file for an incentive that, while not mandated, is being used to comply with mandatory CIP Reliability Standards.[81] TAPS similarly states that the Commission should take a nuanced approach to assess whether a technology exceeds the CIP Reliability Standards when a technology has been used to comply with, but is not specifically mandated by, a CIP Reliability Standard.[82] NRECA urges the Commission to consider whether it will grant incentives for cybersecurity expenditures that enhance the cybersecurity of low impact BES Cyber Systems or only medium or high impact BES Cyber Systems.[83]

37. California Parties support the addition of an eligibility criterion for information-sharing programs that the incentives be conditioned on utilities participating in all applicable regional and State cybersecurity initiatives.[84] DOE recommends that the Commission establish attributes that the Commission will consider when determining the eligibility of information-sharing programs for incentives.[85]

c. Commission Determination

38. We adopt and modify the NOPR proposal by adding § 35.48(d) to the Commission's regulations to permit a utility to receive incentive-based rate

[61] NRECA Initial Comments at 4–5.

[62] *Id.* at 5.

[63] EEI Initial Comments at 8; Ohio FEA Initial Comments at 5–6.

[64] Ohio FEA Initial Comments at 5–6.

[65] EEI Initial Comments at 8.

[66] *Id.* at 8.

[67] *Id.* at 8.

[68] Ohio FEA Initial Comments at 5–6.

[69] INGAA Initial Comments at 3.

[70] DOE Reply Comments at 6.

[71] SecurityScorecard Initial Comments at 4.

[72] DOE Reply Comments at 8–9; EEI Initial Comments at 8–9.

[73] DOE Reply Comments at 8; EEI Initial Comments at 8.

[74] TAPS Initial Comments at 9–12; APPA Initial Comments at 13; Ohio FEA Initial Comments at 6; California Parties Initial Comments at 20; Maryland and Pennsylvania Commissions Initial Comments at 8.

[75] TAPS Initial Comments at 12.

[76] APPA Initial Comments at 13.

[77] TAPS Initial Comments at 12.

[78] The six Regional Entities include the following: Midwest Reliability Organization, Northeast Power Coordinating Council, Inc., ReliabilityFirst Corporation, SERC Reliability Corporation, Texas Reliability Entity, Inc., and Western Electricity Coordinating Council.

[79] NERC Initial Comments at 3.

[80] *Id.* at 4.

[81] *Id.* at 4–5.

[82] TAPS Initial Comments at 12.

[83] NRECA Initial Comments at 5; *see* NERC Glossary defining BES Cyber Systems.

[84] California Parties Initial Comments at 5.

[85] DOE Reply Comments at 10.

treatment for a cybersecurity investment. We establish two eligibility criteria that require that each cybersecurity investment: (1) materially improves cybersecurity through either Advanced Cybersecurity Technology or participation in a cybersecurity threat information sharing program; and (2) is not already mandated by the Reliability Standards, or otherwise mandated by local, State, or Federal law, decision, or directive; otherwise legally mandated; or an action taken in response to a Federal or State agency merger condition, consent decree from Federal or State agency, or settlement agreement that resolves a dispute between a utility and a public or private party.[86]

39. In the NOPR, the Commission identified several sources that the Commission would consider as part of its evaluation of whether a cybersecurity investment would materially improve a utility's security posture, thereby providing quantifiable cybersecurity benefits.[87] Based on the comments received, we modify the NOPR proposal.

40. As recommended by INGAA, we find that the Commission should also consider specific recommendations from the FBI and NSA. Therefore, we find that, in determining which cybersecurity investments will materially improve a utility's security posture, the Commission will consider the following sources: (1) security controls enumerated in the NIST SP 800–53 ''Security and Privacy Controls for Information Systems and Organizations'' catalog; [88] (2) security controls satisfying an objective found in the NIST Cybersecurity Framework [89] technical subcategory; (3) a specific cybersecurity recommendation from a relevant Federal authority, such as DHS's CISA, the FBI, NSA, or DOE; [90] (4) participation in a relevant cybersecurity threat information sharing program; and/or (5) achieving and sustaining one or more of the C2M2 Domains at the highest Maturity Indicator Level.[91] Considering these sources as part of a Commission determination of whether a particular cybersecurity investment would materially improve cybersecurity will allow the Commission to approve objective, targeted, and effective cybersecurity investments for incentive treatment.[92]

41. In addition, we agree with DOE's and Ohio FEA's recommendation that the Commission expand the list of potential eligible cybersecurity threat information sharing programs beyond CRISP. We clarify that a utility may seek an incentive for participation in other cybersecurity threat information sharing programs and the Commission will consider whether such cybersecurity threat information sharing programs would qualify for incentive treatment. We will not, as EEI suggests, consider recommendations other than the five sources described above. Considering other sources would increase subjectivity and unpredictability of incentive-based rate treatment of cybersecurity investments.

42. We agree with DOE's and California Parties' recommendation that the Commission should establish eligibility criteria or attributes in evaluating cybersecurity threat information-sharing programs. The Commission will evaluate any proposed relevant cybersecurity threat information-sharing program to determine whether the program: (1) is sponsored by the Federal or State government; (2) provides two-way communications from and to electric industry and government entities; and (3) delivers relevant and actionable cybersecurity information to program participants from the United States electricity industry.

43. We decline to adopt SecurityScorecard's recommendation that the Commission consider international standards, such as ISO/IEC 27000, when assessing the materiality criteria. Like NIST SP 800–53, ISO/IEC 27000 provides a catalog of information and cyber-related security controls. While there are some differences in focus between the two standards, for the context of determining how to successfully categorize a cybersecurity investment used to improve the security posture of a utility, both standards perform similar functions. Therefore, we believe that considering such international standards in assessing materiality would be duplicative and unnecessary and we will not adopt this recommendation. Instead, we will use NIST SP 800–53 as the foundation of security controls to evaluate whether a cybersecurity investment materially improves the cybersecurity of a utility because NIST SP 800–53 was developed by a Federal agency and is publicly accessible without additional cost.

44. We also decline to adopt DOE and EEI's recommendation that the Commission provide incentives for any incremental steps taken by utilities in connection with C2M2 and not just for achieving the highest Maturity Indicator Level. The C2M2 model contains descriptive cybersecurity measures at a high level rather than prescriptive requirements. Therefore, it would be difficult for the Commission to determine that compliance with incremental steps necessarily materially improves cybersecurity. For these reasons, we are requiring a utility to demonstrate that its proposed cybersecurity investments will cause the utility to achieve Maturity Indicator Level 3 of the C2M2 Domains rather than the incremental steps of the lower Maturity Indicator Levels in order to receive an incentive for its cybersecurity investments.

45. TAPS, APPA, Ohio FEA, California Parties, and the Maryland and Pennsylvania Commissions request that the Commission ensure that investments made to satisfy any type of legal obligation be ineligible for an incentive. The Maryland and Pennsylvania

[86] As the dissent points out, FPA section 219A(c) directs the Commission to establish rate incentives for participation by public utilities in cybersecurity threat information sharing programs and investments by public utilities in Advanced Cybersecurity Technology, which it defines as any technology, operational capability, or service, including computer hardware, software, or a related asset, that enhances the security posture of public utilities through improvements in the ability to protect against, detect, respond to, or recover from a cyber security threat. Public Law 117–58, section 40123(a), 135 Stat. 429, 951 (codified 16 U.S.C. 824s–1(c)). FPA section 219A also specifies that such rate treatments exist for the purpose of benefitting consumers and requires that the Commission ensure that resulting rates be just and reasonable. *See* Public Law 117–58, section 40123(a), 135 Stat. 429, 951 (codified 16 U.S.C. 824s–1(a) & (c)). The materially improves incentive eligibility criterion seeks to balance these statutory requirements. Solely focusing on the term enhance may result in the Commission granting incentives that do not meet these other statutory requirements mentioned above. It is thus reasonable for the Commission to exercise its judgement via the materially improves eligibility criterion to evaluate incentives requests.

[87] In section III.B., we discuss different methods that utilities could use to show how their cybersecurity investments satisfy the eligibility criteria.

[88] NIST, Special Publication 800–53, Revision 5, *Security and Privacy Controls for Information Systems and Organizations,* (Dec. 12, 2020), *https://www.nist.gov/privacy-framework/nist-privacy-framework-and-cybersecurity-framework-nist-special-publication-800-53.*

[89] *See* NIST, *Cybersecurity Framework, https://www.nist.gov/cyberframework.*

[90] *See, e.g.,* CISA, *National Cyber Awareness System Alerts, https://www.cisa.gov/uscert/ncas/alerts.*

[91] *See* DOE, *Cybersecurity Capability Maturity Model, https://www.energy.gov/ceser/cybersecurity-capability-maturity-model-c2m2.*

[92] As we discuss in section III.B.1., when considering whether to add a cybersecurity investment to the PQ List, the Commission will determine whether the cybersecurity investment would materially improve cybersecurity for all utilities. As we discuss in section III.B.2., when evaluating a utility case-by-case application for incentive-based rate treatment for a particular cybersecurity investment, the Commission will determine whether the cybersecurity investment would materially improve cybersecurity for the utility requesting the incentive-based rate treatment.

Commissions comment that utilities should not receive incentives for implementing cybersecurity measures that are already made mandatory by existing and future obligations.[93] APPA comments that the Commission should broaden the second eligibility criterion to clarify that incentives would not be available for cybersecurity investments for mandatory Reliability Standards and that the Commission should replace the reference to the CIP Reliability Standards with Reliability Standards.[94] We agree with both suggestions. Accordingly, we are expanding the second eligibility criterion to emphasize the requirement that the utility must undertake the specific cybersecurity investment voluntarily in order to receive a cybersecurity incentive pursuant to our regulations. Our revised § 35.48(d)(2) provides that a cybersecurity investment is only eligible for an incentive if it is not already mandated by the Reliability Standards as maintained by the Electric Reliability Organization, or otherwise mandated by local, State, or Federal law, decision, or directive; otherwise legally mandated; or an action taken in response to a Federal or State agency merger condition, consent decree from Federal or State agency, or settlement agreement that resolves a dispute between a utility and a public or private party.[95]

46. Additionally, we recognize the concerns raised by NERC and TAPS about the difficulty in determining whether a particular cybersecurity investment is mandatory. Accordingly, as discussed in greater detail in section III.D.3., we are adopting TAPS's suggestion that, in order to demonstrate that the specific cybersecurity investment for which the utility is seeking an incentive is voluntary, the applicant must include an attestation in its filing so stating.[96]

47. TAPS raises issues about technologies that both meet and exceed the Reliability Standards. We recognize that there could be a single Advanced Cybersecurity Technology that provides multiple security controls that allow the utility to meet and potentially exceed compliance with a Reliability Standard. In that instance, where the utility makes a single cybersecurity investment for security controls to comply with a Reliability Standard, that investment will not be incentive-eligible. However, there may be instances where a utility invests in a single Advanced Cybersecurity Technology that while complying with a Reliability Standard also provides enhanced cybersecurity controls that go beyond compliance with a Requirement in the Reliability Standard. In those instances, only the incremental investment to exceed the Requirement of the Reliability Standard would be eligible for an incentive.

48. In response to NRECA's concerns regarding the reliability and security of low impact BES Cyber Systems, we are not requiring any eligibility criteria other than the two discussed above. Therefore, low impact BES Cyber Systems are not excluded from eligibility for incentive-based rate treatment for cybersecurity investments.

49. We disagree with EEI's conclusion that we should omit ''materially improve'' as the standard for the first eligibility criterion due to its absence from the statutory language and possible subjectivity. FPA section 219A requires the Commission to offer incentives for Advanced Cybersecurity Technology investments and participation in information-sharing programs. It does not require that the Commission provide incentives for *all* Advanced Cybersecurity Investments or participation in *any* information-sharing program. FPA section 219A also requires that the Commission ensure that rates are just and reasonable and not unduly discriminatory or preferential.[97] Without a materiality standard in the first criterion (or something similar), any Advanced Cybersecurity Investment that is not mandatory would be incentive-eligible, regardless of whether such investments enhance a utility's security posture or result in just and reasonable rates. Furthermore, use of such a standard is consistent with Commission precedent. In Order No. 679, the Commission required applicants for transmission incentives to show that requested incentives are tailored to the risks and challenges of individual projects, even though such a requirement is not included in the statutory language of FPA section 219.[98]

50. We recognize that the materially improves criterion requires use of Commission subject matter expertise and judgement. In exercising its subject matter expertise and judgement, the Commission will take into account the findings of other Federal agencies to inform its decisions, as described in section III.B.2.c. Although the Commission seeks to maximize predictability and transparency in its provision of incentives, some degree of judgement is necessary given the many types of cybersecurity threats and investments and their rapid evolution. It is for this reason that we also decline NRECA's request that the Commission provide additional criteria or a baseline level of benefit. As discussed in section III.C.3., quantification of benefits may be difficult for cybersecurity investments, such that a bright line benefit requirement is inappropriate. In this final rule, we are establishing eligibility criteria that balance the need to ensure that incentives are targeted at the most beneficial investments with recognizing that there are many potential cybersecurity investments which could provide a wide variety of benefits. We find that overly prescriptive eligibility criteria may unduly preclude incentive-based rate treatment of beneficial cybersecurity investments.

51. Although the Commission sought comment on whether, and if so how, the Commission should evaluate and ensure that the benefits of the cybersecurity investment exceed the combined costs of the cybersecurity investment and the incentive, to ensure that the proposed rates are just and reasonable, we will not at this time predicate incentive eligibility on such a cost-benefit showing. As the Commission proposed in the NOPR and we affirm here, the rates, including the costs of any incentive, must remain within the zone of reasonableness. This is necessary to ensure that the rates that include incentives for cybersecurity investments are just and reasonable and not unduly discriminatory or preferential.

52. Ohio Consumers' Counsel argues that there must be quantifiable, incremental benefits that can be measured in cost-benefit savings to consumers. Nevertheless, we find that quantification of the costs and benefits for each cybersecurity investment is

[93] Maryland and Pennsylvania Commissions Initial Comments at 8.

[94] APPA Initial Comments at 5.

[95] A mandate must either be for a utility to achieve a specific outcome or to require a utility to take a prescribed action. General mandates to improve a utility's cybersecurity may still make specific cybersecurity investments voluntary for purposes of the Commission's evaluation of the eligibility criteria.

[96] The attestation must be made by a senior person within the utility that the utility has authorized to act on behalf of the utility. One example of a senior person could be the CIP Senior Manager as NERC defines that term. NERC Glossary at 10 (defining CIP Senior Manager to mean ''A single senior management official with overall authority and responsibility for leading and managing implementation of and continuing adherence to the requirements within the NERC CIP Standards, CIP–002 through CIP–011.'').

[97] FPA section 219A(e)(1). FPA section 219A(e)(2) also prohibits unjust and unreasonable double recovery for Advanced Cybersecurity Technology. IIJA, Public Law 117–58, section 40123, 135 Stat. at 952 (to be codified at 16 U.S.C. 824s–1(e)(2)).

[98] *See Promoting Transmission Investment Through Pricing Reform,* Order No. 679, 71 FR 43294 (July 31, 2006), 116 FERC ¶ 61,057, at P 26, *order on reh'g,* Order No. 679–A, 72 FR 1152 (Jan. 10, 2007), 117 FERC ¶ 61,345 (2006), *order on reh'g,* 119 FERC ¶ 61,062 (2007).

neither required nor practical. Such a cost-benefit analysis is particularly inapt for cybersecurity where benefits are even harder to identify and quantify than are economic and reliability benefits for transmission investments. The courts have long recognized that a primary purpose of the FPA, and its counterpart the Natural Gas Act (NGA), is to encourage the orderly development of plentiful supplies of electricity and natural gas at reasonable prices.[99] To carry out this purpose, the Commission may consider non-cost factors as well as cost factors.[100] Moreover, Congress' enactment of section 219A reflects its determination that incentives generally can spur cybersecurity investments and their associated consumer benefits.

53. As the Commission proposed in the NOPR, we find that all cybersecurity investments must satisfy both of the eligibility criteria in order to be eligible for incentive treatment. In addition, we now clarify that a utility may not request an incentive for a cybersecurity investment that the utility has already been incurring for more than three months prior to the filing of the incentive application, as discussed in section III.C.2 of this final rule, unless that cybersecurity investment is for participation in an incentive-eligible cybersecurity threat information sharing program.

B. Cybersecurity Investment Incentive Requests

54. In order to maximize predictability and transparency in our provision of incentives, we provide below a framework for evaluating whether certain cybersecurity investments, including expenses and capitalized costs, are eligible for a cybersecurity incentive. First, as the Commission proposed in the NOPR, we include a list of pre-qualified investments, the PQ List, to identify certain cybersecurity investments that the Commission finds merit the rebuttable presumption of eligibility for all utilities and are therefore eligible for incentive-based rate treatment. We also discuss the procedures that we will use to update the PQ List. Second, we adopt the cybersecurity investments proposed in the NOPR for inclusion on the initial PQ List. Third, we describe how the Commission will evaluate whether a utility's cybersecurity investments that are not included on the PQ List may be eligible for incentive-based rate treatment. Finally, we discuss how a utility can seek incentive-based rate treatment for new cybersecurity investments made to comply with a Reliability Standard during the period after the Commission approves a new or modified cybersecurity Reliability Standard but before that new or modified cybersecurity Reliability Standard becomes mandatory and enforceable.

1. PQ List Approach

a. Structure of the PQ List

i. NOPR Proposal

55. In the NOPR, the Commission proposed to create a PQ List that would identify cybersecurity investments that the Commission determined would satisfy the eligibility criteria.[101] The Commission proposed that any cybersecurity investment that the Commission includes on the PQ List would be entitled to a rebuttable presumption of eligibility for an incentive.[102] However, an applicant would still need to demonstrate, and the Commission would need to find, that the proposed rate, inclusive of the cybersecurity incentive, is just and reasonable. The Commission proposed to provide an opportunity for protestors to rebut this presumption by demonstrating that the cybersecurity investment did not meet one or more of the eligibility criteria (*e.g.,* that, given the unique circumstances of the utility, the expenditure for which the utility seeks an incentive would not materially improve cybersecurity or is otherwise mandatory for that utility) or the Commission could make this finding based on other evidence.

56. The Commission explained that the PQ List approach would provide efficiency and transparency benefits.[103] The utility-specific incentive filings under the PQ List approach could be substantially streamlined compared to a case-by-case approach because the Commission would have pre-reviewed the cybersecurity investments included on the PQ List for eligibility for incentives.

57. In the NOPR, the Commission noted the rapidly evolving nature of cybersecurity threats and solutions and that it expected to regularly evaluate the PQ List and update it as necessary.[104] When updating the PQ List, the Commission could add, modify, or remove cybersecurity investments to/from the PQ List. The Commission proposed that it would update the PQ List via a rulemaking, whether *sua sponte* or in response to a petition.

ii. Comments

58. INGAA, Microsoft, TAPS, the Michigan Commission, Ohio Consumers' Counsel, ITC Companies, APPA, Anterix, Inc. (Anterix), OT Coalition, Avangrid, Inc. (Avangrid), MISO Transmission Owners, EPSA, and EEI support the PQ List approach.[105] OT Coalition, Avangrid, MISO Transmission Owners, EPSA, and EEI further urge the Commission to consider using both the PQ List and case-by-case approaches.[106] ITC Companies agree with the Commission that the PQ List approach will decrease the filing and review burden on utilities and the Commission [107] while INGAA and Microsoft agree that the PQ List approach will provide transparency for utilities as to what expenditures will be eligible for incentives.[108] Microsoft and Anterix caveat their support of the PQ List approach by suggesting other items for inclusion on the PQ List, such as security incident and event monitoring, user and entity behavior analysis,[109] and private LTE wireless broadband communication systems.[110] TAPS, Michigan Commission, and Ohio Consumers' Counsel recommend that the PQ List be updated regularly,[111] and APPA underscores the need for stakeholders to have the opportunity to rebut the presumption of eligibility.[112]

59. In contrast, Alliant, the Maryland and Pennsylvania Commissions, and DOE assert that that the PQ List approach with its rebuttable presumption of eligibility will lessen innovation by encouraging utilities to pursue the same types of cybersecurity investments (*i.e.,* those on the PQ List), regardless of the utility's individual

[99] Order No. 679, 116 FERC ¶ 61,057 at P 65 (citing *Pub. Util. Comm'n of the State of Cal.* v. *FERC,* 367 F.3d 925, 929 (D.C. Cir. 2004) (citing *NAACP* v. *FPC,* 425 U.S. 662, 670 (1976))).

[100] *Id.* (citing *Permian Basin Area Rate Cases,* 390 U.S. 747, 791, 815 (1968); *Me. Pub. Utils. Comm'n* v. *FERC,* 454 F.3d 278, 288 (DC Cir. 2006)).

[101] NOPR, 180 FERC ¶ 61,189 at P 25.

[102] *Id.* P 26.

[103] *Id.* P 27.

[104] *Id.* P 31.

[105] INGAA Initial Comments at 4; Microsoft Initial Comments at 2; TAPS Initial Comments at 4; Michigan Commission Initial Comments at 6; Ohio Consumers' Counsel Initial Comments at 8–9; ITC Companies Initial Comments at 4–5; APPA Initial Comments at 17; Anterix Initial Comments at 5; OT Coalition Initial Comments at 2; Avangrid Initial Comments at 5; MISO Transmission Owners Initial Comments at 6–7; EPSA Initial Comments at 5; EEI Initial Comments at 5.

[106] OT Coalition Initial Comments at 2; Avangrid Initial Comments at 5; MISO Transmission Owners Initial Comments at 6–7; EPSA Initial Comments at 5; EEI Comments at 5.

[107] ITC Companies Initial Comments at 4–5.

[108] INGAA Initial Comments at 4; Microsoft Initial Comments at 2.

[109] Microsoft Initial Comments at 1–2.

[110] Anterix Initial Comments at 5.

[111] TAPS Initial Comments at 6; Michigan Commission Initial Comments at 6; Ohio Consumers' Counsel Initial Comments at 8–9.

[112] APPA Initial Comments at 5.

needs and risks.[113] California Parties, while not necessarily opposed to the concept of a PQ List approach, strongly oppose giving filing utilities a rebuttable presumption of eligibility for expenditures on the PQ List.[114] They argue that the burden on a party seeking to rebut the presumption of eligibility is too great.[115]

60. Many commenters raise concerns that finding a balance between transparency and security will prove challenging for the Commission. NRECA cautions that a publicly accessible PQ List will alert adversaries to the cybersecurity activities of utilities and create a security risk.[116] Alliant recommends that, if the Commission decides to proceed with the PQ List approach, it defer to NERC for identification of technologies and designate the PQ List as CEII to protect it from public access.[117] On the other hand, California Parties and the Maryland and Pennsylvania Commissions underscore the need for public transparency and access to allow stakeholders to rebut the presumption of eligibility and utilities to know what types of expenditures are eligible.[118]

61. Some commenters describe the challenges that maintaining an updated PQ List will present for the Commission. Ohio FEA and the Maryland and Pennsylvania Commissions express concern that the Commission may be unable to maintain a current PQ List, due to the lengthy regulatory process required,[119] potentially leading to overinvestment in outdated measures and underinvestment in cutting edge technologies.[120] Most commenters support frequent and regular review and updates to the PQ List.[121] EEI recommends that the Commission commit to reviewing and updating the PQ List on a regular cadence no less than annually, while Anterix, Avangrid, TAPS, and Ohio Consumers' Counsel suggest regular and expeditious updates.[122] TAPS and Ohio Consumers' Counsel recommend that, when the Commission initiates a rulemaking to modify the PQ List, it should assess whether existing expenditures still meet the eligibility criteria in addition to assessing new additions.[123]

62. California Parties and NRECA emphasize that modifications to the PQ List should only be made via a full rulemaking process where stakeholders and customers have the opportunity to comment.[124] California Parties further argue that the Commission should not expand the initial PQ List in its final rule without a full notice-and-comment period for the suggested additions.[125] TAPS highlights that the rulemaking process will improve regulatory certainty for utilities and customers and facilitate participation and input on whether proposed expenditures meet the eligibility criteria.[126]

63. Indicated PJM Transmission Owners [127] and Anterix recommend that the Commission hold a technical conference to inform its decision making on reviewing and updating the eligible expenditures on the PQ List.[128]

iii. Commission Determination

64. We adopt and modify the NOPR's proposal to create a PQ List by adding § 35.48(e)(1) to the Commission's regulations, which establishes the framework for a PQ List of cybersecurity investments that the Commission finds materially improves cybersecurity. We find that the cybersecurity investments on the PQ List would be entitled to a presumption of satisfying the eligibility criteria. As proposed in the NOPR, protestors may seek to rebut this presumption by demonstrating that, given the unique circumstances of the utility, the cybersecurity investment on the PQ List would not materially improve cybersecurity of the utility. We note that the utility would still need to demonstrate that it would make the cybersecurity investment voluntarily. In addition, the Commission will not presume anything about the resulting rates. Utilities seeking an incentive under the PQ List must still show that the proposed rate, including the cybersecurity incentive, is just and reasonable and not unduly discriminatory or preferential.

65. The PQ List approach is also in line with FPA section 219A(d)(2), which allows the Commission to reduce the cybersecurity risks to the facilities of small or medium-sized public utilities with limited cybersecurity resources.[129] While all utilities would benefit from the reduced filing obligations when requesting incentive treatment for cybersecurity investments on the PQ List, we expect that this approach would be particularly beneficial for small and medium-sized utilities with limited cybersecurity resources.

66. We disagree with concerns that including cybersecurity investments on the PQ List would lessen cybersecurity innovation or alert adversaries of utility cybersecurity investment. Regarding lessening innovation, as an initial matter, we note that utilities may still seek to recover in their rates all prudently incurred cybersecurity investments. Furthermore, as described in section III.B.2, we are adding a case-by-case approach that may better incent cybersecurity investments responding to rapidly evolving threats than does the PQ List. Regarding concerns about alerting adversaries, we find that such assertions are speculative and that describing and providing incentives to broadly beneficial cybersecurity investments will not unto itself

[113] Alliant Initial Comments at 4–5; Maryland and Pennsylvania Commissions Initial Comments at 6.

[114] California Parties Initial Comments at 28–29.

[115] *Id.;* California Parties Reply Comments at 11–12.

[116] NRECA Initial Comments at 7–8.

[117] Alliant Initial Comments at 4–5.

[118] California Parties Initial Comments at 28–29; Maryland and Pennsylvania Commissions Initial Comments at 5–6.

[119] Ohio FEA Initial Comments at 14; Maryland and Pennsylvania Commissions Initial Comments at 5.

[120] Maryland and Pennsylvania Commissions Initial Comments at 5.

[121] Avangrid Initial Comments at 5; EEI Initial Comments at 6–7; TAPS Initial Comments at 5; Ohio Consumers' Counsel Initial Comments at 8; Anterix Reply Comments at 4.

[122] EEI Initial Comments at 6–7; Anterix Reply Comments at 4.; Avangrid Initial Comments at 5; TAPS Initial Comments at 5; Ohio Consumers' Counsel Initial Comments at 7.

[123] TAPS Initial Comments at 5; Ohio Consumers' Counsel Initial Comments at 8.

[124] NRECA Initial Comments at 8–9; California Parties Initial Comments at 33–34.

[125] California Parties Initial Comments at 11–12.

[126] TAPS Initial Comments at 5.

[127] Indicated PJM Transmission Owners consist of: American Electric Power Service Corporation on behalf of its affiliates, Appalachian Power Company, Indiana Michigan Power Company, Kentucky Power Company, Kingsport Power Company, Ohio Power Company, Wheeling Power Company, AEP Appalachian Transmission Company, Inc., AEP Indiana Michigan Transmission Company, Inc., AEP Kentucky Transmission Company, Inc., AEP Ohio Transmission Company, Inc., and AEP West Virginia Transmission Company, Inc.; Dayton Power and Light Company d/b/a AES Ohio; Dominion Energy Services, Inc. on behalf of Virginia Electric and Power Company d/b/a Dominion Energy Virginia; Duke Energy Corporation on behalf of its affiliates Duke Energy Ohio, Inc., Duke Energy Kentucky, Inc., and Duke Energy Business Services LLC; Duquesne Light Company; East Kentucky Power Cooperative; Exelon Corporation; FirstEnergy Service Company, on behalf of its affiliates American Transmission Systems, Incorporated, Jersey Central Power & Light Company, Mid-Monongahela Power Company, Keystone Appalachian Transmission Company, and Trans-Allegheny Interstate Line Company; PPL Electric Utilities Corporation; Public Service Electric and Gas Company; Rockland Electric Company; and UGI Utilities Inc.

[128] Indicated PJM Transmission Owners Initial Comments at 5; Anterix Initial Comments at 12–13.

[129] FPA section 219A(d)(2) provides that the Commission may provide additional incentives beyond incentive-based rate treatment in any case which the Commission determines that an investment in Advanced Cybersecurity Technology or in information sharing program costs will reduce cybersecurity risks to facilities of small or medium-sized public utilities with limited cybersecurity resources, as determined by the Commission. IIJA, Public Law 117–58, section 40123, 135 Stat. at 952 (to be codified at 16 U.S.C. 824s–1(d)(2)).

highlight either industry-wide or utility-specific vulnerabilities.

67. We disagree with comments recommending that we designate the PQ List as CEII. The PQ List does not meet the definition of CEII, because the list is general in nature and does not reveal specific vulnerabilities.[130] As discussed in section III.D.3.c., requests for incentive-based rate treatment for cybersecurity investments may include requests for CEII treatment consistent with our regulations.[131] As we approve additional PQ List items, we expect that any future PQ List item will not be more specific than what can be found in the already publicly available materials, such as the NIST publications and CIP Reliability Standards. We decline to adopt Alliant's recommendation that the Commission defer to NERC to identify eligible technologies for the PQ List. The Commission will evaluate potential cybersecurity technologies from time to time, and determine, based on the record evidence, whether it would be appropriate to add the proposed cybersecurity investments in these technologies to the PQ List.

68. We disagree with comments that the PQ List approach places an undue burden on parties seeking to rebut the presumption of eligibility. We believe that the PQ List approach appropriately balances the interests of the utilities and any potential protestors seeking to rebut the presumption of eligibility. By starting with the initial PQ List, we have identified specific cybersecurity investments that we find will materially improve the cybersecurity of utilities broadly, while enabling protestors to demonstrate that the eligibility criteria are not met in a utility's particular circumstance.

69. We acknowledge the concerns raised by commenters regarding the time necessary for the Commission to modify the PQ List. Some commenters request that the Commission commit to a regular update cycle for the PQ List. In this final rule, the Commission modifies the proposed regulation to allow the Commission to post the PQ List on its website and to update it subject to a notice and comment period or in a rulemaking. In addition, the case-by-case approach allows the Commission to evaluate whether a utility's cybersecurity investment would satisfy the eligibility criteria as to that utility. This means that utilities would not have to wait for the Commission to update the PQ List before seeking incentives for cybersecurity investments not yet included on the PQ List. In response to Indicated PJM Transmission Owners and Anterix's suggestion to have a technical conference when considering updates to the PQ List, we note that the Commission will consider such action when undertaking its periodic PQ List reviews.

b. Initial PQ Lis

i. NOPR Proposal

70. The Commission proposed to include two eligible cybersecurity investments on the initial PQ List: (1) expenditures associated with participation in CRISP;[132] and (2) expenditures associated with internal network security monitoring within the utility's cyber systems, which could include IT cyber systems and/or OT cyber systems, and which could be associated with cyber systems that may or may not be subject to the Reliability Standards.[133] The Commission believed that these cybersecurity investments would materially improve cybersecurity[134] and were not already mandated by the Reliability Standards[135] or otherwise mandated by Federal law. The Commission proposed to include CRISP, as its purpose is to facilitate the timely bi-directional sharing of unclassified and classified threat information and development of situational awareness tools that enhance the energy sector's ability to identify, prioritize, and coordinate the protection of critical infrastructure and key resources.[136]

71. The Commission also proposed to include internal network security monitoring on the PQ List because internal network security monitoring may better position a utility to detect malicious activity that has circumvented perimeter controls.[137] The Commission observed that, while the currently effective Reliability Standards do not require internal network security monitoring, NERC has recognized the proliferation and usefulness of such technology.[138] The Commission also sought comments on whether to include any additional cybersecurity investments on the initial PQ List.

ii. Comments

72. NERC, DOE, and Microsoft support the inclusion of CRISP on the PQ List.[139] EEI and American Electric Power Service Corporation (AEP) support incentives for both new and existing participants of CRISP.[140] EEI argues that, because participation in cybersecurity threat information sharing programs is an ongoing action and CRISP participants have to occasionally upgrade technology, existing participants should be eligible to receive an incentive.[141]

73. APPA and California Parties oppose the Commission providing incentives for existing CRISP participants.[142] APPA and California Parties argue that an incentive must be an inducement for future action and cannot provide an incentive for actions already taken, such as recovery of an incentive for ongoing participation in CRISP if a utility is already a participant.[143] APPA further adds that CRISP participants report high satisfaction with the program and thus do not need an incentive to continue participation.[144] The Maryland and Pennsylvania Commissions and California Parties note that most major

[130] *See* 18 CFR 388.113(c).

[131] *See* 18 CFR 388.113.

[132] *See* DOE, *Energy Sector Cybersecurity Preparedness, https://www.energy.gov/ceser/energy-sector-cybersecurity-preparedness.*

[133] NOPR, 180 FERC ¶ 61,189 at P 28.

[134] E.g., both participation in CRISP and internal network security monitoring would fall under recommendations in the NIST SP 800–53 ''Security and Privacy Controls for Information Systems and Organizations'' catalog.

[135] The Commission noted in the NOPR that it had already proposed to require NERC to develop and submit for Commission approval a mandatory Reliability Standard regarding internal network analysis and monitoring technologies for high and medium impact bulk electric system cyber systems. *See* NOPR, 180 FERC ¶ 61,189 at P 28 n.26 (citing *Internal Network Sec. Monitoring for High & Medium Impact Bulk Elec. Sys. Cyber Syss.,* Notice of Proposed Rulemaking, 87 FR 4173 (Jan. 27, 2022), 178 FERC ¶ 61,038 (2022)). The Commission has since issued a final rule directing NERC to develop and submit for Commission approval a Reliability Standard that addresses internal network security monitoring for high impact bulk electric system cyber systems and medium impact bulk electric system cyber systems with external routable connectivity. *Internal Network Sec. Monitoring for High & Medium Impact Bulk Elec. Sys. Cyber Syss.,* Order No. 887, 88 FR 8354 (Feb. 9, 2023), 182 FERC ¶ 61,021 (2023).

[136] DOE, *Energy Sector Cybersecurity Preparedness, https://www.energy.gov/ceser/energy-sector-cybersecurity-preparedness.*

[137] NOPR, 180 FERC ¶ 61,189 at P 29.

[138] *Id.* (citing NERC, *ERO Enterprise CMEP Practice Guide: Network Monitoring Sensors, Centralized Collectors, and Information Sharing,* 1 (June 4, 2021), *https://www.nerc.com/pa/comp/guidance/CMEPPracticeGuidesDL/CMEP%20Practice%20Guide%20-%20Network%20Monitoring%20Sensors.pdf* (explaining that NERC developed the guide in response to a DOE initiative ''to advance technologies and systems that will provide cyber visibility, detection, and response capabilities for [industrial control systems] of electric utilities.'').

[139] NERC Initial Comments at 3; DOE Reply Comments at 7; Microsoft Initial Comments at 2.

[140] EEI Initial Comments at 11; EEI Reply Comments at 5. AEP Initial Comments at 4.

[141] EEI Initial Comments at 11; EEI Reply Comments at 5.

[142] APPA Initial Comments at 5; California Parties Initial Comments at 10; California Parties Reply Comments at 8–9.

[143] APPA Initial Comments at 12–13; California Parties Initial Comments at 10; California Parties Reply Comments at 8–9.

[144] APPA Initial Comments at 13–14.

investor-owned utilities are already part of CRISP, whether individually or as members of a respective regional transmission organization or independent system operator.[145]

74. EEI, UMass Lowell Applied Research Corporation (UMLARC), Ohio FEA, and Microsoft recommend that the Commission consider for inclusion on the PQ List additional eligible cybersecurity threat information sharing programs.[146] EEI recommends that the PQ List be expanded to include other federally funded or supported cybersecurity threat information sharing programs,[147] while Ohio FEA suggests that the National Cyber Security Division cyber-response programs under DHS should be included in the PQ List.[148] Microsoft recommends modifying the proposed language to be solution-neutral and outcome-focused to accommodate other timely bi-directional threat information-sharing programs.[149]

75. Microsoft and EEI support the inclusion of internal network security monitoring on the initial PQ List.[150] EEI further recommends that the Commission broaden the eligibility for incentives to cybersecurity capabilities across protective and detective controls, not only those limited to internal network security monitoring.[151] Similarly, SecurityScorecard suggests that the Commission broaden its focus from internal network security monitoring to continuous monitoring so as to secure both the perimeter and internal network.[152] Microsoft supports eligible expenditures associated with internal network security monitoring as cybersecurity best practices consistent with a Zero Trust security model, including technologies associated with asset discovery, inventory and management, network monitoring, traffic classification, and behavior analytics within the internal environment.[153]

76. While acknowledging the cybersecurity benefits of internal network security monitoring, APPA and California Parties do not support its inclusion on the PQ List.[154] California Parties state that utilities have sufficient financial incentives to allocate funding towards internal network security monitoring through the Commission's existing cost recovery mechanisms, and that mandatory CIP Reliability Standards are better suited than incentives for facilitating widespread adoption of internal network security monitoring.[155] APPA argues that internal network security monitoring is not a category of expenditures that can be presumed to materially improve cybersecurity prior to agreement on best practices.[156] In their reply comments, California Parties echo APPA's concerns and note the lack of consensus between commenters as to what qualifies as internal network security monitoring.[157]

77. NERC notes that the CIP Reliability Standards are technology-neutral and do not prescribe specific technological methods, tools, or approaches to reach compliance.[158] NERC states that utilities and other NERC-registered entities may already be using internal network security monitoring in combination with other tools or processes to comply with Reliability Standards and therefore cautions that it may be difficult to determine whether a particular cybersecurity investment is mandatory for purposes of analyzing the second eligibility criterion.

78. UMLARC argues that defense communities face particular cybersecurity risks. UMLARC explains that certain defense communities are implementing community cyber force pilot programs. UMLARC recommends that the Commission place community cyber forces for information-sharing programs on the PQ List, while noting that these programs are still in pilot phases.[159]

79. NERC recommends that the Commission consider the deployment of sensors as part of an operational technology visibility program, administered by the Electricity Information Sharing and Analysis Center (E–ISAC), for inclusion on the PQ List.[160] Microsoft, MISO Transmission Owners,[161] and EEI support the inclusion of internal network security monitoring on the PQ List but recommend that internal network security monitoring expenditures be consistent with a Zero Trust security model.[162] EEI suggests that technology and processes to implement, manage, and monitor user and endpoint behavioral analysis be added to the PQ List.[163]

80. DOE states that the PQ List should be expanded to include other information sharing programs, as well as permit case-by-case basis evaluation of other investments.[164] When considering whether to expand eligible information-sharing programs on the PQ List, DOE recommends that the Commission consider whether investments for participating in other Department-led cybersecurity programs, such as C2M2, materially improve the security posture of the utility.[165] DOE suggests the specific inclusion of the Cybersecurity for the Operational Technology Environment program on the PQ List.[166] EEI broadly suggests that the Commission expand the PQ List to include other federally funded or supported cybersecurity threat information sharing programs.[167]

81. Anterix recommends that the Commission include expenditures for private LTE wireless broadband communication systems as an item eligible for incentives on the PQ List.[168] MISO Transmission Owners and International Transmission Companies

[145] Maryland and Pennsylvania Commissions Initial Comments at 9; California Parties Initial Comments at 7–8.

[146] EEI Initial Comments at 6; UMLARC Initial Comments at 4; Ohio FEA Initial Comments at 7–8.; Microsoft Initial Comments at 2.

[147] EEI Initial Comments at 6.

[148] Ohio FEA Initial Comments at 7–8.

[149] Microsoft Initial Comments at 2.

[150] *Id.;* EEI Initial Comments at 5.

[151] EEI Initial Comments at 5.

[152] SecurityScorecard Initial Comments at 6.

[153] Microsoft Initial Comments at 2.

[154] APPA Initial Comments at 18; California Parties Initial Comments at 13–14.

[155] California Parties Initial Comments at 13–14.

[156] APPA Initial Comments at 18.

[157] California Parties Reply Comments at 10.

[158] NERC Initial Comments at 4–5.

[159] UMLARC Initial Comments at 4.

[160] NERC Initial Comments at 4.

[161] MISO Transmission Owners consist of: Ameren Services Company, as agent for Union Electric Company d/b/a Ameren Missouri, Ameren Illinois Company d/b/a Ameren Illinois and Ameren Transmission Company of Illinois; American Transmission Company LLC; Big Rivers Electric Corporation; Central Minnesota Municipal Power Agency; City Water, Light & Power (Springfield, IL); Cleco Power LLC; Dairyland Power Cooperative; Duke Energy Business Services, LLC for Duke Energy Indiana, LLC; East Texas Electric Cooperative; Entergy Arkansas, LLC; Entergy Louisiana, LLC; Entergy Mississippi, LLC; Entergy New Orleans, LLC; Entergy Texas, Inc.; Great River Energy; GridLiance Heartland LLC; Hoosier Energy Rural Electric Cooperative, Inc.; Indiana Municipal Power Agency; Indianapolis Power & Light Company; Lafayette Utilities Systems; MidAmerican Energy Company; Minnesota Power (and its subsidiary Superior Water, L&P); Montana-Dakota Utilities Co.; Northern Indiana Public Service Company LLC; Northern States Power Company, a Minnesota corporation, and Northern States Power Company, a Wisconsin corporation, subsidiaries of Xcel Energy, Inc.; Northwestern Wisconsin Electric Company; Otter Tail Power Company; Prairie Power, Inc.; Republic Transmission, LLC; Southern Illinois Power Cooperative; Southern Indiana Gas & Electric Company (d/b/a CenterPoint Energy Indiana South); Southern Minnesota Municipal Power Agency; Wabash Valley Power Association, Inc.; and Wolverine Power Supply Cooperative, Inc.

[162] Microsoft Initial Comments at 2; MISO Transmission Owners Initial Comments at 6–7; EEI Initial Comments at 5–6.

[163] EEI Initial Comments at 5–6.

[164] DOE Reply Comments at 6–12.

[165] *Id.* at 10.

[166] *Id.*

[167] EEI Initial Comments at 6.

[168] Anterix Initial Comments at 5.

(ITC Companies) [169] recommend that the Commission add expenditures for utility-owned private fiber networks to the PQ List, as well as expenditures made to upgrade or replace legacy operating systems.[170] They further suggest that the Commission should expand the PQ List to include advanced cybersecurity expenditures to address physical security, such as biometric identification, access cards or access control systems.[171]

82. Microsoft and EEI both recommend inclusion of user and endpoint behavioral analysis.[172] Avangrid and the Operational Technology Cybersecurity Coalition (OT Coalition) advocate for the addition of hardware and software risk management tools aimed to help identify cybersecurity threats to suppliers and vendors.[173] MISO Transmission Owners additionally propose that the Commission expand the PQ List to include cybersecurity expenditures such as for DHS's CyberSentry hardware and software.[174]

83. Microsoft recommends expanding the PQ List to include cloud-enabled security solutions, threat intelligence, vulnerability assessment, access control and privileged access management, endpoint detection and response, firewall and network management, and multifactor authentication and biometrics.[175] EEI suggests that the Commission consider adding technology and processes to develop threat hunting capability within IT and OT environments (*e.g.,* incident response retainer fees, penetration tests, or vulnerability assessments; secure coding practices and consulting services to navigate Software Bill of Materials requirements; and data loss prevention capabilities).[176]

iii. Commission Determination

84. We adopt and modify the NOPR's proposal and add § 35.48(e)(1) to the Commission's regulations to include two cybersecurity investments on the initial PQ List: (1) cybersecurity investments associated with participation in CRISP and (2) cybersecurity investments associated with internal network security monitoring within the utility's cyber systems. We find that both of these cybersecurity investments satisfy the eligibility criteria and both merit the rebuttable presumption.

85. First, we include cybersecurity investments associated with a utility's participation in CRISP. We find that a utility's participation in CRISP materially improves cybersecurity because it involves utility participation in a cybersecurity threat information sharing program. We note that such participation falls under the recommendations in the NIST SP 800–53 Security and Privacy Controls for Information Systems and Organizations catalog. In addition, CRISP: (1) is facilitated by the Federal Government; (2) provides two-way communications from and to electric industry and government entities; and (3) delivers relevant and actionable cybersecurity information to participants within the United States electricity industry. Having found that participation in CRISP satisfies the first eligibility criterion, we include it on the initial PQ List.

86. We are aware that many, but not all, utilities already participate in CRISP. Our inclusion of CRISP on the initial PQ List reflects the mandate in FPA section 291A(c) to establish incentive-based rate treatments by encouraging *participation* in cybersecurity threat information sharing programs. The mandate to incentivize *participation* indicates that all CRISP participants, not just new entrants, should be eligible to seek an incentive for any new cybersecurity investment associated with their participation, so long as that participation is voluntary.

87. Second, we include cybersecurity investments associated with a utility's investment in internal network security monitoring within the utility's cyber systems. As the Commission explained in the NOPR, a utility's cybersecurity investments associated with internal network security monitoring could include IT cyber systems and/or OT cyber systems and could be associated with cyber systems that may or may not be subject to the Reliability Standards.

88. We find that cybersecurity investments associated with internal network security monitoring within the utility's cyber systems materially improves cybersecurity because they are investments in Advanced Cybersecurity Technology. Internal network security monitoring falls under the recommendations in the NIST SP 800–53 Security and Privacy Controls for Information Systems and Organizations catalog. Having found that cybersecurity investments associated with internal network security monitoring within the utility's cyber systems satisfies the first eligibility criterion, we will include it on the initial PQ List.

89. NERC observes that some utilities may already use internal network security monitoring as part of their compliance with Reliability Standards and therefore cautions that it may be difficult to determine whether a particular cybersecurity investment is mandatory for purposes of determining whether such expenditures would qualify for incentive-based rate treatment. We have addressed this concern primarily in section III.A.3.c., and we reiterate that a utility's cybersecurity investments, including internal network security monitoring, made to comply with a Reliability Standard, will not be incentive-eligible because the utility did not make those investments voluntarily. However, there may be instances where a utility invests in internal network security monitoring that while complying with a Reliability Standard also provides enhanced cybersecurity protections that go beyond compliance with a Requirement in the Reliability Standard.[177] Those incremental cybersecurity investments in internal network security monitoring that go beyond compliance with a Requirement in a Reliability Standard would be eligible for incentive-based rate treatment provided that the utility demonstrates that the incremental cybersecurity investments satisfy the eligibility criteria.[178] With regard to NERC's concern regarding the potential difficulty of discerning which cybersecurity investments for internal network security monitoring qualify for incentive-based rate treatment, it is incumbent upon the utility to demonstrate in its filing seeking an incentive that the associated expenses are for new internal network security monitoring that is in addition to its preexisting cybersecurity programs and go beyond compliance with a Requirement in the Reliability Standard.

90. We decline at this time to add any additional cybersecurity investments to

[169] ITC Companies d/b/a ITC*Transmission,* Michigan Electric Transmission Company, LLC, ITC Midwest LLC, and Great Plains, LLC.

[170] MISO Transmission Owners Initial Comments at 6–7; ITC Companies Initial Comments at 5–6.

[171] MISO Transmission Owners Initial Comments at 6–7; ITC Companies Initial Comments at 5–6.

[172] Microsoft Initial Comments at 2; EEI Initial Comments at 6–7.

[173] Avangrid Initial Comments at 6; OT Coalition Initial Comments at 3.

[174] MISO Transmission Owners Initial Comments at 6.

[175] Microsoft Initial Comments at 2.

[176] EEI Initial Comments at 5–6.

[177] *See infra* section III.C.2.c. (discussing the availability of incentive-based rate treatment for *new* cybersecurity investments).

[178] We discuss in section III.D.3.c. the types of information that a utility would need to include in is filing of a request for incentive-based rate treatment for its cybersecurity investment. A utility seeking an incentive-based rate treatment for the incremental voluntary portion of its cybersecurity investment would need to identify its additional, voluntary cybersecurity investments that exceed the legal requirement. The utility would also need to distinguish the portion of the cybersecurity investment it made to comply with a legal requirement from the voluntary portion.

the initial PQ List. Because of the rebuttable presumption afforded to items on the PQ List, it is important that the Commission have a high degree of confidence that such items will likely materially improve cybersecurity for all utilities. While many of the additional cybersecurity investments commenters suggest to include on the initial PQ List may indeed be beneficial investments that would improve cybersecurity, we find that suggestions offered by commenters either lack sufficient evidence to show they will materially improve cybersecurity across all utilities or lack sufficient specificity to be included on the PQ List at this time.

91. As discussed in section III.B.1.a., the Commission will, from time to time, evaluate whether it would be appropriate to modify the PQ List. As the Commission updates the PQ List over time, entities may propose to add the items that the Commission does not accept in this final rule as well as other items, assuming that the entities can provide adequate support as to why it is appropriate to include these items. We also note that we are adding a case-by-case approach in addition to the PQ List approach, and utilities can seek an incentive for these investments on an individual basis, albeit without the presumption of eligibility.

92. In response to SecurityScorecard's suggestion that the Commission broaden its focus from internal network security monitoring to continuous monitoring, we do not agree that the PQ List should be so expanded at this time, as we note that the CIP Reliability Standards already mandate perimeter monitoring in some form. In response to Microsoft and EEI's suggestions, we recognize the benefits of both the Zero Trust security model and deploying Security Information and Event Management processes. However, both are considered to be frameworks that guide cybersecurity investments rather than specific cybersecurity investments themselves. We note that the Commission could consider providing incentives to specific applications of either the Zero Trust security model or Security Information and Event Management on a case-by-case basis, and, in the future, the Commission could consider adding specific applications of these concepts to the PQ List.

93. We disagree with UMLARC that community cyber force informational-sharing programs should be on the PQ List. Community cyber forces are currently pilot programs. By their nature as pilot programs, community cyber forces do not have standardized specific attributes, nor do they have a proven track record for placement on a pre-qualified list. Given that we do not have a clear understanding of these pilot programs or any associated investments, at this time, we decline to add community cyber forces to the PQ List.

94. We disagree with Anterix, MISO Transmission Owners, and ITC Companies' proposals to include investments in private communication systems such as LTE wireless and fiber networks on the PQ List. The use of private communication systems does not necessarily provide a cybersecurity benefit because the confidentiality of data transiting those networks may not be encrypted.

95. The MISO Transmission Owners recommend that the Commission consider adding expenditures associated with the Department of Homeland Security's CyberSentry hardware and software to the PQ List.[179] CyberSentry is a pilot program, and the record in this proceeding does not include enough evidence for us to determine whether CyberSenrty would materially improve the cybersecurity of all utilities. Nevertheless, CyberSentry uses sensors to monitor the IT and OT Networks for cyber security threats, and incentive-based rate treatment for these cybersecurity investments may already be eligible cybersecurity investments as internal network security monitoring.

96. DOE recommends that the Commission consider including the Cybersecurity for the Operational Technology Environment (CyOTE™) program on the PQ List. According to DOE, this program enhances OT threat information-gathering for the energy sector.[180] CyOTE is currently under development, and the record in this proceeding does not include enough evidence for us to determine whether cybersecurity investments associated with CyOTE would materially improve cybersecurity for all utilities. We find that MISO Transmission Owners' and ITC Companies' proposals to include investments made for physical access control systems, access cards, and biometrics are beyond the scope for this proceeding because they are not investments in Advanced Cybersecurity Technology or related to participation in a cybersecurity threat information sharing program. MISO Transmission Owners and ITC Companies also propose including investments for upgrading or replacing legacy systems. We find there is insufficient evidence in the record to determine whether the specific applications could be considered cybersecurity investments. Accordingly, we decline to include these investments on the PQ List.

97. Cybersecurity investments in Advanced Cybersecurity Technology included on the PQ List must include at least one specific security control that materially improves the cybersecurity of all utilities, thus meriting a rebuttable presumption. We find that the proposals from Microsoft and EEI to expand the PQ List to cover a broader set of advanced cybersecurity solutions such as threat intelligence, vulnerability management, access control, and others are vague and lack the specificity needed to establish a record for inclusion on the PQ List. Proposals from Avangrid and the OT Coalition to include investments for hardware and software risk management tools similarly lack specificity. We therefore decline to include these investments on the PQ List at this time.

98. While proposals from EEI to consider investments related to threat hunting, penetration tests, and consulting services for Software Bill of Materials requirements describe efforts to detect cybersecurity vulnerabilities, they also lack specificity with regard to mitigation and remediation of identified deficiencies. Microsoft and EEI both propose including investments for user and endpoint behavioral analysis, and NERC proposes including investments for the deployment of OT sensors. However, commenters do not demonstrate that these items are different in scope than what is already covered by internal network security monitoring on the PQ List. Therefore, we decline to include these investments on the PQ List at this time.

99. As discussed in section III.B.1.a., the Commission will, from time to time, evaluate whether it would be appropriate to modify the PQ List. We also note that, because we are adding a case-by-case approach in addition to the PQ List approach, utilities can seek an incentive for investments not identified

[179] Department of Homeland Security, *ICS Security Offerings Fact Sheet, https://www.cisa.gov/sites/default/files/publications/ics_security_offerings_fact_sheet_S508C.pdf* (explaining that ''CyberSentry is a voluntary pilot program that leverages best in breed, commercial off-the-shelf technologies, such as network intrusion detection tools, to identify malicious activity in Critical infrastructure (CI) ICS and corporate networks. CyberSentry participation increases real-time visibility into U.S. CI and provides the capability to detect nation-state adversaries on CI networks and derive cross-sector analytic insights.'').

[180] DOE, *Cybersecurity for the Operational Technology Environment (CyOTE), https://www.energy.gov/ceser/cybersecurity-operational-technology-environment-cyote* (stating that CyOTE is a ''research initiative, led by CESER in partnership with Idaho National Laboratory and energy sector partners, aims to develop tools and capabilities that can provide energy asset owners and operators with timely alerts and actionable information.'').

on the PQ List, albeit without the presumption of eligibility.

2. Case-by-Case Approach

a. NOPR Proposal

100. In the NOPR, the Commission recognized the limitations of only adopting the PQ List approach and sought comment on whether and, if so, how it should implement a case-by-case approach to grant incentives.[181] The Commission explained that it could permit a utility to file for incentive-based rate treatment for any cybersecurity investment that the utility believes satisfies the eligibility criteria, and that the Commission would review such filings on a case-by-case basis, to determine whether the proposed cybersecurity expenditure satisfies the eligibility criteria.

101. The Commission further explained that its evaluation of a utility's application under the case-by-case approach would differ from its evaluation of a filing seeking incentives for items on the PQ List, although the eligibility criteria would be the same under either approach. Specifically, the case-by-case application would not receive a presumption of eligibility for any cybersecurity investment and the utility would bear the full burden to demonstrate in its filing that its cybersecurity investment meets the eligibility criteria. Just as it would in a filing for incentive treatment of a cybersecurity investment on the PQ List, the filing utility would also need to demonstrate that its proposed rate, inclusive of the incentive, is just and reasonable.

b. Comments

102. OT Coalition, Avangrid, MISO Transmission Owners, EPSA, INGAA, EEI, Microsoft, Ohio Consumers' Counsel, Anterix, and DOE support the adoption of a case-by-case approach in addition to the PQ List approach.[182] Alliant and the Maryland and Pennsylvania Commissions support the adoption of a case-by-case approach instead of the PQ List approach.[183] TAPS, the Michigan Commission, APPA, and California Parties oppose the Commission adoption of a case-by-case approach.[184]

103. EEI, MISO Transmission Owners, INGAA, and Anterix describe the role of a case-by-case approach as a supplement to the PQ List approach, providing flexibility for the filing utilities.[185] Microsoft, OT Coalition, and Ohio Consumers' Counsel highlight the use of the case-by-case approach as a mechanism both for utilities to file for incentives not on the PQ List and to inform additions to the PQ List.[186] INGAA asserts that the case-by-case approach will encourage utilities to make qualifying investments not included on the PQ List, which will result in strengthening the security posture of the Bulk-Power System.[187] Avangrid states that the Commission should allocate sufficient human and financial resources to ensure timely review of case-by-case incentive requests.[188]

104. Alliant and the Maryland and Pennsylvania Commissions support the adoption of a case-by-case approach over the PQ List. Alliant argues that, due to the dynamic and rapid pace at which cybersecurity solutions become obsolete, the case-by-case approach will allow the Commission to review incentive requests in light of the most current technologies available and the overall needs of the utility.[189] The Maryland and Pennsylvania Commissions assert that the case-by-case approach would encourage utilities to be more innovative in their cybersecurity improvements and allows an applicant to demonstrate how a particular incentive addresses the utility's actual needs or meets the statutory criteria specific to the individual utility.[190] Ohio FEA argues that the PQ List approach alone is an inadequate approach because it will be unable to stay abreast of the ever-changing cybersecurity landscape.[191]

105. TAPS, the Michigan Commission, APPA, and California Parties oppose the adoption of the case-by-case approach. The Michigan Commission supports the transparency and efficiency that the PQ List provides over the case-by-case approach.[192] The Michigan Commission argues that, if a cybersecurity investment materially improves security, the investment should be considered for inclusion in the CIP Reliability Standards.[193] TAPS also enumerates concerns with the efficiency and transparency of the case-by-case approach, as well as the potential for increased litigation expenses and slower adoption of Advanced Cybersecurity Technologies.[194] APPA states that the case-by-case approach would be administratively burdensome and lead to incentives for routine, best practice cybersecurity expenditures.[195] California Parties argue that a case-by-case approach would be administratively infeasible and reduce regulatory certainty for filing utilities.[196]

106. The Iowa Utilities Board states that incentives under the case-by-case approach should be higher than those granted under the PQ List because the case-by-case approach drives innovation.[197]

c. Commission Determination

107. We adopt a case-by-case approach to granting incentives by adding § 35.48(e)(2) to the Commission's regulations, which permits a utility to demonstrate that a cybersecurity investment satisfies each of the eligibility criteria. Unlike the PQ List approach, the Commission will not presume that the requested cybersecurity investment satisfies the eligibility criteria. The utility requesting incentive-based rate treatment would need to demonstrate in its filing that the cybersecurity investment(s) would materially improve cybersecurity for the utility requesting the incentive-based rate treatment.

108. We find that allowing utilities to make case-by-case cybersecurity incentive requests in addition to PQ List requests provides several benefits. The case-by-case approach offers greater flexibility than the PQ List approach alone for utilities to respond to cybersecurity threats. In addition, reviewing cybersecurity investments on a case-by-case basis can help to inform the Commission about potential new additions that it could make to the PQ List in future proceedings. We believe

[181] NOPR, 180 FERC ¶ 61,189 at P 32.

[182] OT Coalition Initial Comments at 2–3; Avangrid Initial Comments at 5, 6. MISO Transmission Owners Initial Comments at 4; EPSA Initial Comments at 5; INGAA Initial Comments at 4; EEI Initial Comments at 4–5; Microsoft Initial Comments at 2; Ohio Consumers' Counsel Initial Comments at 9; Anterix Initial Comments at 12–13; Anterix Reply Comments at 12; DOE Reply Comments at 10.

[183] Alliant Initial Comments at 4–5; Maryland and Pennsylvania Commissions Initial Comments at 7–8.

[184] TAPS Initial Comments at 7; Michigan Commission Initial Comments at 6; APPA Initial Comments at 5; California Parties Initial Comments at 31–32; California Parties Reply Comments at 12–13.

[185] EEI Initial Comments at 4–5; MISO Transmission Owners Initial Comments at 4; INGAA Initial Comments at 4; Anterix Initial Comments at 12–13; Anterix Reply Comments at 12.

[186] Microsoft Initial Comments at 2; OT Coalition Initial Comments at 2, 3; Ohio Consumers' Counsel Initial Comments at 9.

[187] INGAA Initial Comments at 4.

[188] Avangrid Initial Comments at 4.

[189] Alliant Initial Comments at 4–5.

[190] Maryland and Pennsylvania Commissions Initial Comments at 7–8.

[191] Ohio FEA Initial Comments at 9.

[192] Michigan Commission Initial Comments at 6.

[193] *Id.* at 9.

[194] TAPS Initial Comments at 7–9.

[195] APPA Initial Comments at 17.

[196] California Parties Initial Comments at 31–32.

[197] Iowa Utilities Board Initial Comments at 5–6.

that, by allowing utilities to use more than one approach to show that a cybersecurity investment satisfies the eligibility criteria, we strike the right balance between customer protection, transparency, efficiency, and responsiveness to cybersecurity threats.

109. In order to determine on a consistent and transparent basis whether a cybersecurity investment satisfies the first eligibility criterion, the Commission will consider evidence showing that the utility would invest in cybersecurity improvements that: (1) are based on a documented and recommended technical cybersecurity mitigation action published in an alert or advisory by a relevant Federal agency (*e.g.,* CISA, DOE, FBI, DOD, NSA); [198] and (2) respond to an alert or advisory that meets the objective of a subcategory of the NIST Cybersecurity Framework, or its successor, and references the related NIST 800–53 Security Control, or its successor.[199] The Commission would base its assessment of the evidence on whether an incentive is appropriate on the mitigation actions detailed in the specified agencies' alerts and advisories along with the NIST Cybersecurity Framework and NIST 800–53 Security Controls to determine whether the utility's proposed cybersecurity investment would materially improve its cybersecurity.

110. As discussed in section III.A.3. and consistent with the Commission's evaluations of PQ List cybersecurity investments in section III.B.1.a., under the case-by-case approach a utility would still need to demonstrate that it would make the cybersecurity investment voluntarily, and that the proposed rate, including the cybersecurity incentive, is just and reasonable and not unduly discriminatory or preferential.

111. We decline to add any additional eligibility criteria to our regulations that would apply only to cybersecurity investments that are not included on the PQ List. We find that the eligibility criteria in our regulations are sufficient for incentive requests that use either the PQ List or case-by-case approach. Similarly, we decline to offer different forms of incentives for cybersecurity investments based on whether or not the investment appears on the PQ List. We are not convinced that the benefits of cybersecurity investments made that are on the PQ List or for which a utility requests incentives on a case-by-case basis differ and would therefore merit disparate incentive levels because all incentive-eligible investments under both mechanisms must satisfy the requirement to materially improve cybersecurity in the first eligibility criterion.

3. Early Compliance With Approved Reliability Standards

a. NOPR Proposal

112. In the NOPR, the Commission proposed the second eligibility criterion limiting incentive-based rate treatment to cybersecurity investments that a utility made voluntarily.[200] The NOPR also sought comment on whether the second eligibility criterion was appropriate and whether there were additional criteria or limitations that the Commission should consider, including any potential refinements, and any other criteria for incentive eligibility that the Commission should adopt in the final rule. Finally, the NOPR proposed to allow a utility granted a cybersecurity incentive to receive that incentive until the investment or activity that serves as the basis of that incentive become mandatory pursuant to a Reliability Standard approved by the Commission.[201] This would include cybersecurity investments made by a utility to comply with Reliability Standards that the Commission has already approved pursuant to § 39.5(d) of the Commission's regulations, but that have not yet taken effect pursuant to the implementation plan approved by the Commission.

b. Comments

113. Many commenters discuss how the NOPR's proposed incentives would interact with and affect the CIP Reliability Standards and development processes. Indicated PJM Transmission Owners, the Michigan Commission, and EPSA note that incentives could supplement the time-intensive NERC standards development process.[202] APPA and Alliant express concern that providing incentives for cybersecurity investments would disincentivize the timely development of CIP Reliability Standards.[203] NERC advises the Commission to develop rate incentives for voluntary cybersecurity investments that build upon and complement existing CIP Reliability Standards.[204] NERC and TAPS advise the Commission to consider how the proposed incentives will affect compliance with the CIP Reliability Standards.[205]

114. Indicated PJM Transmission Owners support the availability of incentives to early adopters of cybersecurity technology.[206] The Michigan Commission discusses an approach in which the proposed Cybersecurity Regulatory Asset Incentive would be used to facilitate cybersecurity investments during the period in which said investments are evaluated for inclusion in the CIP Reliability Standards.[207] EPSA notes that the nature of the long, detailed process to develop and implement NERC CIP Reliability Standards may not be able to keep up with the rapidly evolving nature of cybersecurity threats.[208] EPSA states that it is prudent to provide incentives for protections to address rapidly evolving technologies to ensure a reliable, resilient, and operational electric grid.[209]

115. The Maryland and Pennsylvania Commissions argue that making incentives available in the period before the completion of mandatory standards does not expedite the standards process or the voluntary adoption of improvements.[210] On the contrary, they assert that the proposed incentives actually would encourage delays in the standards development process so utilities could recover incentives for voluntary implementation.[211] The Maryland and Pennsylvania Commissions further note that the proposed incentives do not provide a tapering off period, such as over the time frame in which a CIP Reliability Standard is being developed. They assert that such a tapering period would

[198] Technical cybersecurity mitigation action means a recommended action requiring the purchase of software, hardware, or third-party services.

[199] Some alerts may reference specific NIST 800–53 Security Controls, while others may reference security controls generally. One example of a case-by-case request for incentive-based rate treatment of cybersecurity investments is a utility requesting an incentive for an implementation of data backup procedures on both the IT and OT networks. This type of action is specifically recommended in the CISA ''Shields Up'' Alert. *See* CISA, *Essential Element: Your Data* (Oct. 15, 2020), *https://www.cisa.gov/sites/default/files/publications/Cyber%20Essentials%20Toolkit%205%2020201015_508.pdf.* Further, this action is covered by the NIST Cybersecurity Framework Category Information Protection Processes and Procedures, subcategory 4 and thus would be evidence that this proposed implementation would materially improve the utility's cybersecurity.

[200] *Id.* PP 20, 22.

[201] *Id.* P 46.

[202] Indicated PJM Transmission Owners Initial Comments at 5; Michigan Commission Initial Comments at 9; EPSA Initial Comments at 2.

[203] APPA Initial Comments at 13–14; Alliant Initial Comments at 7–8.

[204] NERC Initial Comments at 3.

[205] *Id.* at 4; TAPS Initial Comments at 12.

[206] Indicated PJM Transmission Owners Initial Comments at 5.

[207] Michigan Commission Initial Comments at 9.

[208] EPSA Initial Comments at 2.

[209] *Id.*

[210] Maryland and Pennsylvania Commissions Initial Comments at 10.

[211] *Id.* at 10.

motivate utilities to implement material improvements as early as possible.[212]

116. APPA recommends that the Commission modify the proposed eligibility criteria in a manner that would disallow incentives for early adoption of CIP Reliability Standards.[213] Instead of a cybersecurity expenditure losing eligibility when it becomes mandatory pursuant to a CIP Reliability Standard, APPA recommends that the cut off for incentives should be the earlier of: (1) the date of any Commission directive that would require the investment; or (2) the date that a Standards Authorization Request is submitted to NERC to require that incentive.[214] APPA argues that it would not be just or reasonable to provide an incentive to a utility for an investment where a new or revised mandatory Reliability Standard is pending.[215]

c. Commission Determination

117. We adopt an application of the case-by-case method for utilities to satisfy the eligibility criteria by adding § 35.48(e)(3) to the Commission's regulations, which permits utilities to receive incentives for cybersecurity investments made to comply with a cybersecurity-related CIP Reliability Standard (*i.e.,* excluding CIP Reliability Standards that may be related to physical security and not cybersecurity) approved by the Commission before that CIP Reliability Standard becomes mandatory and enforceable for that utility. In general, cybersecurity investments made by a utility to comply and maintain its compliance with a Commission-approved Reliability Standard will materially improve the utility's cybersecurity. Filing utilities would need to demonstrate that the cybersecurity investment(s) it will make are necessary to comply with the Reliability Standard, and that it will make those cybersecurity investments prior to the date that the Reliability Standard is mandatory and enforceable for that utility.[216] Those cybersecurity investments made by the utility before the newly-approved Reliability Standard becomes effective (*i.e.,* mandatory and enforceable) are voluntary. Those cybersecurity investments made by the utility after the newly-approved Reliability Standard becomes effective and mandatory are no longer voluntary. As required by the second eligibility criteria, all of the utility's cybersecurity investments incurred to comply with a Reliability Standard after the Reliability Standard becomes mandatory and enforceable for that utility are ineligible for incentive-based rate treatment.

118. We find that allowing utilities to receive an incentive to comply with a Commission-approved cybersecurity-related CIP Reliability Standard before it becomes mandatory and enforceable could materially improve their cybersecurity posture during that period. In addition, we find that permitting an incentive for early compliance with approved cybersecurity-related CIP Reliability Standards will help to bridge gaps between voluntary cybersecurity measures and the cybersecurity measures mandated in the CIP Reliability Standards. It is possible that allowing utilities to receive incentives for early compliance could unintentionally incentivize standards drafting teams' artificial lengthening of the implementation period to increase the amount of time a utility could receive incentives. Nevertheless, the Commission would continue to consider whether the implementation time is reasonable when determining whether to approve the proposed CIP Reliability Standard.[217]

119. We clarify that the cybersecurity investments made by a utility to achieve early compliance with an approved cybersecurity-related CIP Reliability Standard may be eligible for incentive-based rate treatment. We reiterate that, after receiving Commission authorization for incentive-based rate treatment, the utility may only collect the incentive during the period that begins with the utility achieving compliance with the approved cybersecurity-related CIP Reliability Standard and that ends according to the duration provisions of § 35.48(g), as further discussed in section III.D.[218] Therefore, the earlier that a utility complies with a new CIP Reliability Standard, the longer the utility's incentive recovery period may be.

C. Cybersecurity Investment Rate Incentives

120. The Commission proposed two potential rate incentive options for utilities that make eligible cybersecurity investments: (1) the Cybersecurity ROE Incentive, an ROE adder of 200 basis points that would be applied to the incentive-eligible investments; [219] and (2) the Cybersecurity Regulatory Asset Incentive, deferral of certain eligible expenses for rate recovery, enabling them to be part of rate base such that a return can be earned on the unamortized portion.[220] The Commission stated that both offer meaningful incentives to encourage cybersecurity investments that improve a utility's cybersecurity posture.[221] The Commission also sought comment on whether, and if so how, the principles of performance-based regulation could apply to utilities with respect to cybersecurity investments.[222]

121. The Commission also noted that most utility IT investments (general and intangible plant) and expenses (administrative and general costs) support functions of the entire utility, not just the transmission function.[223] Consequently, the Commission found that only a portion of those costs are allocated to transmission customers, typically based on wages and salaries allocators.[224]

1. Cybersecurity ROE Incentive

a. NOPR Proposal

122. The Commission proposed to allow a utility that makes cybersecurity investments that are eligible for incentives to request the Cybersecurity ROE Incentive that would be applied to the incentive-eligible investments.[225] The Commission explained that any

[212] *Id.* at 10.

[213] APPA Initial Comments at 13–14.

[214] *Id.* at 13–14.

[215] *Id.* at 13–14.

[216] In addition, as explained below, filings seeking the incentives would have to comply with the filed rate doctrine. *See Exxon Mobil Corp.* v. *FERC,* 571 F.3d 1208, 1211 (D.C. Cir. 2009) (citing *Towns of Concord, Norwood, & Wellesley* v. *FERC,* 955 F.2d 67, 71 & n.2 (D.C. Cir. 1992); *Ark. La. Gas Co.* v. *Hall,* 453 U.S. 571, 577–578 (1981)) (''The Commission may not retroactively alter a filed rate to compensate for prior over- or underpayments. A corollary to this rule against retroactive ratemaking, the filed rate doctrine, forbids a regulated entity to charge rates for its services other than those properly filed with the appropriate regulatory authority. Together, these rules generally limit the relief the Commission may order to prospective [rates].'') (cleaned up).

[217] *See Rules Concerning Certification of the Elec. Reliability Org.; & Procs. for the Establishment, Approval, & Enf't of Elec. Reliability Standards,* Order No. 672, 71 FR 8662 (Feb. 17, 2006), 114 FERC ¶ 61,104, at P 333, *order on reh'g,* Order No. 672–A, 71 FR 19814 (Apr. 18, 2006), 114 FERC ¶ 61,328 (2006) (''In considering whether a proposed Reliability Standard is just and reasonable, the Commission will consider also the timetable for implementation of the new requirements, including how the proposal balances any urgency in the need to implement it against the reasonableness of the time allowed for those who must comply'').

[218] In addition to having its rate that includes incentive-based treatment on file with the Commission, a utility must submit an informational filing to the Commission notifying the Commission of the date that it has achieved compliance with the approved cybersecurity-related CIP Reliability Standard.

[219] NOPR, 180 FERC ¶ 61,189 at P 36.

[220] *Id.* P 39.

[221] *Id.* P 33.

[222] *Id.* P 45.

[223] *Id.* P 36.

[224] *Id.* P 36.

[225] *Id.* P 36.

incentive granted under this proposal would be subject to the total base and incentive return being capped at the top of the utility's zone of reasonableness.[226] The Commission stated that the 200-basis point ROE adder would provide a meaningful incentive to encourage utilities to improve their systems' cybersecurity. The Commission recognized that this amount exceeds the ROE incentives for transmission facilities that the Commission typically provides pursuant to FPA section 219. The Commission explained that, because cybersecurity investments are relatively small compared to conventional transmission projects, a higher ROE may be necessary to affect the expenditure decisions of utilities, without unduly burdening ratepayers.

123. The Commission also proposed that enterprise-wide investments, which are not specific to transmission or the sale for resale of electric energy in interstate commerce, but a portion of which are recovered through rates on file with the Commission, may also be eligible for the 200-basis point ROE adder incentive if the Commission determines that the investments merit incentives, based on the eligibility criteria described above.[227] However, consistent with both longstanding cost-causation ratemaking principles [228] and the statutory requirement that rates inclusive of incentives be just and reasonable and not unduly discriminatory or preferential, the Commission proposed that only the conventionally allocated portion of such investments that flows through to cost-of-service rates on file with the Commission would be eligible for this rate treatment.

b. Comments

124. EEI, MISO Transmission Owners, and Indicated PJM Transmission Owners support the proposed ROE incentive.[229] EEI notes that some cybersecurity investments involve relatively low dollar amounts, compared with other capital investments.[230] Therefore, in addition to the fact that these investments are recovered over a short period, EEI believes that the proposed 200-basis point adder is reasonable and has the potential to create an incentive that will shift utility cybersecurity expenditures in the manner intended by the Commission and Congress.[231]

125. EEI and MISO Transmission Owners support the Commission's proposal to include enterprise-wide costs as eligible for incentive treatment.[232] EEI states that the Commission's enterprise-wide approach avoids the potential for investments to be funneled to only certain assets, leaving other areas (*e.g.,* network assets, generation) potentially ineligible, and aligns with Commission policies on enabling access for, and deployment of, distributed energy resources and advanced technologies.[233] MISO Transmission Owners state that the inclusion of enterprise-wide costs encourages enterprise-wide strategic security investments, which provide benefits to a utility's security program efficiency more broadly, as well as to ratepayers.[234]

126. APPA and Alliant agree with the proposal in the NOPR to cap total base and incentive ROE at the top of the zone of reasonableness.[235] APPA asks the Commission to clarify that, in applying the cap at the top end of the zone of reasonableness, a public utility would be required to take into account ROE adders other than the cybersecurity investment adder.[236]

127. Alliant, APPA, Iowa Utilities Board, Joint Consumer Advocates, the Michigan Commission, Ohio FEA, Ohio Consumers' Counsel, and TAPS do not support the proposed ROE adder of 200 basis points.[237] Alliant, APPA, California Parties, Ohio Consumers' Counsel, and Ohio FEA argue that the proposed 200-basis points adder is not just and reasonable.[238] APPA, California Parties, and TAPS also argue that the Commission has not sufficiently supported or explained why a 200-basis point return is necessary.[239]

128. APPA, California Parties, and TAPS argue that eligible cybersecurity investments are not ''relatively small'' as the NOPR suggests.[240] California Parties state that, in recent years, the California Public Utilities Commission has authorized significant amounts for State jurisdictional cybersecurity capital expenditures and annual IT physical and cybersecurity activities for utilities.[241] TAPS comments that the Commission has found that Duke Energy has made over $137 million in capital investments as part of its cybersecurity program that is designed based on the NIST Framework.[242] TAPS further states that, in 2019, Dominion Energy Virginia received State approval to spend $910.3 million on cyber and physical security and telecommunications over 10 years, with $154.4 being spent in the first three years related to improved monitoring and alarm capabilities and enhanced utility security.[243] TAPS argues that these sums illustrate that cybersecurity investments are not relatively small compared to conventional transmission projects.[244]

129. The Michigan Commission states that the potential financial risks that cyberattacks can pose on electric utilities already serve as a strong incentive for investment, much stronger than an additional 200 basis points would provide when applied to what the NOPR recognizes are relatively low-cost investments.[245]

130. Alliant states that using a 200-basis point ROE incentive would impose unnecessary administrative burdens on the Commission and all parties affected, as processing requests for incentives would consume valuable and limited resources of the Commission.[246] Iowa Utilities Board argues that an incentive rate adder could have a cascading impact on

[226] *See, e.g., Emera Me.* v. *FERC,* 854 F.3d 9, 23 (D.C. Cir. 2017) (''The zone of reasonableness informs FERC's selection of a just and reasonable rate.''); *see also Permian Basin,* 390 U.S. 747, 767 (1968) (stating that as long as the rate selected by the Commission is within the zone of reasonableness, the Commission is not required to adopt as just and reasonable any particular rate level).

[227] NOPR, 180 FERC ¶ 61,189 at P 37.

[228] *See Old Dominion Elec. Coop.* v. *FERC,* 898 F.3d 1254, 1255 (D.C. Cir. 2018), (''For decades, the Commission and the courts have understood this requirement to incorporate a 'cost-causation principle'—the rates charged for electricity should reflect the costs of providing it.''); *see, e.g., Ala. Elec. Coop., Inc.* v. *FERC,* 684 F.2d 20, 27 (D.C. Cir. 1982).

[229] EEI Initial Comments at 9; MISO Transmission Owners Initial Comments at 10; Indicated PJM Transmission Owners Initial Comments at 4.

[230] EEI Initial Comments at 9–10.

[231] *Id.* at 9–10.

[232] MISO Transmission Owners Initial Comments at 10.

[233] EEI Initial Comments at 10.

[234] MISO Transmission Owners Initial Comments at 10–11.

[235] APPA Initial Comments at 19; Alliant Initial Comments at 6.

[236] APPA Initial Comments at 19.

[237] Alliant Initial Comments at 6, APPA Initial Comments at 10; Iowa Utilities Board Initial Comments at 4; Joint Consumer Advocates Initial Comments at 3; Michigan Commission at 9; Ohio FEA Initial Comments at 10; TAPS Initial Comments at 16.

[238] Alliant Comments at 5–6; California Parties Initial Comments at 22; ITC Companies Initial Comments at 3; Joint Consumer Advocates Initial Comments at 3; Michigan Commission Initial Comments at 9; Ohio Consumers' Counsel Initial Comments at 12; Ohio FEA Initial Comments at 11.

[239] Alliant Comments at 5–6; APPA Initial Comments at 11; California Parties Initial Comments at 22; Ohio Consumers' Counsel Initial Comments at 12; Ohio FEA Initial Comments at 11.

[240] APPA Initial Comments at 11; California Parties Initial Comments at 23; TAPS Initial Comments at 17.

[241] California Parties Initial Comments at 23.

[242] TAPS Initial Comments at 17.

[243] *Id.* at 17.

[244] *Id.* at 17.

[245] Michigan Commission Initial Comments at 8–9.

[246] Alliant Initial Comments at 6.

economic activity, might adversely impact inflation, and could provide a perverse incentive to invest in unneeded technologies.[247] Ohio Consumers' Counsel comments that a 200-basis point adder is not necessary and is unreasonably costly for consumers, and also defies the logic of Order No. 679, which contemplated ROE adders of 100 and 150 basis points only, with the higher ROEs for more complicated and expensive transmission projects.[248]

131. Several commenters argue for a modification to the Commission's proposal of 200 basis points. NRECA requests that the Commission revise its proposal to allow for a request of up to 200-basis points, and questions whether it is appropriate to grant the same ROE adder for all cybersecurity expenditures or whether the Commission instead should tie the amount of the ROE incentive to the projected impact of the cybersecurity expenditure.[249] APPA asks whether the Commission has considered whether applying a smaller ROE adder would be sufficient to encourage investment.[250] Ohio Consumers' Counsel states that, instead of proposing a flat 200-basis point ROE adder, the Commission should provide for a pool of potential adders, ranging from 25 basis points up to a cap of 50 basis points, depending on the magnitude of the investment and the complexity or proven track record for the technology or activity.[251]

132. The Maryland and Pennsylvania Commissions suggest tapering incentives over time to encourage utilities to implement material improvements as early as possible. They argue that such tapering adds a ''performance-based'' aspect to the NOPR proposals.

133. AEP and ITC Companies request that the Commission apply incentives to the entire rate base.[252] ITC Companies state that it might be better to offer a general rather than asset-specific ROE adder for utilities that adopt a sufficient level of additional Advanced Cybersecurity Technologies and cybersecurity threat information sharing program participation.[253] ITC Companies argue that this would reflect the fact that an entity's individual cybersecurity assets and practices are part of a cohesive defensive framework that applies to its entire operation.[254] ITC Companies explain that the type of cybersecurity investment to which the ROE incentive might apply is not a financially significant portion of total rate base for most responsible entities and, in many instances, it is likely that the marginal benefit of this incentive will not justify the administrative cost of obtaining this incentive (even with a PQ List in place), especially where the zone of reasonableness applicable to a responsible entity's overall rate of return further diminishes the impact of the incentive.[255] AEP argues that an incentive adder applied system-wide to the transmission rate base would not need to rise to the level contemplated in the NOPR, *e.g.,* 50 basis points, and would be sufficient to incentivize industry participants to adopt cybersecurity programs that go above and beyond existing cybersecurity requirements.[256]

c. Commission Determination

134. We decline to adopt an ROE incentive adder, as proposed in the NOPR. We conclude that the Cybersecurity Regulatory Asset Incentive satisfies the statutory obligation to benefit consumers by encouraging investments by utilities in Advanced Cybersecurity Technology and participation by utilities in cybersecurity threat information sharing programs. We believe that expenses, which include cybersecurity assessments, architectural reviews, maturity model evaluations, software subscriptions, monitoring, training, procuring outside services, and cloud computing services, constitute a large portion of overall expenditures for many cybersecurity investments, including cybersecurity threat information sharing programs. We find that the provision of the Cybersecurity Regulatory Asset Incentive alone provides the encouragement that Congress intended without unduly increasing costs on consumers.

2. Cybersecurity Regulatory Asset Incentive

a. NOPR Proposal

135. The Commission proposed a Cybersecurity Regulatory Asset Incentive to allow a utility that makes cybersecurity investments that are eligible for incentives to seek deferred cost recovery.[257] The Commission explained that, in limited circumstances, it may be appropriate to allow a utility to defer recovery of certain cybersecurity costs that are generally expensed as they are incurred, and treat them as regulatory assets, while also allowing such regulatory assets to be included in transmission rate base. Many costs associated with cybersecurity are in the form of expenses, often to third-party vendors, rather than capital investments. Moreover, certain cost categories that companies historically have purchased and capitalized, such as software, are now often procured as services with periodic payments to vendors that are recorded as expenses. Therefore, to encourage investment in cybersecurity, the Commission proposed to allow utilities to defer and amortize eligible costs that are typically recorded as expenses, including those that are associated with third-party provision of hardware, software, and computing and networking services. The Commission also sought comment on whether it would be preferable to permit only 50% of incentive-eligible expenses to be treated as regulatory assets.

136. The Commission observed that a range of implementation costs associated with cybersecurity investments could be eligible for deferred rate treatment.[258] Such costs may include, for example, training to implement new cybersecurity practices and systems. However, the Commission proposed that, to be eligible for the incentive of deferred cost recovery, such training costs must be distinct from costs associated with pre-existing training on cybersecurity practices. The Commission stated that another potentially eligible implementation cost may be internal system evaluations and assessments or analyses by third parties, to the extent that they are associated with a capitalizable item and are part of eligible capitalizable costs. The Commission proposed that any implementation costs that are not conventionally booked as plant and thus capitalized can be considered for deferral as a regulatory asset. Recurring costs may be eligible for deferral as a regulatory asset and may include, for example, subscriptions, service agreements, and post-implementation training costs. Specifically, the Commission proposed to allow utilities, under this incentive, to include ongoing dues and other expenses directly associated with participation by utilities in cybersecurity threat information sharing programs that satisfy the eligibility criteria.

[247] Iowa Utilities Board Initial Comments at 4.

[248] Ohio Consumers' Counsel Initial Comments at 12–13.

[249] NRECA Initial Comments at 10.

[250] APPA Initial Comments at 11.

[251] Ohio Consumers' Counsel Initial Comments at 13.

[252] AEP Initial Comments at 6; ITC Companies Initial Comments at 4.

[253] ITC Companies Initial Comments at 4.

[254] *Id.* at 4.

[255] *Id.* at 3.

[256] AEP Initial Comments at 6.

[257] NOPR, 180 FERC ¶ 61,189 at P 39.

[258] *Id.* P 40.

137. The Commission observed that, because FPA section 219A(c)(2) directs the Commission to offer incentives to encourage *participation* by public utilities in cybersecurity threat information sharing programs, it proposed to allow utilities that are currently participating in such programs to seek incentives for any new cybersecurity investment associated with their participation, so long as that participation is voluntary.[259] The Commission sought comment on whether to allow utilities who are already participating in an eligible cybersecurity threat information sharing program to be eligible for this incentive.[260]

138. The Commission also noted that the Commission's rules and regulations in the Uniform System of Accounts [261] already require public utilities to maintain records supporting any entries to the regulatory asset account so that the public utility can furnish full information as to the nature and amount of, and justification for, each regulatory asset recorded in the account.[262] The Commission explained that, pursuant to its existing regulations, utilities must maintain sufficient records to support the distinction of any investments that are afforded incentive-based rate treatment.[263]

139. Additionally, the Commission proposed that only directly-assigned utility costs or the conventionally allocated portion of enterprise-wide expenses (*e.g.,* using the wages and salaries allocator) would be eligible for the Cybersecurity Regulatory Asset Incentive in rates on file with the Commission.[264]

b. Comments

140. EEI, Iowa Utilities Board, the Michigan Commission, and MISO Transmission Owners support the Commission's proposal.[265] The Michigan Commission states that the Commission's acknowledgement that many cybersecurity costs have shifted to expenses rather than capital costs is valid.[266] The Michigan Commission adds that the proposed Cybersecurity Regulatory Asset Incentive could help facilitate these types of investments during the time in which such investments are evaluated for inclusion in the CIP Reliability Standards, and that the proposed Cybersecurity Regulatory Asset Incentive would allow for reasonable facilitation of cybersecurity investments in advance of CIP Reliability Standard updates and would avoid unjust and unreasonable rates.[267] Iowa Utilities Board comments that allowing a utility to capitalize the operational expenses for cybersecurity expenditures is by itself an adequate incentive because it reduces cash flow demands and provides an opportunity for the utility to earn a return on those expenditures.[268]

141. MISO Transmission Owners support the proposal to allow utilities to defer and amortize eligible costs that are typically recorded as expenses that are associated with third-party hardware, software, and computing and networking services.[269] MISO Transmission Owners state that allowing transmission owners to capitalize costs and investments associated with cybersecurity investment, including up-front training and implementation expenses, will enable utilities to fully realize the relative security benefits that rapid adoption of cybersecurity investment can generate, as well as the often-lower cost that such solutions impose on ratepayers relative to physical infrastructure.[270]

142. MISO Transmission Owners ask the Commission to clarify that cybersecurity-related operation and maintenance expenses, labor costs, and post-implementation training costs may be included as part of the Cybersecurity Regulatory Asset Incentive.[271] EEI suggests that the Commission include training, implementation, software costs, and allow cloud computing expenses to also be allowed to be deferred as a regulatory asset.[272] EEI expresses concern with the proposal to limit the eligible costs to those associated with implementing cybersecurity upgrades and to not include ongoing costs including system maintenance, surveillance, and other labor costs, either in the form of employee salaries or third-party service contracts.[273] EEI argues that including these costs would support the Commission's cybersecurity goals, incent best practices, and benefit customers by reducing the possibility of interruptions from cyber-attacks.[274]

143. Ohio Consumers' Counsel opposes the proposal to allow deferred accounting and recovery of a return on the unamortized portion of the costs for cybersecurity expenses.[275] Ohio Consumers' Counsel states that deferred accounting and cost collection of cybersecurity expenses as regulatory assets will cost consumers more over time than would recovery of the expense all in one year.[276]

144. APPA and California Parties contend that the Cybersecurity Regulatory Asset Incentive should be limited to 50% of eligible investment in cybersecurity initiatives.[277] California Parties comment that the Commission should allow no more than 50% of eligible expenses to be treated as a regulatory asset included in transmission rate base to reduce the burden on consumers.[278] California Parties argue that the Commission failed to offer any explanation as to why its proposal that 100% of eligible expenses should be able to receive incentive treatment is properly calibrated to induce the desired investment.[279]

c. Commission Determination

145. We adopt the NOPR's proposal to add § 35.48(f) to the Commission's regulations to include a Cybersecurity Regulatory Asset Incentive that allows a utility to seek deferred cost recovery for cybersecurity investments that are eligible for incentives. We find that, in limited circumstances that are specific to cybersecurity investments, it is appropriate to allow a utility to defer recovery of certain cybersecurity costs that are generally expensed as they are incurred, and treat them as regulatory assets, while also allowing such regulatory assets to be included in the utility's rate base.

146. In response to Ohio Consumers' Counsel's concerns about consumer costs, as an initial matter, we note that increased consumer costs in isolation do not impugn the reasonableness of an incentive, provided the rates are still just and reasonable. The Commission has long offered transmission incentives, which increase rates, because they encourage investments and activities that the Commission has found provide consumer benefits. The Cybersecurity Regulatory Asset

[259] *Id.* P 41.

[260] *Id.* P 41.

[261] *See* 18 CFR pt. 101, Account Definition Account 182.3, Other Regulatory Assets, paragraph D.

[262] NOPR, 180 FERC ¶ 61,189 at P 42.

[263] *Id.*

[264] *Id.* P 43.

[265] EEI Initial Comments at 11; Iowa Utilities Board Initial Comments at 3–4; Michigan Commission Initial Comments at 9; MISO Transmission Owners Initial Comments at 11.

[266] Michigan Commission Initial Comments at 9.

[267] *Id.*

[268] Iowa Utilities Board Initial Comments at 4.

[269] MISO Transmission Owners Initial Comments at 11.

[270] *Id.*

[271] *Id.*

[272] EEI Initial Comments at 11.

[273] *Id.* at 11.

[274] *Id.* at 11–12.

[275] Ohio Consumers' Counsel Initial Comments at 10.

[276] *Id.*

[277] APPA Initial Comments at 12; California Parties Initial Comments at 24.

[278] California Parties Initial Comments at 24.

[279] *Id.* at 24.

Incentive nominally increases rates, though consumers benefit from the time value of money associated with later recovery through rate base than immediate recovery as an expense. Based on the expense-heavy nature of many cybersecurity investments, we find this appropriate to effectuate Congress' requirement that the Commission offer cybersecurity incentives. We also will not, as suggested by California Parties and APPA, limit this incentive to 50% of eligible expenses. Given the comparatively small amount of many cybersecurity expenses, we find that such a limitation may inadequately provide incentives to meaningfully encourage utilities to improve their cybersecurity posture.

147. In response to MISO Transmission Owners' and EEI's comments, we clarify that utilities may seek this incentive for a range of expenses including operation and maintenance expenses, labor costs, implementation costs, network monitoring, and training costs. Additionally, ongoing expenses, either incurred by utility employees or utility payments to third parties may be eligible. Software purchases typically would not qualify for the Cybersecurity Regulatory Asset Incentive because they generally constitute capital investments; however, software-as-a-service expenses could qualify for the Cybersecurity Regulatory Asset Incentive.

148. We find it appropriate to limit eligibility for incentive-based rate treatment to new cybersecurity investments. As also discussed in section III.D.3.c., we add § 35.48(h)(5) to our regulations to provide that the Cybersecurity Regulatory Asset Incentive may be applied to new cybersecurity investments that: (1) occur after the effective date of the Commission's approval of incentive-based rate treatment; and (2) are materially different from cybersecurity investments already incurred by the utilities more than three months prior to the incentive request. Utilities may seek incentives for one-time cybersecurity expenses and/or recurring ones.

149. We generally define new cybersecurity investments to include investments for those activities that have occurred no more than three months prior to the date that the utility files its incentive request with the Commission. We provide one exception and one clarification to this general three-month rule. First, a utility may seek incentive-based rate treatment for its future cybersecurity investments made to participate in cybersecurity threat information sharing programs even if the utility began its participation and therefore made cybersecurity investments related to its participation more than three months before filing its request for incentive-based rate treatment with the Commission. We clarify that utilities seeking incentive-based rate treatment for cybersecurity investments made to comply with a Commission-approved cybersecurity-related CIP Reliability Standard before it becomes mandatory and enforceable for that utility will be permitted to seek incentive-based rate treatment for its cybersecurity expenses that began no earlier than three months before the date that the Commission's approval of the Reliability Standard becomes effective. A utility's cybersecurity expenses that began more than three months before the date that the Commission order or final rule approving a new or modified Reliability Standard becomes effective will not be considered new and will be considered materially similar and duplicative. Therefore, the cybersecurity investments made more than three months before the Commission approves a new or modified Reliability Standard would be ineligible to receive incentive-based rate treatment as early compliance with an approved Reliability Standard.

150. To be clear, this prior three-month provision only determines whether a utility's cybersecurity investment is new and therefore eligible for incentive-based rate treatment. The filed rate doctrine and the rule against retroactive ratemaking preclude the Commission from granting a utility incentive-based rate treatment for cybersecurity investments made before the Commission acts on a request for declaratory order or the effective date of an FPA section 205 filing requesting the incentive-based rate treatment for cybersecurity incentives.[280]

151. Moreover, we find it appropriate that only new cybersecurity investments, and not duplicative or materially similar ones to existing expenses, be eligible. As discussed in section III.D.3., we will require utilities to attest that the cybersecurity investments that are the basis for the incentive-based rate treatments are new cybersecurity investment and not duplicative or materially similar to preexisting expenses. For instance, investment in training associated with a new cybersecurity system may be eligible while annual basic cybersecurity training may not, even if the contents slightly change year-to-year. This will ensure that incentives encourage cybersecurity investments that improve a utility's cybersecurity posture rather than just reward ongoing or recurring activities. The three-month period to determine eligibility of incentives for pre-existing expenses allows for utilities making new cybersecurity investments to respond to immediate cybersecurity vulnerabilities while giving them time to request incentives. We reiterate that utilities may not recover incentives on specific investments that predate the effective date of filing requesting incentive-based rate treatment. We find that this grace period could incentivize utilities not to wait until the effective date of requested incentives to undertake urgent cybersecurity action.

152. FPA section 219A(c)(2) requires the Commission to offer incentives to encourage *participation* by public utilities in cybersecurity threat information sharing programs. Furthermore, participation in information-sharing programs provides cybersecurity benefits to the participating utility that applies for an incentive-based rate treatment, the other program participants, and their customers. Consequently, unlike other expenses, we find that utilities may request the Cybersecurity Regulatory Asset Incentive for expenses associated with participation in cybersecurity threat information sharing programs regardless of how long the utilities have participated in the programs—although only expenses prospective from the effective date of the Commission's approval of the cybersecurity incentives in the utility's rate(s) on file with the Commission shall be eligible.

153. The Commission's rules and regulations in the Uniform System of Accounts[281] require public utilities to maintain records supporting any entries to the regulatory asset account so that the public utility can furnish full information as to the nature and amount of, and justification for, each regulatory asset recorded in the account. Pursuant to our existing regulations, any utility receiving an incentive must maintain sufficient records to support the distinction of any investments that are afforded incentive-based rate treatment.[282] Given the novelty of allowing incentive recipients to include certain expenses in rate base, it is essential that the utilities keep records in a manner that allows the Commission and other parties to ensure that no double-recovery occurs.

[280] *See* n.216, *supra.*

[281] *See* 18 CFR pt. 101, Account Definition Account 182.3, Other Regulatory Assets, paragraph D.

[282] *Id.*

154. We also find that, consistent with the Commission's longstanding cost-causation ratemaking principles, only costs directly assigned to a function or the conventionally allocated portion of enterprise-wide expenses (*e.g.,* using the wages and salaries allocator) would be eligible for the Cybersecurity Regulatory Asset Incentive in rates specific to that function. For example, only incentives for transmission-specific or transmission-allocated costs may be recovered in transmission rates.

3. Performance-Based Rates

a. NOPR Proposal

155. In the NOPR, the Commission noted that FPA section 219A(c) directs the Commission to establish incentive-based, including performance-based, rate treatments.[283] The Commission observed that, because it is difficult to directly observe the level of effort a utility expends on ensuring cybersecurity, performance-based regulation could theoretically provide a valuable tool to motivate utilities to maintain and operate their systems reliably and efficiently. The Commission explained that performance-based ratemaking can take multiple forms, but ultimately requires the ability to measure and tie rate treatments to actual performance.[284]

156. The Commission sought comment on performance-based rates and whether and how the principles of performance-based regulation could apply to utilities with respect to cybersecurity investments.[285] The Commission also sought comment on specific cybersecurity performance metrics that could be subject to a performance standard.[286] In particular, the Commission sought comment on whether any widely accepted metrics for cybersecurity performance could lend themselves as benchmarks for performance-based rates, or whether new appropriate metrics could be developed. The Commission further sought comment on what rate mechanisms could accompany such metrics. The Commission asked that any proposed mechanisms: (1) rely on cybersecurity performance benchmarks and not expenditures or practices; and (2) consider ratepayer impacts, given the relatively small costs of cybersecurity expenditures compared to utilities' overall cost-of-service.

b. Comments

157. No commenter explicitly supports performance-based rates with respect to cybersecurity investments. EEI, Iowa Utilities Board, and Ohio Consumers' Counsel all filed comments opposing this approach.[287] EEI argues that, without clear, industry-wide metrics, a performance-based program would be difficult to implement.[288] Ohio Consumers' Counsel states that setting a performance threshold for advanced cybersecurity investment and activities is likely to be challenging, given the rapid pace of development in both the types of cybersecurity threats experienced and the technological advances used to counter those threats.[289] Iowa Utilities Board comments that performance measurement for cybersecurity investments is difficult because, more often than not, it would be difficult to pinpoint the root cause of failure on a particular entity or process when there is a performance failure.[290]

158. Ohio FEA states that, if the Commission adopts performance-based rates for cybersecurity incentives, it should neither choose which expenses to approve nor check whether incurred expenses comply with the utility's plans but should simply verify whether predetermined outcomes have been achieved.[291] Ohio FEA recommends that the Commission consider developing resources, such as C2M2, to achieve a performance monitoring tool that will aid in performance-based rates.[292]

c. Commission Determination

159. We interpret the directive to establish incentive-based, including performance-based, rate treatments in FPA section 219A to require the Commission to consider performance-based rates as an option among incentive ratemaking treatments. This interpretation is consistent with the Commission's finding in Order. No. 679 regarding the directive to establish incentive-based (including performance-based) rate treatments for investments in transmission infrastructure in FPA section 219.[293] Because of the Congressional directive to encourage performance-based rates, the Commission signaled its intention to reevaluate previous Commission policies on performance-based rate treatments and attempt to offer such incentives in the cybersecurity context. We recognize that performance-based regulation could theoretically provide a valuable tool to motivate utilities to maintain and operate their systems reliably and efficiently. Performance-based ratemaking can take multiple forms, but ultimately requires the ability to measure and tie rate treatments to actual performance (*i.e.,* the number and severity of cybersecurity incidents) rather than intermediate steps such as specific cybersecurity protocols or cybersecurity investments that intend to achieve that performance.

160. However, after evaluating the comments, we continue to find that it is difficult to directly observe the success of a cybersecurity investment. We share the view of commenters that it would be premature to adopt generic performance-based rate measures at this time. However, the development of performance-based rate measures may represent a long-term goal for utilities and the Commission to pursue.

D. Cybersecurity Investment Incentive Implementation

1. Cybersecurity ROE Incentive Duration

a. NOPR Proposal

161. The Commission proposed to allow a utility granted a Cybersecurity ROE Incentive to receive that incentive until the earliest of: (1) the conclusion of the depreciation life of the underlying asset; (2) five years from when the cybersecurity investment(s) enter service; [294] (3) the time that the investment(s) or activities that serve as the basis of that incentive become mandatory pursuant to a Reliability Standard approved by the Commission, or local, State, or Federal law; or (4) the recipient no longer meets the requirements for receiving the incentive.[295] The Commission recognized that incentive-eligible cybersecurity investments primarily include equipment or system modifications that typically have short depreciation lives, as opposed to long-lived assets like physical structures. The Commission believed that most cybersecurity incentives granted under this rulemaking would remain in effect

[283] NOPR, 180 FERC ¶ 61,189 at P 44.

[284] *Id.* P 44.

[285] The Commission also explained that, consistent with Order No. 679, which implemented FPA section 219, it interpreted the directive to establish incentive-based, including performance-based, rate treatments in FPA section 219A to require the Commission to consider performance-based rates as an option among incentive ratemaking treatments. *Id.* P 46 n.41.

[286] *Id.* P 45.

[287] EEI Initial Comments at 12–13; Iowa Utilities Board Initial Comments at 4; Ohio Consumers' Counsel Initial Comments at 14.

[288] EEI Initial Comments at 12.

[289] Ohio Consumers' Counsel Initial Comments at 14.

[290] Iowa Utilities Board Initial Comments at 4.

[291] Ohio FEA Initial Comments at 12.

[292] *Id.* at 12.

[293] Order No 679, 116 FERC ¶ 61,057 at P 270.

[294] For participation in a cybersecurity threat information sharing program, the ''investment'' would recur annually.

[295] NOPR, 180 FERC ¶ 61,189 at P 46.

until the conclusion of the depreciation life of the underlying asset. However, for investments with useful lives exceeding five years, the Commission proposed that the incentive end at the conclusion of five years from the time that the asset receiving the cybersecurity incentive entered service, noting that most IT investments feature useful lives no longer than five years. The Commission preliminarily found that five years is a reasonable expected life to encourage utilities to make an investment and to ensure just and reasonable rates. The Commission also sought comment on whether the proposed duration should be three years instead of five years.

b. Comments

162. EEI comments that the five-year depreciation period may be reasonable, but, if the utility has a cybersecurity asset with a longer depreciation life, the utility should have the option to make an argument for a longer incentives period, depending on the investment on a case-by-case basis.[296] EEI further comments that, if an incentive becomes mandatory, it is not clear why it must end automatically. EEI argues that, for example, if the investment is in year three and then in year four it becomes a mandatory standard, the utility would lose the incentive moving forward and that this approach will dampen potential incentives to do the work to be an early adopter of promising, qualifying cybersecurity measures.[297] AEP comments that the proposed five-year duration is unlikely to drive utilities to meaningfully reconsider their current and future investment in cybersecurity.[298]

163. APPA, California Parties, the Electricity Consumers Resource Council (ELCON), Ohio Consumers' Counsel, and TAPS state that the Commission should limit the duration proposal to a maximum of three years.[299] California Parties, TAPS, and Ohio Consumers' Counsel argue that setting the limit at three years better aligns with the fast-evolving nature of cybersecurity technology, and that consumers should not have to pay for technology that has become obsolete.[300] APPA comments that, where an asset has a useful life of no more than five years, a three-year Cybersecurity ROE Incentive would apply to a large portion, and potentially all, of the asset's useful life.[301] APPA states that the value of the Cybersecurity ROE Incentive to a utility would decline over time as the underlying asset depreciates and reduces the rate base to which the ROE adder is applied.[302]

c. Commission Determination

164. As discussed in section III.C.1.c., we do not adopt the NOPR's proposed Cybersecurity ROE Incentive. Consequently, we need not address the duration of this incentive.

2. Cybersecurity Regulatory Asset Incentive Duration and Amortization Period

a. NOPR Proposal

165. The Commission proposed to specify that a utility granted the Cybersecurity Regulatory Asset Incentive must amortize the regulatory asset over five years.[303] The Commission stated that this may reflect the generally short-lived nature of cybersecurity activities and corresponds to the depreciation rates for investments described above.[304] The Commission observed that this period generally relates to the expected useful life and associated cost-of-service amortization period of cybersecurity investments.

166. The Commission also proposed to specify that a utility granted the Cybersecurity Regulatory Asset Incentive may defer eligible expenses for up to five years from the date of Commission approval of the incentive.[305] Under this provision, the Commission proposed that eligible expenses incurred for five years could be added to the regulatory asset that is allowed in rate base and amortized over five subsequent years.[306] The Commission preliminarily found that this limit would be appropriate, given the potentially indefinite nature of certain expenses. The Commission stated that such a limit would also reflect that cybersecurity risks and solutions evolve over time and matches the proposed five-year maximum duration of the Cybersecurity ROE Incentive. The Commission preliminarily found that a five-year limit appropriately balances the goal of providing an incentive of a sufficient size to encourage utilities to make eligible improvements in their cybersecurity posture with the requirement to protect ratepayers.

167. However, the Commission proposed to make an exception to this sunsetting provision for eligible cybersecurity threat information sharing programs.[307] The Commission noted that FPA section 219A(c)(2) directs the Commission to provide incentives for *participation* in cybersecurity threat information sharing programs. The Commission preliminarily found that participation in such cybersecurity threat information sharing programs, which provide participants with ongoing updates about active cybersecurity threats and are therefore distinct from other cybersecurity investments that may become obsolete with the passage of time, warrants a different incentive treatment than other investments. Consequently, the Commission proposed that utilities be able to continue deferring these ongoing expenses and including them in their rate base for each annual tranche of expenses, for as long as: (1) the utility continues incurring costs for its participation in the program; and (2) the program remains eligible for incentives.

b. Comments

168. EEI supports the NOPR proposal to make an exception to the sunsetting provision for eligible cybersecurity threat information sharing programs on the basis that they are distinct from discrete cybersecurity investments that may become obsolete with the passage of time.[308] EEI comments that sharing information about the nature of threats can help electric utilities react to and mitigate the threat.[309]

169. EEI requests clarification that the amortization period would be up to five years, but that five years is not the only duration permissible for amortization.[310]

170. TAPS agrees with the Commission's preliminary finding that the five-year limit balances the goals of ratepayer protection with inducing the desired investment.[311] However, TAPS argues that the NOPR unjustifiably proposed to depart from that balance

[296] EEI Initial Comments at 13.

[297] *Id.* at 14.

[298] AEP Initial Comments at 4–5.

[299] APPA Initial Comments at 5; California Parties Initial Comments at 22; ELCON Initial Comments at 4; Ohio Consumers' Counsel Initial Comments at 15; TAPS Initial Comments at 18–19.

[300] California State Parties Initial Comments at 25; Ohio Consumers' Counsel Initial Comments at 15; TAPS Initial Comments at 19.

[301] APPA Initial Comments at 16.

[302] *Id.* at 16.

[303] As noted above, the cybersecurity investment for participation in a cybersecurity threat information sharing program would recur annually.

[304] NOPR, 180 FERC ¶ 61,189 at P 47.

[305] *Id.* P 48.

[306] The Commission proposed that, in their FPA section 205 filings, incentive recipients must include notes to their formula rates specifying the Commission order(s) which approved the incentive and stating that the associated Cybersecurity Regulatory Asset Incentive must terminate in the earlier of: (1) five years from the date of the later of the Commission approving the incentive or the expense being incurred; or (2) the cybersecurity investment becoming mandatory.

[307] NOPR, 180 FERC ¶ 61,189 at P 49.

[308] EEI Initial Comments at 14.

[309] *Id.* at 14.

[310] *Id.* at 14.

[311] TAPS Initial Comments at 20–21.

with regard to expenses incurred for eligible cybersecurity threat information sharing programs by allowing a perpetual incentive on those investments.[312] TAPS argues that the Commission should not adopt such an exception for cybersecurity threat information sharing programs, because it gives no consideration of the requirement to protect ratepayers.[313] TAPS states that the NOPR's distinction from other discrete cybersecurity investments that may become obsolete with the passage of time does not support granting a perpetual incentive for cybersecurity threat information sharing programs.[314] TAPS further argues that the fact that participants are provided with ongoing updates after joining such programs is a recurring benefit that likely increases retention, even absent any incentive.[315]

171. California Parties also oppose the NOPR's exception to the sunsetting provision for eligible cybersecurity threat information sharing programs.[316] California Parties state that, once a utility has elected to participate in CRISP and has paid the requisite start-up costs, there is no longer a purpose served by incentive treatment, given that the utility is able to readily recover all ongoing costs of participation (along with the start-up costs) in transmission rates.[317] California Parties argue that, to provide incentives in this circumstance—where they are simply not needed to induce prudent spending on an annual subscription to CRISP and associated staff time—would result in unjust and unreasonable rates.[318]

c. Commission Determination

172. We adopt the NOPR's proposal to add § 35.48(g)(1) to the Commission's regulations, with one modification. As suggested by EEI, we will modify the NOPR proposal to allow, at the request of the utility, the Cybersecurity Regulatory Asset Incentive duration to be *up to* five years. This revision provides flexibility to requesting utilities while maintaining ratepayer protections. A utility granted the Cybersecurity Regulatory Asset Incentive must amortize the regulatory asset for up to five years. Additionally, a utility granted the Cybersecurity Regulatory Asset Incentive may defer eligible expenses for up to five years from the date of Commission approval of the incentive. Consistent with the NOPR proposal, we find that a five-year amortization period balances the Commission's goals of ratepayer protection and providing an appropriate incentive to encourage utilities to improve their cybersecurity posture. To clarify, incentive-eligible, cybersecurity expenses for each of the five years may be included in rate base and amortized for up to five years, essentially creating five tranches of cybersecurity expenses. We also clarify that if and when cybersecurity measures become mandatory, utilities will cease receiving the Cybersecurity Regulatory Asset Incentive for taking such measures.[319] No additional expenses will be converted to regulatory assets and the unamortized portions of regulatory assets must be incurred as expenses in the year when they were converted back to expenses and immediately removed from rate base.

173. We add § 35.48(g)(2) to the Commission's regulations to provide an exception to the five-year duration limit to the incentive-based rate treatment of cybersecurity investments made to participate in a cybersecurity threat information sharing program. We find that the duration exception for participation in eligible cybersecurity threat information sharing programs as proposed in the NOPR is appropriate. As discussed in the body of this rule, the Congressional mandate to incentivize participation indicates that all participants should be eligible to seek cybersecurity incentives for their participation in eligible programs. Therefore, we decline to remove the exception to the sunsetting provision for participation in an eligible cybersecurity threat sharing program.

3. Filing Process

a. NOPR Proposal

174. The Commission proposed to require a utility's request for one or more incentive-based rate treatments to be made in a filing pursuant to FPA section 205. As proposed in the NOPR, such a request must include a detailed explanation of how the utility plans to implement one or both of the proposed incentive approaches and the requested rate treatment.[320] The Commission proposed to require utilities to provide detail on the expenditures for which they seek incentives and show how the cybersecurity-related expenditures meet the eligibility requirements, as described in more detail below.

175. In addition, the Commission proposed that a utility seeking one or more incentive-based rate treatments must receive Commission approval prior to implementing any incentive in its rate on file with the Commission. The Commission stated that, in order to effectuate an incentive in rates, utilities would need to propose in their FPA section 205 filing conforming revisions to their formula rates to reflect incentive rate treatment granted pursuant to these proposed regulations. The Commission explained that utilities with stated rates may file under FPA section 205 to seek incentives as part of a larger rate case or make a request for single issue ratemaking, which the Commission will evaluate on a case-by-case basis to ensure that the rate, inclusive of the incentive, is just and reasonable and not unduly discriminatory or preferential.[321]

176. The Commission proposed that filings under the PQ List approach must provide evidence that the utility has made one or more pre-qualified cybersecurity expenditures and otherwise complies with all appropriate requirements.[322]

177. The Commission also proposed that a utility requesting the Cybersecurity ROE Incentive must provide the anticipated cost of the capital investment and the identity of the rate schedule(s) on file with the Commission under which it will recover the increased ROE.[323] The Commission alternatively proposed that a utility requesting the Cybersecurity Regulatory Asset Incentive must provide a description of the covered expense(s), including whether the expense(s) are associated with the third-party provision of hardware, software, and computing network services or incurred for training to implement network analysis and monitoring programs, as well as an estimate of the cost of such expense(s) and when the cost is expected to be incurred.

178. The Commission preliminarily found that the same cybersecurity investment should not be eligible for both the Cybersecurity ROE Incentive and the Cybersecurity Regulatory Asset Incentive. Given that regulatory asset treatment may be approved for costs that are normally treated as expenses (*i.e.,* as regulatory assets), the Commission preliminarily found that costs that are allowed to be deferred as a regulatory asset should be included in rate base for determination of the base return but not for the additional return

[312] *Id.* at 21.
[313] *Id.* at 21.
[314] *Id.* at 22.
[315] *Id.* at 22.
[316] California Parties Initial Comments at 27.
[317] *Id.* at 27.
[318] *Id.* at 27.
[319] *See Cal. Pub. Util. Comm'n* v. *FERC,* 879 F.3d 966 (9th Cir. 2018).
[320] NOPR, 180 FERC ¶ 61,189 at P 50.
[321] *Id.* P 51 & n.47.
[322] *Id.* P 52.
[323] *Id.* P 53.

associated with the 200-basis point ROE adder.[324]

b. Comments

179. Ohio Consumers' Counsel requests that the Commission require any incentive application (whether an application for incentives for advanced technologies and actions on the pre-qualification list or for incentives that are not included on that list) to be made in a FPA section 205 filing.[325] Ohio Consumers' Counsel further requests that the Commission require that both types of applications explicitly identify in which accounts the utility will book the costs associated with the investment, expense or action.[326] Ohio Consumers' Counsel comments that such a requirement is needed to ensure transparency and proper rate treatment for these investments.[327]

180. California Parties ask the Commission to clarify the incentive application procedures to ensure that stakeholders have adequate time and information to meaningfully review and comment on incentive requests.[328] California Parties argue that the usual filing procedures under FPA section 205 are not sufficient because they neither provide ample time for review, given the more complex nature of cybersecurity incentive applications, nor do the procedures ensure the development of an adequate factual record, especially given the CEII considerations.[329] In support, California Parties state that the filing procedures under FPA section 205 provide only 21 days for an interested party to intervene and comment and do not ensure the opportunity for discovery or evidentiary hearings.[330] California Parties request that the Commission make clear that all cybersecurity incentive applications will be presumed to raise issues of material fact and will thus be subject to an evidentiary hearing with an opportunity for discovery.[331] California Parties aver that evidentiary hearings and discovery would provide a critical measure of transparency regarding the use of ratepayer funds, provided appropriate safeguards are in place.[332]

181. NRECA seeks additional detail on the NOPR's proposed filing process.[333] Specifically, NRECA requests that the Commission propose language addressing applications under the case-by-case approach.[334] NRECA also asks the Commission to describe the anticipated composition of teams responsible for reviewing and evaluating requests under the proposed new provisions.[335] NRECA states that, given the wide-ranging implications of granting cybersecurity incentives, the reviewing team should include staff with diverse backgrounds, including electrical engineers who understand the structure of the transmission and generations assets that may be affected by the proposed cybersecurity investment, system or computer science engineers who understand the nature of the proposed investments, and analysts with ratemaking experience who can balance the increased benefits of the proposed investment against the cost to the ratepayers.[336]

182. MISO Transmission Owners caution that, while the inclusion of cybersecurity threat information sharing programs on the PQ List will provide certainty, efficiency, and transparency for utilities seeking an incentive, public disclosure through the filing process could put utilities at risk.[337] MISO Transmission Owners recommend that the Commission adopt filing procedures that would protect the confidentiality of utilities requesting incentives, including the use of a public cover sheet disclosing what incentives are being applied for with the remainder of the application being confidential.[338] In contrast, NRECA acknowledges the need for utilities to submit certain information under CEII filing regulations but warns that the more information filing utilities are able to hide from the public, the greater the burden on interested parties.[339] NRECA cautions that the consolidation of incentive applications containing sensitive information may increase the overall risk to the bulk electric system.[340]

c. Commission Determination

183. We adopt the NOPR's proposal and add § 35.48(h) to the Commission's regulations, which specifies the details required in applications to the Commission to receive incentive-based rate treatment for cybersecurity investments. We clarify that utilities may request Commission approval of incentives for cybersecurity investments pursuant to FPA section 219A by filing an FPA section 205 filing or by seeking a ruling on eligibility by filing a petition for declaratory order followed-up by an FPA section 205 filing. Utilities must propose to revise their rates to reflect such incentives pursuant to FPA section 205. Pursuant to FPA section 219A(f), § 35.48(h) permits utilities to seek cybersecurity incentives either as part of a larger rate case or make a request for single issue ratemaking.[341]

184. With regard to Ohio Consumers' Counsel's suggestion that the Commission require any incentive application (whether an application for incentives for Advanced Cybersecurity Technologies and actions on the PQ List or for incentives that are not included on that list) to be made in a FPA section 205 filing, we agree that an FPA section 205 filing is necessary for any incentives to be effectuated in utility rates. However, consistent with the Commission's precedent with respect to transmission incentives, we will allow utilities to seek declaratory orders finding expenditures to be eligible for incentives prior to making FPA section 205 filings to implement incentives in rates. A request for a declaratory order must include all necessary information for the Commission to determine whether the investment merits an incentive. The FPA section 205 filing necessary to add incentive-based rate treatment to a utility's rate on file with the Commission, whether filed in conjunction with a petition for declaratory order or on its own, must provide information required for the Commission to determine that the rate inclusive of the incentives is just and reasonable and not unduly discriminatory or preferential.[342]

185. The filing process is similar for incentives requested for cybersecurity investments that are on the PQ List and case-by-case requests. The distinction is that requests for incentives for cybersecurity investments that are on the PQ List have the rebuttable presumption that the items on the PQ List satisfy the eligibility criteria, *i.e.,* materially improving cybersecurity posture and not already being mandatory. By contrast, applicants under a case-by-case approach must provide a detailed description of how the cybersecurity investments will satisfy the eligibility criteria and thereby materially improve the cybersecurity posture for their utility. To make this demonstration, in addition to describing

[324] *Id.* P 38.

[325] Ohio Consumers' Counsel Initial Comments at 9.

[326] *Id.* at 9–10.

[327] *Id.* at 10.

[328] California Parties Initial Comments at 30.

[329] *Id.* at 30.

[330] *Id.* at 30.

[331] *Id.* at 31.

[332] *Id.* at 31.

[333] NRECA Initial Comments at 10–12.

[334] *Id.* at 11.

[335] *Id.* at 11.

[336] *Id.* at 11–12.

[337] MISO Transmission Owners Initial Comments at 7.

[338] *Id.*

[339] NRECA Initial Comments at 13.

[340] *Id.* at 13.

[341] IIJA, Public Law 117–58, section 40123, 135 Stat. at 952 (to be codified at 16 U.S.C. 824s–1(f)).

[342] 18 CFR pt. 35.

the cybersecurity investments, applicants should: (1) describe their prevailing cybersecurity posture including existing equipment, processes, and ongoing expenses; and (2) describe how the cybersecurity investment for which an incentive is sought would elevate the utility's cybersecurity posture. The application should include evidence sufficient to demonstrate that the cybersecurity investment(s) would be for activities that are consistent with the discussion in section III.B. regarding the PQ List and case-by-case approaches. We also clarify that, for incentive requests either for PQ List items or on a case-by-case basis, utilities must include in their transmittal letter an attestation that, to their knowledge, the cybersecurity investments are not mandatory, as described in section III.A.3. above. Additionally, for the Cybersecurity Regulatory Asset Incentive, the transmittal letter must include an attestation that the utility has not already been undertaking materially the same cybersecurity expenses for more than three months (with the exception of participation in cybersecurity threat information sharing programs).[343] As described in III.C.2. only new types of cybersecurity investments, and not materially similar ones to existing expenses, will be eligible for incentive-based rate treatment.

186. As described in § 35.48(h), requests for the Cybersecurity Regulatory Asset Incentive must provide: (1) a description of the relevant cybersecurity expenses; (2) estimates of the costs of cybersecurity expenses; (3) a description of when the cybersecurity expenses are expected to be incurred; and (4) an attestation that the utility's cybersecurity expenses are new, *i.e.,* the utility has not already been undertaking materially the same cybersecurity expenses for more than three months prior to the date of filing its request with the Commission. Descriptions of expenses should include details such as whether they are conducted by utility employees or third parties and whether they are for training or the direct carrying out of cybersecurity tasks. This last requirement seeks to ensure that cybersecurity incentives encourage utilities to improve their cybersecurity posture rather than provide a return on expenses that the utility is already undertaking. Incentive-eligible expenses should be meaningfully distinct from past ones and not only contain small variations or incremental modifications from existing expenses.

187. Consistent with the Commission's implementation of transmission incentives under FPA section 219, interested parties will have a 21-day comment period, unless otherwise provided by the Commission.[344] We find that California Parties have not justified departing from the Commission's comment period convention. Doing so could impede the timeliness of the Commission's evaluation of cybersecurity incentives. Furthermore, we will not presume that every request for cybersecurity incentives will have issues of material fact requiring hearing and settlement judge procedures. Such a presumption would also constitute an unjustified departure from Commission incentive precedent under FPA section 219 and may unnecessarily delay the incentive-based rate treatment of cybersecurity investments as well as the utility's underlying cybersecurity investments.

188. In response to Ohio Consumers' Council suggested requirement that utilities identify the accounts that cybersecurity investment will be booked in, as described in section III.C.2, pursuant to our existing regulations, any utility that receives an incentive must maintain sufficient records to support the distinction of any investments that are afforded incentive-based rate treatment.

189. We will not, as NRECA suggests, describe the anticipated composition of Commission staff responsible for reviewing and evaluating requests under the proposed new provisions. Such description is neither necessary nor consistent with Commission procedures.

190. Consequently, for a given cybersecurity investment, utilities will be able to receive a single incentive-based rate treatment, as discussed in section III.B., for each voluntary cybersecurity investment that the utility makes. Utilities must specify which incentive they seek in their filings with the Commission.

191. We note that § 35.48(j) to the Commission's regulations declares that utilities may request CEII treatment pursuant to § 35.48(k) to the Commission's regulations for the portions of their cybersecurity incentive-based rate filings that contains CEII. This is consistent with § 388.113 of the Commission's regulations.[345] In addition, FPA section 219A(g) declares that Advanced Cybersecurity Technology Information provided to the Commission under FPA 219A(b), (c), or (f) ''shall be considered to be Critical Electric Infrastructure Information under [FPA] section 215A.'' [346]

4. Reporting Requirements

a. NOPR Proposal

192. In order to ensure that a utility receiving incentive rate treatment has implemented the requirements of the incentive and to ensure that it continues to adhere to the requirements, the Commission proposed to require utilities to submit informational reports to the Commission for the duration of the incentive.[347]

193. The Commission also proposed that a utility that has received cybersecurity incentives under this section must make an annual informational filing by June 1, provided that the utility has received Commission-approval for the incentive at least 60 days prior to June 1 of that year.[348] Utilities that receive Commission-approval for an incentive later than 60 days prior to June 1 would be required to submit an annual informational filing beginning on June 1 of the following year. The Commission proposed that the annual filing should detail the specific investments, if any, as of that date, that were made pursuant to the Commission's approval and the corresponding FERC account for which expenditures are booked. For recipients of the Cybersecurity ROE Incentive, the Commission proposed that each annual informational filing should describe the parts of its network that it upgraded in addition to the nature and cost of the various investments. For recipients of the Cybersecurity Regulatory Asset Incentive, the Commission proposed that each annual informational filing should describe such expenses in sufficient detail to demonstrate that such expenses are specifically related to the eligible cybersecurity investment underlying the incentives and not for ongoing services including system maintenance, surveillance, and other labor costs.

194. The Commission noted that it could also conduct periodic verification to assess cybersecurity investments and expenses for which it has approved

[343] For ongoing cybersecurity investments made to comply with approved Reliability Standards, the three-month period begins on the date that the Commission's approval of the Reliability Standard becomes effective. For approvals that the Commission issues by order, the effective date is the date of the order. For approvals that the Commission issues by rulemaking, the effective date occurs on a specified date that occurs after the later of Congress receiving notice from the Commission or the final rule is published in the **Federal Register**.

[344] 18 CFR 35.8.

[345] 18 CFR 388.113.

[346] IIJA, Public Law 117–58, section 40123, 135 Stat. at 951 (to be codified at 16 U.S.C. 824s–1(g)).

[347] NOPR, 180 FERC ¶ 61,189 at P 54.

[348] *Id.* P 55.

incentives.[349] The Commission could perform such verifications through multiple means (*i.e.,* directing further informational filings, audits, etc.). The Commission stated that the annual informational filings would inform the Commission on how and when any additional verification is warranted.

b. Comments

195. Ohio Consumers' Counsel supports the NOPR's proposal and recommends that the Commission and consumers must both be able to verify that the investments are being made and that the intended benefits are being received.[350]

196. Several commenters ask for the Commission to require additional information beyond the proposed reporting requirements. NRECA requests that the Commission require that the annual informational filings include any changes to the categorization of any incentivized enhancements and affirmatively state that the previously incentivized enhancement remains valid.[351] NRECA states that this modification will address the burden placed on ratepayers to review and analyze the information provided to ensure the accuracy of formulas applying different ROEs, especially where certain of those ROEs are capped.[352] NRECA also asks that the Commission consider issuing responses confirming the continued applicability of incentive rate treatment in response to the annual informational filings.[353] Ohio FEA recommends that verification methods should be established that go beyond the annual information filings proposed by the NOPR to ensure that cybersecurity benefits are realized and that double recovery of incentives is avoided.[354] NRECA also recommends that the Commission establish a process to confirm whether a utility's cybersecurity investment had the security effects described.[355]

197. California Parties urge the Commission to require utilities awarded cybersecurity incentives to submit aggregated data and, consistent with the Commission's CEII regulations, provide vetted State officials access to it.[356] California Parties argue that the provision of such data will, in turn, enable the relevant State officials to improve the cybersecurity protection of utility assets in their respective states.[357]

198. While not opposed to the NOPR proposal, EEI states that the Commission should allow the annual reports to be filed under the CEII regulations because the information the Commission seeks, while innocuous on its own, could be coupled with other information and used by those seeking to attack the reliability of U.S. energy infrastructure.[358] EEI states that, given the sensitivity of information filed as part of an annual report, electric companies would need assurances regarding how the various intervenor/third-party recipients of CEII would comply with sensitive data and information protection requirements, the obligation to destroy CEII when requested to do so, the prohibition on sharing CEII, and immediate reporting of unauthorized access of CEII.[359]

c. Commission Determination

199. Consistent with the NOPR, in order to ensure that a utility receiving incentive-based rate treatment has implemented and continues to adhere to the requirements of the incentive, we require utilities to submit informational reports to the Commission for the duration of the cybersecurity incentive, pursuant to § 35.48(i), which we are adding to the Commission's regulations. We continue to find that cybersecurity investments, unlike many others, may not otherwise be observable and verifiable by other parties. Consistent with the comments of Ohio Consumers' Counsel and California Parties, this requirement should provide State commissions and other stakeholders enhanced visibility into the cybersecurity investments that utilities are making for which they receive incentives.

200. Consistent with the NOPR, a utility that has received cybersecurity incentives under this section must make an annual informational filing by June 1 of that calendar year, provided that the utility has received Commission-approval for the incentive at least 60 days prior to June 1 of that year. Utilities that receive Commission-approval for an incentive within 60 days before June 1 must submit an annual informational filing beginning on June 1 of the following year.[360] The annual filing must detail the specific investments, if any, as of that date, that were made pursuant to the Commission's approval and the corresponding FERC account for which the cybersecurity investments are booked. For recipients of the Cybersecurity Regulatory Asset Incentive, annual informational filings should describe expenses in sufficient detail to demonstrate that such expenses specifically relate to the eligible cybersecurity investment and not to ongoing services including system maintenance, surveillance, and other labor costs that are materially the same as those that existed prior to the incentive request. Additionally, consistent with NRECA's comments, annual informational filings must specify any material changes in the nature of such expenses from prior filings. Unlike capital investments, ongoing expenses could potentially change in nature over time, and this provision ensures that the incentives in utility rates correspond to the precise expenses for which the Commission approved incentives.

201. We will not, as requested by NRECA, include a requirement for the Commission to issue responses confirming the continued applicability of incentive rate treatment in response to the annual informational filings. We do not find that such affirmative confirmation is necessary to ensure that incentives continue to be just and reasonable.

202. We also decline to establish a process to confirm whether a utility's cybersecurity investment had the security effects described as recommended by NRECA.[361] The annual informational filings will enable the Commission and interested parties to confirm that utilities have made the cybersecurity investments for which they receive incentives. Establishing a process to review the efficacy of each cybersecurity investment would create a substantial regulatory burden on utilities and other parties, including the Commission. Furthermore, measuring the ultimate effect of specific cybersecurity investments may be difficult given that security defenses can act as a deterrence to cyberattack and therefore it is impossible to know what cyberattacks have been prevented.

203. We note that § 35.48(j) to the Commission's regulations declares that utilities may request CEII treatment pursuant to § 35.48(i) to the Commission's regulations for the portions of their cybersecurity incentive-based rate informational reports that contain CEII. This is consistent with § 388.113 of the

[349] *Id.* P 56.

[350] Ohio Consumers' Counsel Initial Comments at 16.

[351] NRECA Initial Comments at 12.

[352] *Id.* at 12.

[353] *Id.* at 12.

[354] Ohio FEA Initial Comments at 13.

[355] NRECA Initial Comments at 9.

[356] California Parties Initial Comments at 34.

[357] *Id.* at 34–35.

[358] EEI Initial Comments at 16.

[359] *Id.* at 17.

[360] If a utility first receives Commission-approval for the incentive on April 1 or later, its initial annual informational filing would be due on June 1 of the following year.

[361] NRECA Initial Comments at 9.

Commission's regulations.[362] In addition, FPA section 219A(g) declares that Advanced Cybersecurity Technology Information provided to the Commission under FPA 219A(b), (c), or (f) ''shall be considered to be Critical Electric Infrastructure Information under [FPA] section 215A.'' [363]

E. Other Issues

1. Comments

204. INGAA and the International Pipeline Resilience Organization (IPRO) support the Commission's efforts to provide cybersecurity incentives to electric utilities but argue that rate-based incentives should also be available to owners and operators of interstate natural gas pipelines under the Commission's authority.[364] Both commenters assert that, due to the highly interconnected nature of the electric and gas industries and the similarities in threats faced by both industries, the Commission is overlooking a security threat by solely focusing on incentives for electric utilities.[365] IPRO argues that the Commission has the requisite authority under the NGA and the Interstate Commerce Act (ICA) to offer incentives to the oil and gas industry.[366] In contrast, California Parties assert that, because the NOPR does not cite the NGA or ICA, the Commission cannot include incentives for pipeline owners and operators in the final rule.[367]

205. EPSA urges the Commission to prevent cross-subsidization among vertically integrated entities. EPSA avers that, while these companies may have separate legal entities for their transmission and generation operations, cybersecurity programs are often administered as a shared service. EPSA argues that the Commission must ensure that any entities to which it extends incentives on the transmission side are not cross-subsidizing cybersecurity operations for their generation arms.[368]

2. Commission Determination

206. We will not, as IPRO advocates, extend incentives to natural gas pipelines and oil pipelines in this proceeding. This rulemaking effectuates Congress' requirement that the Commission develop cybersecurity incentives for utilities pursuant to FPA section 219A. As noted by California Parties, incentives under the NGA and the ICA are beyond the scope of this proceeding. We also note that the application of longstanding cost-of-service cost-allocation practices to enterprise-wide costs, described in sections III.C.1 and III.C.2 above, will address EPSA's cross-subsidization concerns.

IV. Information Collection Statement

207. The information collection requirements contained in this final rule are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 at 44 U.S.C. 3507(d). OMB's regulations require approval of certain information collection requirements imposed by agency rules.[369] Upon approval of a collection of information, OMB will assign an OMB control number and expiration date. Respondents subject to the filing requirements of this proposed rule will not be penalized for failing to respond to this collection of information unless the collection of information displays a valid OMB Control Number. This final rule establishes the Commission's regulations with respect to the implementation of FPA section 219A.[370]

208. Interested persons may obtain information on the reporting requirements by contacting Ellen Brown, Office of the Executive Director, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426 via email (*DataClearance@ferc.gov*) or telephone (202) 502–8663).

209. The Commission solicited comments on the NOPR and the collection of information in that NOPR.

Title: FERC–725B, Incentives for Advanced Cybersecurity Investment.

Action: Proposed revision of FERC–725B.

OMB Control No.: 1902–0248.

Respondents for this Rulemaking: Public utilities and non-public utilities that have or will have a rate on file with the Commission.

Frequency of Information Collection:

On occasion: Voluntary filings seeking incentive-based rate treatment for cybersecurity expenditures; and

Annually: An informational filing on June 1 of each year, required of entities that have been granted and are receiving incentive-based rate treatment for cybersecurity expenditures.

Abstract: The final rule provides that a utility may seek incentive-based rate treatment for cybersecurity investments by making a rate filing in accordance with section 205 of the FPA. The final rule states that one approach the Commission may use in evaluating such a filing is to consider whether prospective cybersecurity investments would match one of the types of investments listed at proposed 18 CFR 35.48(d). The final rule refers to this list of pre-qualified expenditures that are eligible for incentives as the PQ List. Any cybersecurity expenditure that is on the PQ List is entitled to a rebuttable presumption of eligibility for an incentive.

210. The final rule also discusses a different approach, in which a utility's cybersecurity expenditure would be evaluated on a case-by-case basis to determine if it is eligible for an incentive. Under that approach, the utility would need to demonstrate that the prospective investment is voluntary and would materially improve cybersecurity through either an investment in Advanced Cybersecurity Technology or participation in cybersecurity threat information sharing program. Under either approach, the utility would need to demonstrate that its rate, inclusive of the incentive, is just and reasonable and not unduly discriminatory or preferential.

211. The final rule also provides that a utility that is granted incentive-based rate treatment must submit an annual informational filing to the Commission by June 1 of each year, provided that the utility has received Commission approval of the incentive at least 60 days prior to June 1 of that year. Utilities that receive Commission approval of an incentive later than 60 days prior to June 1 would be required to submit an annual informational filing beginning on June 1 of the following year. The informational filing must describe the specific investments, if any, as of that date, that were made pursuant to the Commission's approval and the corresponding FERC account for which expenditures are booked. For incentives where the Commission allows deferral of expenses, annual informational filings should describe such expenses in sufficient detail to demonstrate that such expenses are specifically related to the cybersecurity investment for which the incentive was granted, and not for ongoing services including system maintenance, surveillance, and other labor costs.

Necessity of Information: Required to obtain or retain benefits.

Internal Review: The Commission has reviewed the changes and has determined that such changes are necessary. These requirements conform to the Commission's need for efficient

[362] 18 CFR 388.113.

[363] IIJA, Public Law 117–58, section 40123, 135 Stat. at 951 (to be codified at 16 U.S.C. 824s–1(g)).

[364] INGAA Initial Comments at 2; IPRO Initial Comments at 2–3.

[365] INGAA Initial Comments at 2; IPRO Initial Comments at 2–3.

[366] IPRO Initial Comments at 9–10.

[367] California Parties Reply Comments at 14.

[368] EPSA Initial Comments at 9.

[369] 5 CFR 1320.11.

[370] Public Law 117–55, 135 Stat. 951 (2021) (to be codified at 16 U.S.C. 824s–1).

information collection, communication, and management within the energy industry. The Commission has specific, objective support for the burden estimates associated with the information collection requirements.

212. The NERC Compliance Registry, as of August 5, 2022, identifies approximately 1,669 utilities, both public and non-public, in the U.S. that would be eligible for this proposed incentive and rate treatment. The Commission estimates that the NOPR may affect the burden [371] and cost [372] as follows:

FERC–725B—CHANGES IN FINAL RULE IN DOCKET NO. RM22–19–000

A. Area of modification	B. Number of respondents	C. Annual estimated number of responses per respondent	D. Annual estimated number of responses (Column B × Column C)	E. Average burden hours & cost ($) per response	F. Total estimated burden hours & total estimated cost ($)(Column D × Column E)
Voluntary filing seeking incentive rate treatment for cybersecurity investment. 18 CFR 35.48(b).	50	1	50	80 hours; $7,280 ...	4,000 hours; $364,000
Annual informational filing required where Commission has granted incentive rate treatment. 18 CFR 35.48(h).	50	1	50	40 hours; $3,640 ...	2,000 hours; $182,000
Totals	.....	.....	.....	.....	6,000 hours; $546,000

V. Environmental Analysis

213. The Commission is required to prepare an Environmental Assessment or an Environmental Impact Statement for any action that may have a significant adverse effect on the human environment.[373] We conclude that that neither an Environmental Assessment nor an Environmental Impact Statement is required for this final rule under § 380.4(a)(15) of the Commission's regulations, which provides a categorical exemption for approval of actions under sections 205 and 206 of the FPA relating to the filing of schedules containing all rates and charges for the transmission or sale of electric energy subject to the Commission's jurisdiction, plus the classification, practices, contracts, and regulations that affect rates, charges, classifications, and services.[374]

VI. Regulatory Flexibility Act

214. The Regulatory Flexibility Act of 1980 (RFA) [375] generally requires a description and analysis of final rules that will have significant economic impact on a substantial number of small entities. The Small Business Administration's (SBA) Office of Size Standards develops the numerical definition of a small business.[376] The SBA size standard for electric utilities is based on the number of employees, ranging from 250 to 1,000 employees based on the electric utility type.[377] While this final rule is applicable to all small utilities, participation with this final rule is voluntary for all respondents, including small utilities. We estimate that the average cost of voluntary participation for each utility to be $7,280 (initial filing) plus an annual estimated cost of $3,640 for up to five years. These initial and annual estimated costs would not constitute a significant economic impact on affected entities of any size, including small entities. Accordingly, the Commission certifies that this final rule will not have a significant economic impact on a substantial number of small entities.

VII. Document Availability

215. In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*http://www.ferc.gov*). At this time, the Commission has suspended access to the Commission's Public Reference Room due to the President's March 13, 2020 proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19).

216. From FERC's Home Page on the internet, this information is available on eLibrary. The full text of this document is available on eLibrary in PDF and Microsoft Word format for viewing, printing, and/or downloading. To access this document in eLibrary, type the docket number excluding the last three digits of this document in the docket number field.

217. User assistance is available for eLibrary and the FERC's website during normal business hours from FERC Online Support at 202–502–6652 (toll free at 1–866–208–3676) or email at *ferconlinesupport@ferc.gov,* or the Public Reference Room at (202) 502–8371, TTY (202)502–8659. Email the Public Reference Room at *public.referenceroom@ferc.gov.*

VIII. Effective Date and Congressional Notification

218. These regulations are effective [insert date 60 days from publication in **Federal Register**]. The Commission has determined, with the concurrence of the Administrator of the Office of Information and Regulatory Affairs of OMB, that this rule is not a ''major rule'' as defined in section 351 of the Small Business Regulatory Enforcement Fairness Act of 1996.

List of Subjects in 18 CFR Part 35

Electric power rates, Electric utilities, Reporting and recordkeeping requirements.

[371] ''Burden'' is the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. For further explanation of what is included in the information collection burden, refer to 5 CFR 1320.3.

[372] Commission staff estimates that respondents' hourly wages (including benefits) are comparable to those of FERC employees in Fiscal Year 2022. Therefore, the hourly cost used in this analysis is $91 and $188,992 annually.

[373] *Regs. Implementing the Nat'l Env'l Pol'y Act,* Order No. 486, 52 FR 47897 (Dec. 17, 1987), FERC Stats. & Regs. ¶ 30,783 (1987) (cross-referenced at 41 FERC ¶ 61,284).

[374] 18 CFR 380.4(a)(15).

[375] 5 U.S.C. 601–612.

[376] 13 CFR 121.101.

[377] 13 CFR 121.201.

By the Commission. Commissioner Danly is dissenting with a separate statement attached.

Issued: April 21, 2023.

Debbie-Anne A. Reese,

Deputy Secretary.

In consideration of the foregoing, the Commission hereby amends part 35, chapter I, title 18, Code of Federal Regulations, as follows:

PART 35—FILING OF RATE SCHEDULES AND TARIFFS

■ 1. The authority citation for part 35 continues to read as follows:

Authority: 16 U.S.C. 791a–825r, 2601–2645; 31 U.S.C. 9701; 42 U.S.C. 7101–7352.

■ 2. Add subpart K, consisting of § 35.48, to read as follows:

Subpart K—Cybersecurity Investment Provisions

§ 35.48 Cybersecurity investment.

(a) *Purpose.* This section establishes rules for incentive-based rate treatments for utilities with rates on file with the Commission that voluntarily make cybersecurity investments as described in this section.

(b) *Definitions.* As used in this section:

Advanced Cybersecurity Technology means any technology, operational capability, or service, including computer hardware, software, or a related asset, that enhances the security posture of public utilities through improvements in the ability to protect against, detect, respond to, or recover from a cybersecurity threat (as defined in section 102 of the Cybersecurity Act of 2015 (6 U.S.C. 1501)).

Advanced Cybersecurity Technology Information means information relating to Advanced Cybersecurity Technology or proposed Advanced Cybersecurity Technology that is generated by or provided to the Commission or another Federal agency. Pursuant to FPA section 219A(g), Advanced Cybersecurity Technology Information is considered to be Critical Electric Infrastructure Information.

Critical Energy/Electric Infrastructure Information (CEII) has the same meaning as defined in 18 CFR 388.113.

Electric Reliability Organization has the same meaning as defined in § 39.1 of this subchapter.

Reliability Standard has the same meaning as defined in § 39.1 of this subchapter.

(c) *Incentive-based rate treatment for cybersecurity investment.* The Commission will authorize incentive-based rate treatment for a utility that voluntarily makes an investment in Advanced Cybersecurity Technology and for a utility that voluntarily participates in a cybersecurity threat information sharing program under this section, provided that the utility meets the requirements of this section and the utility demonstrates that the resulting rate is just and reasonable and not unduly discriminatory or preferential, as required by sections 205 and 206 of the Federal Power Act. Incentive-based rate treatment is available to both public and non-public utilities that have or will have a rate on file with the Commission. A utility may request a single incentive-based rate treatment as specified in paragraph (f) of this section for an eligible cybersecurity investment that meets the eligibility criteria set forth in paragraph (d) of this section.

(d) *Eligibility criteria.* Pursuant to paragraphs (e) through (k) of this section, a utility may receive incentive-based rate treatment for a cybersecurity investment that:

(1) Materially improves cybersecurity through either Advanced Cybersecurity Technology or participation in a cybersecurity threat information sharing program; and

(2) Is not already mandated by the Reliability Standards as maintained by the Electric Reliability Organization, or otherwise mandated by local, State, or Federal law, decision, or directive; otherwise legally mandated; or an action taken in response to a Federal or State agency merger condition, consent decree from Federal or State agency, or settlement agreement that resolves a dispute between a utility and a public or private party.

(e) *Demonstrating satisfaction of the eligibility criteria.* A utility shall demonstrate to the Commission that a proposed cybersecurity investment satisfies the eligibility criteria in paragraph (d) of this section. Such demonstration shall show that the cybersecurity investment fulfills at least one of the provisions in the following paragraphs (e)(1) through (3):

(1) A utility shall demonstrate that a cybersecurity investment qualifies as one or more of the pre-qualified cybersecurity investments. The Commission shall rebuttably presume that pre-qualified cybersecurity investments satisfy the eligibility criteria. The Commission shall maintain a list on its website of pre-qualified cybersecurity investments and shall update such list from time to time either subject to notice and comment procedures or in a rulemaking.

(2) A utility shall demonstrate that a cybersecurity investment satisfies each of the eligibility criteria in paragraph (d) of this section. The Commission shall not presume that such demonstration satisfies the eligibility criteria.

(3) A utility shall demonstrate that it will make cybersecurity investments to comply with a Reliability Standard that is approved by the Commission but has not yet taken effect as approved by the Commission. The Commission shall not presume that such demonstration satisfies the eligibility criteria. Any incentives authorized by the Commission pursuant to this section shall terminate when the Reliability Standard takes effect.

(f) *Types of incentive-based rate treatment for cybersecurity investment.* For purposes of this section, incentive-based rate treatment shall mean deferral of expenses as a regulatory asset.

(g) *Incentive duration.* (1) A deferred Advanced Cybersecurity Technology regulatory asset whose costs are typically expensed shall be:

(i) Amortized over a period of up to five years;

(ii) Limited to expenses incurred in the first five years following Commission approval of the incentive;

(iii) Limited to ongoing expenses that the applicable utility was not already undertaking more than three months prior to filing an incentive request; and

(iv) Terminated when the cybersecurity investment or activity that serves as the basis of that incentive becomes mandatory.

(2) An incentive granted for participation in a qualified cybersecurity threat information sharing program will not be subject to the five-year duration limitation provisions of paragraph (g)(1)(ii) of this section for as long as the utility participates in the qualified cybersecurity threat information sharing program and such participation is not mandatory as to the utility. A utility participating in a qualified cybersecurity threat information sharing program is eligible to continue deferring expenses associated with such participation, which for each year would be amortized over the next five years.

(h) *Incentive applications.* For the purpose of this section, a utility's request for incentive based-rate treatments for one or more cybersecurity investments must be made in a filing pursuant to section 205 of the Federal Power Act, or in a petition for a declaratory order that precedes a filing pursuant to section 205 of the Federal Power Act. Utilities may file such a request either as a part of a general rate request or on a single-issue basis. Such a request shall include a detailed explanation to include the following information:

(1) A demonstration that the cybersecurity investment satisfies the eligibility criteria, which includes an attestation that cybersecurity investment is not mandatory, as required by paragraph (d)(2) of this section, and that the resulting rate is just and reasonable and not unduly discriminatory or preferential; and

(2) A detailed description of relevant cybersecurity expenses, including whether such cybersecurity expenses are:

(i) Associated with third-party provision of hardware, software, computing networking services, and/or cybersecurity monitoring services;

(ii) For training to implement network analysis and monitoring programs, and/or other cybersecurity protocols; and/or

(iii) Other cybersecurity expenses;

(3) Estimates of the cost of such cybersecurity expenses;

(4) When the cybersecurity expenses are expected to be incurred; and

(5) An attestation that the utility either has not already been undertaking duplicative or materially the same expenses for more than three months or that the utility is participating in a cybersecurity threat information-sharing program for the expense at issue. In the case of cybersecurity investments made to comply with a Reliability Standard that is approved by the Commission but has not yet taken effect as approved by the Commission pursuant to paragraph (e)(3) of this section, the utility must attest that it has not already been undertaking duplicative or materially the same expenses for more than three months prior to the date that the Commission's approval of the Reliability Standard becomes effective.

(i) *Reporting requirements.* A utility that has received Commission approval for incentive-based rate treatment under this section shall make an annual informational filing on June 1, provided that the utility has received such Commission approval at least 60 days prior to June 1 of that year. A utility that receives Commission approval of an incentive-based rate treatment under this section later than 60 days prior to June 1 shall submit an annual informational filing beginning on June 1 of the following year. The annual filing shall detail the specific cybersecurity investments that were made pursuant to the Commission's approval and the corresponding FERC account used. The annual informational filing shall describe the deferred expenses in sufficient detail to demonstrate that such expenses are specifically related to the cybersecurity investment granted incentives and not for ongoing services including system maintenance, surveillance, and other labor costs. Utilities shall provide a detailed description of any material changes in the nature of such expenses from prior year informational filings.

(j) *Transmittal of CEII in incentive applications and annual reports.* As appropriate, any CEII submitted to the Commission in a utility's incentive application made pursuant to paragraph (k) of this section or contained in its reporting requirements made pursuant to paragraph (i) of this section shall be filed consistent with 18 CFR part 388.

Note: The following will not appear in the Code of Federal Regulations.

UNITED STATES OF AMERICA

Incentives for Advanced Cybersecurity Investment, Docket No. RM22–19–000

DANLY, Commissioner, *dissenting:*

1. I dissent from today's Final Rule [378] because it is not in line with the Infrastructure Investment and Jobs Act (IIJA) directive to establish incentive-based rate treatments that ''encourag[e]'' ''investments by public utilities in advanced cybersecurity technology'' and ''participation by public utilities in cybersecurity threat information sharing programs.'' [379] Some have stated that Congress intended for the IIJA to ''shore up cybersecurity'' across the energy sector and other critical infrastructure.[380] The Final Rule provides cybersecurity incentives to select energy sector participants and only a few cybersecurity investments. This rule does not ''shore up cybersecurity'' of the bulk power system. At best, it is a tepid response to a clear Congressional mandate.

2. *First,* the Final Rule limits incentives and cost recovery to those public and non-public utilities ''that have or will have a [cost-based] rate [tariff] on file with the Commission.'' [381] Put differently, the Final Rule excludes public and non-public utilities that sell electricity at market-based rates. This exclusion is not narrow. In 2019, the Commission estimated that there were over 2,500 market-based rate sellers.[382]

3. Given the size of the population excluded, one would expect the IIJA to have directed such limitation. It does not. The statute directs the Commission to establish incentive-based rate treatments that ''encourage'' ''public utilities'' to make cybersecurity investments and participate in cybersecurity information sharing programs. It allows for single-issue rate filings and does not distinguish between those utilities with cost-of-service rates from those with market-based rates.

4. Nor does the broader context of the IIJA support such exclusion.[383] A reading of the IIJA's cybersecurity provisions in their entirety make evident that Congress intended for agencies to immediately undertake a broad campaign to support cybersecurity investment in the energy sector. The IIJA directed the Commission to establish cybersecurity incentives within 1.5 years of its enactment.[384] Further, as noted by the Electric Power Supply Association (EPSA), ''Congress specifically cites small or medium-sized public utilities with limited cybersecurity resources as being potentially eligible for *additional* incentives beyond those identified in the legislation, demonstrating the Congressional intent to fortify the entirety of the [Bulk Power System] to the greatest extent that is reasonably possible.'' [385] The IIJA also directed the Secretary of Energy to ''*enhance*[ ] grid security,'' [386] ''*deploy* advanced cybersecurity technologies for electric utility systems,'' [387] and ''*increase* the

[378] *Incentives for Advanced Cybersecurity Investment,* 183 FERC ¶ 61,033 (2023) (Final Rule).

[379] Public Law 117–58, section 40123(c), 135 Stat. 429, 952 (codified 16 U.S.C. 824s–1(c)).

[380] *See, e.g.,* Senate Committee on Energy & Natural Resources, Chairman Manchin Opening Remarks, at 6 (Mar. 23, 2023), *https://www.energy.senate.gov/services/files/3D1ABB79-6CBF-4786-872A-E708A87CB6AB* (''We took action last Congress by providing $1.9 billion in the Infrastructure Investment and Jobs Act to shore up cybersecurity across the transportation, energy, and water sectors by supporting utilities and State and local governments. I am immensely proud of this work.'').

[381] Final Rule, 183 FERC ¶ 61,033 at P 23 (citation omitted).

[382] *Data Collection for Analytics & Surveillance & Market-Based Rate Purposes,* Order No. 860, 168 FERC ¶ 61,039, at P 324 (2019).

[383] *See McCarthy* v. *Bronson,* 500 U.S. 136, 139 (1991) (''[S]tatutory language must always be read in its proper context.''); *Crandon* v. *U.S.,* 494 U.S. 152, 158 (1990) (''In determining the meaning of the statute, we look not only to the particular statutory language, but to the design of the statute as a whole and to its object and policy.'') (citations omitted).

[384] Public Law 117–58, section 40123(b)–(c), 135 Stat. 429, 952 (codified 16 U.S.C. 824s–1(b)–(c)) (requiring the Commission to conduct a study to identify incentive-based rate treatments within 180 days after the enactment of the section and establish a rule for incentive-based rate treatment within one year thereafter).

[385] EPSA, November 7, 2022 Comments, at 6 (Accession No. 20221107–5130) (emphasis in original) (EPSA Comments). The IIJA also authorized the Commission to provide ''additional incentives'' if that ''investment in advanced cybersecurity technology or information sharing program costs will reduce cybersecurity risks to . . . defense critical electric infrastructure.'' Public Law 117–58, section 40123(d), 135 Stat. 429, 952 (codified at 16 U.S.C. 824s–1(d)).

[386] *Id.,* section 40121, 135 Stat. 429, 949 (emphasis added).

[387] *Id.,* section 40124(c), 135 Stat. 429, 954 (emphasis added).

participation of eligible entities in cybersecurity threat information sharing programs.'' [388] Simply put, excluding 2,500 market-based rate sellers from cybersecurity incentives and cost recovery is not in line with Congressional intent. It should also not go unnoticed that the majority fails to include the provisions from the IIJA in its revised regulations regarding additional incentives for certain utilities, including defense critical electric infrastructure and small and medium utilities,[389] without any explanation although there really can be none.

5. What Congress intended is of no consequence to the majority. On top of failing to respond meaningfully to EPSA's argument regarding Congressional intent (an Administrative Procedure Act violation),[390] my colleagues declare (without citing to any provision in the IIJA) that ''utilities that make sales of energy, capacity, or ancillary services at market-based rates should [not] be able to continue to make those sales and also separately recover the costs of, and receive incentive-based rate treatment on, eligible cybersecurity investments.'' [391] Then the majority goes on to claim that the ''final rule meets the requirements of [the IIJA]'' because ''[a]ll sellers of energy, capacity, and ancillary services are free to file cost-of-service rates under FPA section 205 . . . to recover their entire cost of service'' and ''proceed to make sales exclusively under that cost-based rate.'' [392] In other words, the Commission has fulfilled the Congressional mandate because 2,500 market-based rate sellers can always abandon their market-based rate authority and make filings to transact only at cost-based rates.

6. That reasoning is untenable. The IIJA intended agencies to adopt policies and rules that would induce swift and efficient investments in cybersecurity by the entire energy sector—it was not designed to undermine competitive markets. Moreover, the majority's interpretation effectively voids the IIJA's directive that ''[t]he Commission *shall permit* public utilities to apply for incentive-based rate treatment under a rule issued under this section on a single-issue basis by submitting to the Commission a tariff schedule under [FPA] section [205 [393]] . . . that permits recovery of costs and incentives over the depreciable life of the applicable assets, without regard to changes in receipts or other costs of the public utility.'' [394]

7. Public utilities submit revisions both to market-based rate tariffs and cost-based rate tariffs under FPA section 205. While the proposed rule stated that utilities must file to recover costs and incentives in accordance with FPA section 205 and identified certain filing requirements as to utilities with formula rates and stated rates,[395] at no time did the Commission suggest that entities currently making sales of energy, capacity and ancillary services under market-based rate tariffs must make a filing to recover their *entire* cost of service, including costs of and an incentive return on, cybersecurity investments and proceed to make sales *exclusively* under that cost-based rate, as set forth in the final rule. The final rule is not a ''logical outgrowth'' [396] of the proposed rule, and its sharp departure from the proposed rule violates that the Administrative Procedure Act (APA) requirement that agencies engaged in a rulemaking must provide interested parties adequate notice and opportunity to comment on a proposed rule.[397] It also is nonsensical. Even under the construct today, a generation utility may have both a market-based rate tariff under which it sells energy, capacity and ancillary services and a cost-based rate tariff under which it recovers a reactive power revenue requirement. There is no requirement that such generation utility abandon its market-based rate tariff to recover its cost-based rates. Because the proposed rule failed to provide adequate notice to the public of any change as to market-based rate sellers, this violation of the APA is an obvious legal error.

8. *Second,* the Final Rule unilaterally imposes the heightened requirement that each ''cybersecurity investment[s] [must] . . . *materially improve* cybersecurity through either an investment in Advanced Cybersecurity Technology or participation in a cybersecurity threat information sharing program.'' [398] The IIJA includes no such materiality requirement. Congress directed the Commission to ''encourage[ ]—(1) investments by public utilities in advanced cybersecurity technology; and (2) participation by public utilities in cybersecurity threat information sharing programs.'' [399]

9. The IIJA already limits what qualifies as ''advanced cybersecurity technology'' to ''any technology, operational capability, or service, including computer hardware, software, or a related asset, that *enhances* the security posture of public utilities through improvements in the ability to protect against, detect, respond to, or recover from a cybersecurity threat.'' [400] The ordinary meaning of ''enhance'' is ''to improve the quality, amount, or strength of something.'' [401] It is not to ''materially improve the quality, amount or strength of something.''

10. While the IIJA does not explicitly define ''cybersecurity threat information sharing program,'' [402] it can be inferred that the statute requires (1) that there is a ''program,'' (2) that ''information [is] shar[ed],'' and (3) that information relates to ''cybersecurity.'' The statute cannot be read as inferring a requirement that the utility's participation must ''materially improve'' the security posture of that utility. The additional requirements in the Final Rule that the information be ''relevant and actionable'' and program be ''sponsored by the federal or state government'' are arbitrary and subjective and also is not in line with

[388] *Id.* (emphasis added).

[389] *See id.,* section 40123(d), 135 Stat. 429, 952 (codified 16 U.S.C. 824s–1(d)).

[390] *See TransCanada Power Mktg. Ltd.* v. *FERC,* 811 F.3d 1, 12 (D.C. Cir. 2015) (''It is well established that the Commission must 'respond meaningfully to the arguments raised before it.''') (quoting *Pub. Serv. Comm'n* v. *FERC,* 397 F.3d 1004, 1008 (D.C. Cir. 2005)).

[391] Final Rule, 183 FERC ¶ 61,033 at P 26.

[392] *Id.* (citation omitted).

[393] 16 U.S.C. 824d.

[394] Public Law 117–58, section 40123(f), 135 Stat. 429, 953 (codified 16 U.S.C. 824s–1(f)) (emphasis added).

[395] *See Incentives for Advanced Cybersecurity Investment,* 180 FERC ¶ 61,189, at P 2 (2022) (citation omitted) (Cybersecurity Incentives NOPR); *id.* PP 24, 50–51; *see also id.* P 51 (''In order to effectuate an incentive in rates, utilities would need to propose in their FPA section 205 filing conforming revisions to their formula rates, *as appropriate,* to reflect incentive rate treatment granted pursuant to these proposed regulations.'') (emphasis added); *id.* P 51 n.47 (''Utilities with stated rates may file under FPA section 205 to seek incentives as part of a larger rate case or make a request for single issue ratemaking, which the Commission will evaluate on a case-by-case basis to ensure that the rate, inclusive of the incentive, is just and reasonable.'').

[396] *See, e.g., Am. Fed. Of Labor & Congress of Indus. Org.* v. *Donovan,* 757 F.2d 330, 339 (D.C. Cir. 1985) (''the modification cannot reasonably be seen as the 'logical outgrowth' of a proposal that gave no indication of any change at all in this respect.''); *Shell Oil Co.* v. *EPA,* 950 F.2d 741, 751 (D.C. Cir. 1991) (''Even if the mixture and derived-from rules had been widely anticipated, comments by members of the public would not in themselves constitute adequate notice. Under the standards of the APA, 'notice necessarily must come—if at all—from the Agency.'''') (citations omitted); *id.* (''Moreover, while a comment may evidence a recognition of a problem, it can tell us nothing of how, or even whether, the agency will choose to address it.'').

[397] *See* 5 U.S.C. 553.

[398] Final Rule, 183 FERC ¶ 61,033 at P 28.

[399] Public Law 117–58, section 40123(c)(2), 135 Stat. 429, 952 (codified 16 U.S.C. 824s–1(c)(2)).

[400] *Id.,* section 40123(a), 135 Stat. 429, 951–52 (codified 16 U.S.C. 824s–1(a)).

[401] Cambridge Dictionary, *https://dictionary.cambridge.org/us/dictionary/english/enhance* (defining ''enhance'').

[402] Public Law 117–58, section 40123(c), 135 Stat. 429, 952 (codified 16 U.S.C. 824s–1(c)).

the IIJA.[403] Congress knows how to say ''materially improve,'' and in fact, did so elsewhere in the IIJA,[404] but did not do so to limit the cybersecurity investments eligible for an incentive.

11. To make matters worse, the majority provides no meaningful objective criteria for satisfying its materiality requirement. While the Final Rule lists specific sources that the Commission will ''consider'' in its determination,[405] even when parties demonstrate that an investment meets the requisite number of sources the Commission finds that it does not ''have a *high degree of confidence* that such item[ ] will likely materially improve cybersecurity.'' [406] What could be more arbitrary than a ''standard'' based upon how confident an agency feels?

12. *Third,* the majority eliminates the 200-basis point ROE Adder incentive because ''[cybersecurity] expenses . . . constitute a large portion of overall expenditures for many cybersecurity investments'' and ''the Cybersecurity Regulatory Asset Incentive alone provides the encouragement that Congress intended without unduly increasing costs on consumers.'' [407] I disagree. Like Chairman Phillips, then Commissioner, stated in his concurrence to the NOPR:

> I believe the 5-year proposed duration and the 200-basis point adder are adequate to properly incent utilities. Unlike expenses in the traditional transmission incentives context, the dollar amounts in cybersecurity investments are typically small. Yet, the benefits of additional, advanced cybersecurity investments cannot be ignored. Offering anything less than what is proposed would likely be insufficient to incent any action by utilities, as required by Congress.[408]

13. Moreover, Congress required the Commission to establish a rule to provide incentives to investments in ''*any* technology, operational capability, or service'' [409] not just ''many cybersecurity investments.'' [410]

14. *Finally,* Congress did not require the Commission to simply ''consider performance-based rates as an option among incentive ratemaking treatments'' [411] as the majority contends. The statutory text states that ''the Commission *shall establish, by rule, incentive-based, including performance-based, rate treatments.*'' [412] There is no ambiguity here that could allow for, or support, the majority's ''interpretation.''

15. The word ''consider[ ],'' while used elsewhere in FPA section 219A,[413] is absent from that provision. And the majority should not place too much weight on Order No. 679, which interpreted a provision in FPA section 219 similarly.[414] The Commission's interpretation in Order No. 679 was arguably not in accordance with law and was never upheld by a court on appeal. My colleagues cannot rewrite a Congressional mandate because they believe that the statute is ''difficult'' to implement.[415]

16. Nor is compliance with this provision as ''difficult'' as the majority claims. The Commission could comply simply by establishing a rule that entities can propose on a case-by-case basis a performance-based rate treatment that would measure and tie the rate treatment to the number and severity of cybersecurity incidents. No more is required on the Commission's part.

17. Congress has made it clear that the Commission must provide incentives to shore up the security of the bulk power system. President Biden has ''urge[d] our private sector partners to harden [their] cyber defenses immediately.'' [416] Former President Trump issued an Executive Order declaring that ''[i]t is the policy of the executive branch to use its authorities and capabilities to support the cybersecurity risk management efforts of the owners and operators of the Nation's critical infrastructure.'' [417] Former President Obama warned that cybersecurity threats are ''the most serious economic and national security challenge[ ] we face as a nation'' and ''America's economic prosperity . . . will depend on cybersecurity.'' [418] Similarly, last fall in his concurrence to the Cybersecurity Incentives NOPR, Chairman Phillips, then Commissioner, stated, ''the nation's security and economic well-being depends on reliable and cyber-resilient energy infrastructure.'' [419] Instead of following Congress' instructions, and taking this reliability threat seriously, the majority passes up the opportunity to harden the cybersecurity defenses of the nation's critical energy infrastructure.

For these reasons, I respectfully dissent.

James P. Danly,
Commissioner.

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[403] Final Rule, 183 FERC ¶ 61,033 at P 42.

[404] *See* Public Law 117–58, section 22420(a), 135 Stat. 429, 749 (''The Administrator of the Federal Railroad Administration shall conduct a study of the potential installation and use in new passenger rail rolling stock of passenger rail vehicle occupant protection systems that could *materially improve* passenger safety.''). *C.f. Cent. Bank of Denver* v. *First Interstate Bank,* 511 U.S. 164, 176–77 (1994) (''Congress knew how to impose aiding and abetting liability when it chose to do so.'') (citation omitted).

[405] Final Rule, 183 FERC ¶ 61,033 at P 40 (''Considering these sources as part of a Commission determination of whether a particular cybersecurity investment would materially improve cybersecurity''); *id.* P 109 (''the Commission will consider evidence'').

[406] *Id.* P 90.

[407] *Id.* P 134 (''We decline to adopt an ROE incentive adder, as proposed in the NOPR.'').

[408] Cybersecurity Incentives NOPR, 180 FERC ¶ 61,189 (Phillips, Comm'r, concurring, at P 7) (citations omitted).

[409] Public Law 117–58, section 40123(a), 135 Stat. 429, 951 (codified 16 U.S.C. 824s–1(a)) (emphasis added).

[410] Final Rule, 183 FERC ¶ 61,033 at P 134.

[411] *Id.* P 159.

[412] Public Law 117–58, section 40123(c), 135 Stat. 429, 952 (codified 16 U.S.C. 824s–1(c)) (emphasis added).

[413] *Id.,* section 40123(d), 135 Stat. 429, 952 (codified 16 U.S.C. 824s–1(d)) (*i.e.,* factors for consideration).

[414] *See* Final Rule, 183 FERC ¶ 61,033 at P 159 (citing *Promoting Transmission Investment through Pricing Reform,* Order No. 679, 116 FERC ¶ 61,057, at P 270 (2006)).

[415] *Id.* P 160.

[416] *Statement by President Biden on Our Nation's Cybersecurity,* The White House (Mar. 21, 2022), *https://www.whitehouse.gov/briefing-room/statements-releases/2022/03/21/statement-by-president-biden-on-our-nations-cybersecurity; see also* Cybersecurity Incentives NOPR, 180 FERC ¶ 61,189 (Phillips, Comm'r, concurring at P 8 n.17) (quoting *Statement by President Biden on Our Nation's Cybersecurity*).

[417] Exec. Order No. 13800, 82 FR 22391, section 2 (May 11, 2017).

[418] *Remarks by the President on Securing Our Nation's Cyber Infrastructure,* The White House (May 29, 2009), *https://obamawhitehouse.archives.gov/the-press-office/remarks-president-securing-our-nations-cyber-infrastructure#:~:text=In%20short%2C%20America%27s%20economic%20prosperity%20in%20the%2021st,them%20for%20public%20transportation%20and%20air%20traffic%20control.*

[419] Cybersecurity Incentives NOPR, 180 FERC ¶ 61,189 (Phillips, Comm'r, concurring at P 1).

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Last List April 12, 2023

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