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Presidential Documents

Title 3—

The President

Proclamation 9948 of October 11, 2019

National School Lunch Week, 2019

By the President of the United States of America

A Proclamation

During National School Lunch Week, we recognize the school lunch programs across our country that nourish our children with nutritious, American-grown food that they need to learn in the classroom and work toward bright futures. By ensuring all students have access to well-balanced meals, we can help our Nation's youth maintain healthy lifestyles and help them achieve success in the classroom and beyond.

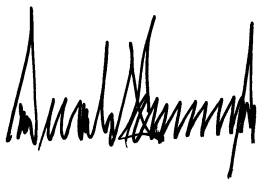
Established in 1946, the National School Lunch Program provides low-cost or free lunches to more than 29 million children in nearly 100,000 public and residential child-care institutions across our country. Since its creation, the number of students served by the program has quadrupled, and school cafeterias now serve nearly 5 billion lunches annually. This successful Federal, State, and local partnership would not be possible without the assistance of thousands of food service professionals, school administrators, community members, and parents. As a nation, we are grateful for those who go above and beyond to ensure all children are able to focus on their education and development instead of worrying about their next lunch.

America's farmers, ranchers, and producers also play a role in ensuring our children's plates are filled with healthy, domestically sourced foods. This year, my Administration awarded a record high of more than $9 million in Farm to School Program grants, increasing access to local food and strengthening links to agriculture for more than 3.2 million children in 42 States, the District of Columbia, and Puerto Rico. Through our efforts to increase the amount of local food in our country's schools, we are promoting the success of both our farmers and ranchers and our Nation's children.

To emphasize the importance of the National School Lunch Program to our youth's nutrition, the Congress, by joint resolution of October 9, 1962 (Public Law 87–780), has designated the week beginning on the second Sunday in October each year as ''National School Lunch Week'' and has requested the President to issue a proclamation in observance of this week.

NOW, THEREFORE, I, DONALD J. TRUMP, 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 October 13 through October 19, 2019, as National School Lunch Week. I call upon all Americans to join the countless individuals who administer the National School Lunch Program in activities that support and promote awareness of the health and well-being of our Nation's children.

IN WITNESS WHEREOF, I have hereunto set my hand this eleventh day of October, in the year of our Lord two thousand nineteen, and of the Independence of the United States of America the two hundred and forty-fourth.



[FR Doc. 2019–22797
Filed 10–16–19; 8:45 am]
Billing code 3295–F0–P

Presidential Documents

Proclamation 9949 of October 11, 2019

Columbus Day, 2019

By the President of the United States of America

A Proclamation

On October 12, 1492, after a perilous, two-month journey across the treacherous Atlantic Ocean, Christopher Columbus and his crew aboard the Niña, Pinta, and Santa Maria landed in what is today The Bahamas. This watershed voyage ushered in the Age of Exploration, changing the course of history and setting the foundation for development of our Nation. Today, we commemorate this great explorer, whose courage, skill, and drive for discovery are at the core of the American spirit.

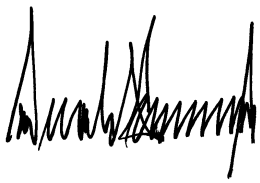
While Columbus sailed from the port of Palos under the Spanish flag, he took pride in the fact that he was a citizen of Genoa, Italy. The celebration of Columbus Day is, therefore, an appropriate opportunity to recognize the more than 16 million Americans who claim Italian heritage and to carry forth the legacy of generations of Italian Americans who helped shape our Nation. The United States greatly values its close bond with Italy, a long-standing friend, ally, and economic partner. Our relationship, built on shared values and a commitment to furthering peace and prosperity, continues to benefit both of our nations.

Columbus's daring voyage to the New World brought two continents together, enabling a global perspective for the first time. The bold legacy of Columbus and his crew spun a thread that weaves through the extensive history of Americans who have pushed the boundaries of exploration. On Columbus Day, we draw inspiration from this intrepid pioneer's spirit of adventure. We also affirm our commitment to continuing our quest to discover and better understand the wonders of our Nation, the world, and beyond.

In commemoration of Christopher Columbus's historic voyage, the Congress, by joint resolution of April 30, 1934, and modified in 1968 (36 U.S.C. 107), as amended, has requested the President proclaim the second Monday of October of each year as ''Columbus Day.''

NOW, THEREFORE, I, DONALD J. TRUMP, 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 October 14, 2019, as Columbus Day. I call upon the people of the United States to observe this day with appropriate ceremonies and activities. I also direct that the flag of the United States be displayed on all public buildings on the appointed day in honor of our diverse history and all who have contributed to shaping this Nation.

IN WITNESS WHEREOF, I have hereunto set my hand this eleventh day of October, in the year of our Lord two thousand nineteen, and of the Independence of the United States of America the two hundred and forty-fourth.



[FR Doc. 2019–22807
Filed 10–16–19; 8:45 am]
Billing code 3295–F0–P

Presidential Documents

Proclamation 9950 of October 11, 2019

Blind Americans Equality Day, 2019

By the President of the United States of America

A Proclamation

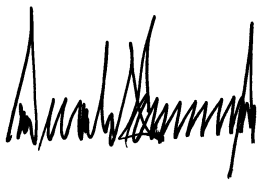
Blind Americans Equality Day pays tribute to our fellow Americans who are blind or visually impaired for their many contributions to the strength and vitality of our Nation. We renew our steadfast commitment to ensuring their full participation in our communities, workplaces, and social life.

My Administration is committed to promoting policies that foster greater liberty, prosperity, and equality. We are expanding educational, social, technological, and employment opportunities for Americans with disabilities, including blind or visually impaired individuals. We have partnered with States to promote independent living and equal employment opportunities, as well as social, cultural, and athletic activities. Additionally, the President's National Council for the American Worker is developing a national employment strategy to ensure that we have a highly qualified and trained workforce to meet our growing economic needs. We are working to address barriers to employment, combat stigmas, and confront stereotypes that make it more difficult for blind or visually impaired individuals to find and maintain employment. My Administration is also encouraging Federal contractors to take proactive steps to recruit, hire, retain, and advance blind or visually impaired people.

By joint resolution approved on October 6, 1964 (Public Law 88–628), the Congress authorized the President to designate October 15 of each year as ''White Cane Safety Day'' to recognize the contributions of Americans who are blind or have impaired vision. With the strongest economy our Nation has ever experienced, these Americans are empowered to seek new opportunities for success. Today, and every day, we will continue our efforts to ensure and champion the full and active participation of all Americans, including blind or visually impaired Americans, in every facet of our society.

NOW, THEREFORE, I, DONALD J. TRUMP, 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 October 15, 2019, as Blind Americans Equality Day, to celebrate and recognize the accomplishments and contributions of Americans who are blind or visually impaired. I call upon all Americans to observe this day with appropriate ceremonies and activities to reaffirm our commitment to achieving equality for all Americans.

IN WITNESS WHEREOF, I have hereunto set my hand this eleventh day of October, in the year of our Lord two thousand nineteen, and of the Independence of the United States of America the two hundred and forty-fourth.



[FR Doc. 2019–22809
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Rules and Regulations

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2019–0404; Product Identifier 2019–NM–007–AD; Amendment 39–19754; AD 2019–20–01]

RIN 2120–AA64

Airworthiness Directives; Airbus SAS Airplanes

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: The FAA is superseding Airworthiness Directive (AD) 2018–26–07, which applied to all Airbus SAS Model A350–941 and –1041 airplanes. AD 2018–26–07 required repetitive greasing of the thrust reverser actuators (TRAs), dispatch restrictions, and maintenance procedure revisions. This AD requires actions specified in a European Union Aviation Safety Agency (EASA) AD, which is incorporated by reference. This AD was prompted by the FAA's determination to add a requirement to replace the TRAs, which AD 2018–26–07 specified was not required at the time to provide the opportunity for the public to comment on the merits of that action. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective November 21, 2019.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of November 21, 2019.

The Director of the Federal Register approved the incorporation by reference of a certain other publication listed in this AD as of January 15, 2019 (83 FR 67677, December 31, 2018).

ADDRESSES: For the material incorporated by reference (IBR) in this AD, contact the EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 89990 1000; email *ADs@easa.europa.eu;* internet *www.easa.europa.eu.* You may find this IBR material on the EASA website at *https://ad.easa.europa.eu.* You may view this IBR material at the FAA, Transport Standards Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. It is also available in the AD docket on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2019–0404.

Examining the AD Docket

You may examine the AD docket on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2019–0404; 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 final rule, the regulatory evaluation, any comments received, and other information. The address for Docket Operations is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Kathleen Arrigotti, Aerospace Engineer, International Section, Transport Standards Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; phone and fax: 206–231–3218.

SUPPLEMENTARY INFORMATION:

Discussion

The EASA, which is the Technical Agent for the Member States of the European Union, has issued EASA AD 2018–0234R2, dated September 17, 2019 (''EASA AD 2018–0234R2'') (referred to after this as the Mandatory Continuing Airworthiness Information, or ''the MCAI''), to correct an unsafe condition for all Airbus SAS Model A350–941 and –1041 airplanes.

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to supersede AD 2018–26–07, Amendment 39–19538 (83 FR 67677, December 31, 2018) (''AD 2018–26–07''). AD 2018–26–07 applied to all Airbus SAS Model A350–941 and –1041 airplanes. The NPRM published in the **Federal Register** on June 6, 2019 (84 FR 26373). The NPRM was prompted by the FAA's determination to add a requirement to replace the TRAs, which AD 2018–26–07 specified was not required at the time to provide the opportunity for the public to comment on the merits of that action. The NPRM proposed to require actions specified in an EASA AD, which is incorporated by reference.

This AD was prompted by reports of TRAs jamming and the determination that a one-time replacement of affected TRAs (all part numbers) is necessary. We are issuing this AD to address jamming of the TRAs, which could lead to an inadvertent thrust reverser sleeve deployment, possibly resulting in reduced control or performance of the airplane. See the MCAI for additional background information.

Comments

The FAA gave the public the opportunity to participate in developing this final rule. The following presents the comments received on the NPRM and the FAA's response to each comment.

Request To Change Compliance Time for Replacement of the TRAs

The Air Line Pilots Association, International (ALPA) stated partial agreement with the NPRM, and disagreement with the compliance time for replacement of the TRAs. ALPA mentioned that it had commented on AD 2018–26–07 that, based on the required inspection intervals of the MCAI and the low time of the affected U.S. fleet, the inclusion of the TRA replacement would not create an increased financial or undue burden. ALPA stated their belief that correlating the compliance time to the effective date of the new AD instead of using the effective date of AD 2018–26–07 is inadequate.

The FAA infers that the commenter is requesting a change to the compliance time for replacement of the TRAs. The FAA disagrees with the commenter's request. As noted in AD 2018–26–07, the FAA could not include the replacement in that AD because it was an immediately adopted rule and the planned compliance time for the replacement allowed enough time to provide notice and opportunity for prior public comment on the merits of the replacement. The FAA is now issuing this AD to require the replacement.

The only compliance time that is based on the effective date of this AD is specified in condition 3 in Table 3 of the MCAI. For airplanes with condition 3, the compliance time is the later of (A) before exceeding 2,400 flight cycles; or (B) within 250 flight cycles or 4 months, whichever occurs first after the effective date of this AD. Because the U.S. fleet is approximately two years younger than the oldest airplane in the global fleet and the affected U.S. airplanes have TRAs with a lower flight cycle age, we have determined the additional compliance time is appropriate and provides an acceptable level of safety. The FAA has not changed this AD in this regard.

Request To Remove Requirement To Change Master Minimum Equipment List (MMEL)

Delta Air Lines (DAL) requested that the FAA remove the requirement to change the MMEL in paragraph (h)(4) of the proposed AD. DAL pointed out that the updates required by paragraph (h)(4) of the proposed AD have been incorporated into the FAA MMEL as of Revision 4. DAL also mentioned that the FAA MMEL and the EASA MMEL are not identical. DAL stated that the FAA MMEL is more restrictive and does not allow the deactivation of both thrust reversers at the same time. DAL also stated that the differences, combined with possible future revisions of either the FAA MMEL or the EASA MMEL, could lead to confusion. DAL also pointed out that U.S. operators must follow the FAA MMEL.

The FAA agrees for the reasons provided. The FAA has revised paragraph (h)(3) of this AD to specify that the MMEL changes specified in EASA AD 2018–0234R1 and EASA AD 2018–0234R2 are not required by this AD, removed paragraph (h)(4) of this AD, and redesignated subsequent paragraphs accordingly.

Changes to This AD

Since the FAA issued the NPRM, EASA issued AD 2018–0234R2. EASA AD 2018–0234R2 refines the definition of affected TRAs and introduces a longer interval for repetitive greasing of certain affected TRAs. The FAA has determined that no additional work is required for airplanes on which the requirements specified in EASA AD 2018–0234R1, dated November 13, 2018 (''EASA AD 2018–0234R1'') have been accomplished. Therefore, the agency has revised all applicable sections in this final rule to also specify EASA AD 2018–0234R2.

In addition, the FAA has revised the terminology in paragraph (h)(1) of this AD to clarify the retained requirements.

Conclusion

The FAA reviewed the relevant data, considered the comments received, and determined that air safety and the public interest require adopting this final rule with the changes described previously and minor editorial changes. The FAA has determined that these minor changes:

- Are consistent with the intent that was proposed in the NPRM for addressing the unsafe condition; and
- Do not add any additional burden upon the public than was already proposed in the NPRM.

The FAA also determined that these changes will not increase the economic burden on any operator or increase the scope of this final rule.

Related IBR Material Under 1 CFR Part 51

EASA AD 2018–0234R2 describes procedures for repetitive greasing of the TRAs, maintenance procedure revisions, and replacement of the TRAs, among other actions.

This AD also requires EASA AD 2018–0234R1, which the Director of the Federal Register approved for incorporation by reference as of January 15, 2019 (83 FR 67677, December 31, 2018).

These documents are distinct since EASA AD 2018–0234R2 includes updated requirements and definitions, and a longer interval for repetitive greasing of certain affected TRAs. This material is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

Interim Action

The FAA considers this AD interim action. If final action is later identified, The FAA might consider further rulemaking then.

Costs of Compliance

The FAA estimates that this AD affects 11 airplanes of U.S. registry. The FAA estimates the following costs to comply with this AD:

ESTIMATED COSTS FOR REQUIRED ACTIONS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Retained actions from AD 2018-26-07	10 work-hours × $85 per hour = $850	$0	$850	$9,350
New actions	12 work-hours × $85 per hour = $1,020	(*)	*1,020	*11,220

*The FAA has received no definitive data that would enable the agency to provide parts cost estimates for the replacement specified in this AD.

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.

This AD is issued in accordance with authority delegated by the Executive Director, Aircraft Certification Service, as authorized by FAA Order 8000.51C. In accordance with that order, issuance of ADs is normally a function of the Compliance and Airworthiness Division, but during this transition period, the Executive Director has delegated the authority to issue ADs applicable to transport category airplanes and associated appliances to the Director of the System Oversight Division.

Regulatory Findings

We determined that this AD will not have federalism implications under

Executive Order 13132. This AD will 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 this AD:

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

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

(3) Will 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.

Adoption of the Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA amends 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 removing Airworthiness Directive (AD) 2018–26–07, Amendment 39–19538 (83 FR 67677, December 31, 2018), and adding the following new AD:

2019–20–01 Airbus SAS: Amendment 39–19754; Docket No. FAA–2019–0404; Product Identifier 2019–NM–007–AD.

(a) Effective Date

This AD is effective November 21, 2019.

(b) Affected ADs

This AD replaces AD 2018–26–07, Amendment 39–19538 (83 FR 67677, December 31, 2018) (''AD 2018–26–07'').

(c) Applicability

This AD applies to all Airbus SAS Model A350–941 and –1041 airplanes, certificated in any category.

(d) Subject

Air Transport Association (ATA) of America Code 78, Engine Exhaust.

(e) Reason

This AD was prompted by reports of thrust reverser actuators (TRAs) jamming and the determination that a one-time replacement of affected TRAs (all part numbers) is necessary. The FAA is issuing this AD to address jamming of the TRAs, which could lead to an inadvertent thrust reverser sleeve deployment, possibly resulting in reduced control or performance of the airplane.

(f) Compliance

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

(g) Requirements

Except as specified in paragraph (h) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, the European Union Aviation Safety Agency (EASA) ADs specified in paragraph (g)(1) or (2) of this AD.

(1) EASA AD 2018–0234R1, dated November 13, 2018 (''EASA AD 2018–0234R1''). All provisions specified in EASA AD 2018–0234R1 apply in this AD.

(2) EASA AD 2018–0234R2, dated September 17, 2019 (''EASA AD 2018–0234R2''). All provisions specified in EASA AD 2018–0234R2 apply in this AD.

(h) Exceptions to EASA AD 2018–0234R1 and EASA AD 2018–0234R2

(1) For purposes of determining compliance with the maintenance procedure revisions and repetitive TRA greasing requirements of this AD: Where EASA AD 2018–0234R1 and EASA AD 2018–0234R2 refer to the effective date of EASA AD 2018–0234R1 (November 13, 2018), this AD requires using January 15, 2019 (the effective date of AD 2018–26–07).

(2) For purposes of determining compliance with the TRA replacement requirements of this AD: Where EASA AD 2018–0234R1 and EASA AD 2018–0234R2 refer to their effective dates or November 13, 2018 (the effective date of EASA AD 2018–0234R1), this AD requires using the effective date of this AD.

(3) The master minimum equipment list (MMEL) changes specified in paragraph (1) of EASA AD 2018–0234R1 and EASA AD 2018–0234R2 are not required by this AD.

(4) The ''Remarks'' sections of EASA AD 2018–0234R1 and EASA AD 2018–0234R2 do not apply to this AD.

(5) Where EASA AD 2018–0234R1 and EASA AD 2018–0234R2 refer to the ''the MER,'' that document is not required by this AD, and it is not applicable to U.S. operators.

(i) No Reporting Requirement

Although the service information referenced in EASA AD 2018–0234R1 and EASA AD 2018–0234R2 specifies to submit certain information to the manufacturer, this AD does not include that requirement.

(j) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, International Section, Transport Standards 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 local Flight Standards District Office, as appropriate. If sending information directly to the International Section, send it to the attention of the person identified in paragraph (k) of this AD. Information may be emailed to: *9-ANM-116-AMOC-REQUESTS@faa.gov.* Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(2) *Contacting the Manufacturer:* For any requirement in this AD to obtain instructions from a manufacturer, the instructions must be accomplished using a method approved by the Manager, International Section, Transport Standards Branch, FAA; or EASA; or Airbus SAS's EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(3) *Required for Compliance (RC):* For any service information referenced in EASA AD 2018–0234R1 or EASA AD 2018–0234R2 that contains RC procedures and tests: Except as specified by paragraph (j)(2) of this AD, RC procedures and tests must be done to comply with this AD; any procedures or tests that are not identified as RC are recommended. Those procedures and tests that are not identified as RC may be deviated from using accepted methods in accordance with the operator's maintenance or inspection program without obtaining approval of an AMOC, provided the procedures and tests identified as RC can be done and the airplane can be put back in an airworthy condition. Any substitutions or changes to procedures or tests identified as RC require approval of an AMOC.

(k) Related Information

For more information about this AD, contact Kathleen Arrigotti, Aerospace Engineer, International Section, Transport Standards Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; phone and fax: 206–231–3218.

(l) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless this AD specifies otherwise.

(3) The following service information was approved for IBR on November 21, 2019.

(i) European Union Aviation Safety Agency (EASA) AD 2018–0234R2, dated September 17, 2019.

(ii) [Reserved]

(4) The following service information was approved for IBR on January 15, 2019 (83 FR 67677, December 31, 2018).

(i) European Aviation Safety Agency (EASA) AD 2018–0234R1, dated November 13, 2018.

(ii) [Reserved]

(5) For EASA ADs 2018–0234R1 and 2018–0234R2, contact the EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 89990 6017; email *ADs@easa.europa.eu;* Internet *www.easa.europa.eu.* You may find this EASA AD on the EASA website at *https://ad.easa.europa.eu.*

Note 1 to paragraph (l)(5): EASA AD 2018–0234R1 can be accessed in the zipped file at the bottom of the web page for EASA AD

2018–0234R2. When EASA posts a revised AD on their website, they watermark the previous AD as ''Revised,'' alter the file name by adding ''_revised'' to the end, and move it into a zipped file attached at the bottom of the AD web page.

(6) You may view this material at the FAA, Transport Standards Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. AD 2018–0234R1 and 2018–0234R2 may be found in the AD docket on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2019–0404.

(7) You may view this material that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued in Des Moines, Washington, on September 3, 2019.

Michael Kaszycki,

Acting Manager, System Oversight Division, Aircraft Certification Service.

[FR Doc. 2019–22565 Filed 10–16–19; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

18 CFR Part 385

[Docket No. RM19–18–000; Order No. 862]

Formal Requirements for Filings in Proceedings Before the Commission

AGENCY: Federal Energy Regulatory Commission, Department of Energy.

ACTION: Final rule; delay of effective date.

SUMMARY: The Federal Energy Regulatory Commission (Commission or FERC) published a final rule on September 4, 2019, to require that hand deliveries of filings and submissions other than by the United States Postal Service be sent to an off-site facility for security screening and processing. The final rule indicated that the new regulation would take effect 60 days after the date of publication in the **Federal Register**, which is November 4, 2019. After issuance of the final rule, the Commission has determined that the effective date for this new regulation should be indefinitely postponed to ensure that the public and the Commission may make an effective transition to utilizing the off-site facility.

DATES: The effective date of the final rule published on September 4, 2019 (84 FR 46438), is delayed indefinitely.

FOR FURTHER INFORMATION CONTACT: Christopher Cook, Office of the Secretary, 888 First Street NE, Washington, DC 20426, (202) 502–8102, *christopher.cook@ferc.gov.* Mark Hershfield, Office of the General Counsel, 888 First Street NE, Washington, DC 20426, (202) 502–8597, *mark.hershfield@ferc.gov.*

SUPPLEMENTARY INFORMATION: On August 29, 2019, the Commission issued a final rule in Docket No. RM19–18–000 revising 18 CFR 385.2001(a) to require that hand deliveries of filings and submissions other than by the United States Postal Service be sent to an off-site facility for security screening and processing.[1] The final rule indicated that the new regulation would take effect 60 days after the date of publication in the **Federal Register**, which is November 4, 2019.

After issuance of the final rule, the Commission has determined that the effective date for this new regulation should be indefinitely postponed to ensure that the public and the Commission may make an effective transition to utilizing the off-site facility. A copy of this notification will be published in the **Federal Register** and will be prominently placed on the Commission's website (*http://www.ferc.gov*) to ensure that mail continues to come directly to the Commission's headquarters during this period. A subsequent notification will be issued regarding an effective date for the final rule in Docket No. RM19–18–000.

Dated: October 11, 2019.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2019–22664 Filed 10–16–19; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

25 CFR Part 170

[192A2100DD/AAKC001030/A0A501010.999900 253G]

RIN 1076–AF50

Tribal Transportation Program; Delay of Compliance Date

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Interim final rule.

SUMMARY: This interim final rule updates the Tribal Transportation Program regulations to delay the deadline for Tribes to comply with requirements to collect data on proposed roads for the National Tribal Transportation Facility Inventory (NTTFI).

DATES: This rule is effective October 17, 2019. Submit comments by November 18, 2019. Compliance with § 170.443 for proposed roads currently in the NTTFI to remain in the inventory is required by March 6, 2020.

ADDRESSES: You may submit comments by any of the following methods:

- Federal rulemaking portal *www.regulations.gov.* The rule is listed under the agency name ''Bureau of Indian Affairs.''
- *Mail, Hand Delivery, or Courier:* Ms. Elizabeth Appel, Office of Regulatory Affairs & Collaborative Action, U.S. Department of the Interior, 1849 C Street NW, Mail Stop 4660, Washington, DC 20240.
- We cannot ensure that comments received after the close of the comment period (see **DATES**) will be included in the docket for this rulemaking and considered. Comments sent to an address other than those listed above will not be included in the docket for this rulemaking.

FOR FURTHER INFORMATION CONTACT: Mr. LeRoy Gishi, Division of Transportation, Office of Indian Services, Bureau of Indian Affairs, (202) 513–7711, *leroy.gishi@bia.gov.*

SUPPLEMENTARY INFORMATION:

I. Summary of Rule

Regulations governing the Tribal Transportation Program were published in 2016. *See* 81 FR 78456 (November 7, 2016). The regulations became effective on December 7, 2016, except for § 170.443, which required Tribes' compliance at a later date: On November 7, 2019. *See* 83 FR 8609 (February 28, 2018). Section 170.443 requires Tribes to collect data for proposed roads to be added to, or remain in, the NTTFI.

This interim final rule affects only § 170.443. The rule delays the current November 7, 2019, deadline for compliance with that section to March 6, 2020. This delay will allow the Bureau of Indian Affairs time to complete the rulemaking that is reexamining the need for this data collection in the NTTFI and determining whether revision or deletion of the data collection requirements in § 170.443 is appropriate. The Bureau of Indian Affairs finds that there is good cause to

[1] *Formal Requirements for Filings in Proceedings Before the Commission,* 84 FR 46438 (Sept. 4, 2019), 168 FERC ¶ 61,120 (2019).

place this rule into immediate effect before receiving public comment and without a 30-day waiting period because the delay in the compliance deadline is expected to be uncontroversial with both the impacted Tribes and the public, and placing into immediate effect will eliminate potentially needless expenditure of resources by Tribes.

II. Procedural Requirements

A. Regulatory Planning and Review (E.O. 12866 and 13563)

Executive Order (E.O.) 12866 provides that the Office of Information and Regulatory Affairs (OIRA) at the Office of Management and Budget (OMB) will review all significant rules. OIRA has determined that this rule is not significant.

E.O. 13563 reaffirms the principles of E.O. 12866 while calling for improvements in the nation's regulatory system to promote predictability, to reduce uncertainty, and to use the best, most innovative, and least burdensome tools for achieving regulatory ends. The E.O. directs agencies to consider regulatory approaches that reduce burdens and maintain flexibility and freedom of choice for the public where these approaches are relevant, feasible, and consistent with regulatory objectives. E.O. 13563 emphasizes further that regulations must be based on the best available science and that the rulemaking process must allow for public participation and an open exchange of ideas. We have developed this rule in a manner consistent with these requirements.

B. Regulatory Flexibility Act

This rule will not have a significant economic effect on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) because Tribes are not small entities under the Regulatory Flexibility Act.

C. Small Business Regulatory Enforcement Fairness Act

This rule is not a major rule under 5 U.S.C. 804(2), the Small Business Regulatory Enforcement Fairness Act. This rule:

(a) Does not have an annual effect on the economy of $100 million or more because this rule affects only surface transportation for Tribes.

(b) Will not cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions because it does not affect costs or prices.

(c) Does not have significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of U.S.-based enterprises to compete with foreign-based enterprises because the rule addresses Tribal surface transportation within the United States.

D. Unfunded Mandates Reform Act

This rule does not impose an unfunded mandate on State, local, or Tribal governments or the private sector of more than $100 million per year. The rule does not have a significant or unique effect on State, local, or Tribal governments or the private sector. A statement containing the information required by the Unfunded Mandates Reform Act (2 U.S.C. 1531 *et seq.*) is not required.

E. Takings (E.O. 12630)

This rule does not affect a taking of private property or otherwise have taking implications under E.O. 12360. A takings implication assessment is not required.

F. Federalism (E.O. 13132)

Under the criteria in section 1 of E.O. 13132, this rule does not have sufficient Federalism implications to warrant the preparation of a summary impact statement, because the rule primarily addresses the relationship between the Federal Government and Tribes. A Federalism summary impact statement is not required.

G. Civil Justice Reform (E.O. 12988)

This rule complies with the requirements of E.O. 12988. Specifically, this rule:

(a) Meets the criteria of section 3(a) requiring that all regulations be reviewed to eliminate errors and ambiguity and written to minimize litigation; and

(b) Meets the criteria of section 3(b)(2) requiring that all regulations be written in clear language and contain clear legal standards.

H. Consultation With Indian Tribes (E.O. 13175 and Departmental Policy)

The Department of the Interior strives to strengthen its government-to-government regulations with Indian Tribes through a commitment to consultation with Indian Tribes and recognition of their right to self-governance and Tribal sovereignty. We have evaluated this rule under the Department's consultation policy and have identified substantial direct effects on federally recognized Indian Tribes that will result from this rule. This rule will relieve a regulatory burden from Tribes and allow time for consultation on an appropriate replacement or deletion of regulatory requirements.

I. Paperwork Reduction Act

This rule contains information collection requirements, and the Office of Management and Budget (OMB) has approved the information collections under the Paperwork Reduction Act (PRA) under OMB Control Number 1076–0161, which expires December 31, 2019.

Please note that an agency may not sponsor or request, and an individual need not respond to, a collection of information unless it displays a valid OMB Control Number.

J. National Environmental Policy Act

This rulemaking does not constitute a major Federal action significantly affecting the quality of the human environment because it is of an administrative, technical, and procedural nature. It is therefore subject to categorical exclusion, see 43 CFR 46.210(i), and no extraordinary circumstances exist. *See* 43 CFR 46.215.

K. Effects on the Energy Supply (E.O. 13211)

This rulemaking is not a significant energy action under the definition in E.O. 13211. A Statement of Energy Effects is not required.

L. Clarity of This Regulation

We are required by Executive Orders 12866 (section 1(b)(12)), and 12988 (section 3(b)(1)(B)), and 13563 (section 1(a)), and by the Presidential Memorandum of June 1, 1998, to write all rules in plain language. This means that each rule we publish must:

(a) Be logically organized;

(b) Use the active voice to address readers directly;

(c) Use common, everyday words and clear language rather than jargon;

(d) Be divided into short sections and sentences; and

(e) Use lists and tables wherever possible.

If you feel that we have not met these requirements, send us comments by one of the methods listed in the **ADDRESSES** section. To better help us revise the rule, your comments should be as specific as possible. For example, you should tell us the numbers of the sections or paragraphs that you find unclear, which sections or sentences are too long, the sections where you think lists or tables would be useful, etc.

M. E.O. 13771: Reducing Regulation and Controlling Regulatory Costs

This rule is not an E.O. 13771 regulatory action because this rule is not significant under E.O. 12866.

List of Subjects in 25 CFR Part 170

Highways and roads, Indians—lands.

For the reasons stated in the preamble, the Department of the Interior, Bureau of Indian Affairs, amends part 170 in title 25 of the Code of Federal Regulations as follows:

PART 170—TRIBAL TRANSPORTATION PROGRAM

■ 1. The authority for part 170 continues to read as follows:

Authority: Pub. L. 112–141, Pub. L. 114–94; 5 U.S.C. 2; 23 U.S.C. 201, 202; 25 U.S.C. 2, 9.

■ 2. Revise § 170.443(b) to read as follows:

§ 170.443 What is required to successfully include a proposed transportation facility in the NTTFI?

* * * * *

(b) For those proposed roads that currently exist in the NTTFI, the requirements identified above as paragraphs (a)(1) through (8) of this section, must be completed and submitted for approval to BIA and FHWA by March 6, 2020, in order to remain on the inventory.

Dated: September 26, 2019.

Tara Sweeney,

Assistant Secretary—Indian Affairs.

[FR Doc. 2019–22682 Filed 10–16–19; 8:45 am]

BILLING CODE 4337–15–P

DEPARTMENT OF LABOR

Mine Safety and Health Administration

30 CFR Parts 56 and 57

[Docket No. MSHA–2014–0030]

RIN 1219–AB92

Examinations of Working Places in Metal and Nonmetal Mines

AGENCY: Mine Safety and Health Administration, Labor.

ACTION: Notification of public stakeholder meetings.

SUMMARY: The Mine Safety and Health Administration (MSHA) is announcing the dates and locations of public stakeholder meetings on the Agency's standards for Examinations of Working Places in Metal and Nonmetal Mines.

DATES: The meeting dates and locations are listed in the **SUPPLEMENTARY INFORMATION** section of this document.

ADDRESSES: ***Federal Register*** *Publications:* Access rulemaking documents electronically at *http://www.msha.gov/regsinfo.htm* or *http://www.regulations.gov* [Docket Number: MSHA–2014–0030].

FOR FURTHER INFORMATION CONTACT: Sheila A. McConnell, Director, Office of Standards, Regulations, and Variances, MSHA, at *mcconnell.sheila.a@dol.gov* (email), 202–693–9440 (voice), or 202–693–9441 (fax). These are not toll-free numbers.

SUPPLEMENTARY INFORMATION:

I. Stakeholder Meetings

MSHA will hold five public stakeholder meetings to inform the mining community of the requirements of the Examinations of Working Places in Metal and Nonmetal Mines final rule, which was effective September 30, 2019. At the meetings, MSHA will provide training and compliance assistance materials to attendees. Most of the public meetings will begin at 9 a.m. local time. The meetings in Birmingham and Bloomington will start at 1:30 p.m. local time. The following table lists the dates and start times at the locations indicated:

EXAMINATIONS OF WORKING PLACES IN METAL AND NONMETAL MINES

[Stakeholder meetings dates, times, and locations]

Date/time	Location	Contact No.
October 29, 2019, 9 a.m. Central Daylight Savings Time	DoubleTree by Hilton Hotel Dallas—Market Center, 2015 Market Center Blvd., Dallas, Texas 75207.	(214) 741–7481
Nov. 7, 2019, 1:30 p.m. Central Standard Time	Renaissance Birmingham, Ross Bridge, 4000 Grand Ave., Birmingham, Alabama 35226.	(205) 916–7677
November 12, 2019, 1:30 p.m. Central Standard Time	DoubleTree by Hilton Hotel Bloomington, 10 Brickyard Drive, Bloomington, Illinois 61701.	(309) 664–6446
November 14, 2019, 9 a.m. Mountain Standard Time	Hilton Garden Inn, Denver Tech Center, 7675 E Union Ave., Denver, CO 80237.	(303) 770–4200
November 21, 2019, 9 a.m. Eastern Standard Time	Hilton Garden Inn, Pittsburgh Downtown, 250 Forbes Avenue, Pittsburgh, Pennsylvania 15222.	(412) 281–5557

II. Background

On September 30, 2019, MSHA published a technical amendment, Examinations of Working Places in Metal and Nonmetal (MNM) Mines (84 FR 51400). The technical amendment recognized the legal effect of the D.C. Circuit Court's June 11, 2019, order and August 23, 2019, mandate that MSHA revise 30 CFR 56.18002 and 57.18002 to reinstate the regulatory provisions established by the Agency's January 23, 2017, final rule, Examinations of Working Places in Metal and Nonmetal Mines (''January 2017 rule'') (82 FR 7680).

The reinstated January 2017 rule requires: (1) That an examination of the working place be conducted at least once each shift before miners begin working in the place; (2) that operators notify miners in the affected areas of any conditions found that may adversely affect their safety or health; (3) that operators promptly initiate corrective actions; and (4) that a record be made of the examination. The final rule requires the examination record to include: The name of the person conducting the examination, the date of the examination, the location of all areas examined, a description of each condition found that may adversely affect the safety and health of miners, and the date of corrective action. The final rule also requires the operator to make the examination record available to the authorized representative of the Secretary and miners' representatives and provide a copy upon request (84 FR 51400).

Currently, compliance assistance materials are available at *https://www.msha.gov/regulations/rulemaking/examinations-working-places-metal-and-nonmetal-mines*. These materials include Frequently Asked Questions and mine operators' sample templates and checklists provided as best practices.

David G. Zatezalo,

Assistant Secretary of Labor for Mine Safety and Health Administration.

[FR Doc. 2019–22497 Filed 10–16–19; 8:45 am]

BILLING CODE 4520–43–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2019–0814]

RIN 1625–AA00

Safety Zone; Kanawha River, Charleston, WV

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is temporary safety zone for the navigable waters of the Kanawha River from mile marker (MM) 59.5 to MM 60.5. The safety zone is needed to protect personnel, vessels, and the marine environment from potential hazards resulting from a fireworks display. Entry of vessels or persons into the zone is prohibited unless specifically authorized by the Captain of the Port Ohio Valley or designated represented.

DATES: This rule is effective from 6:15 p.m. through 7:15 p.m. on October 24, 2019.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *https://www.regulations.gov,* type USCG–2019–0814 in the ''SEARCH'' box and click ''SEARCH.'' Click on Open Docket Folder on the line associated with this rule.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email MST3 Wesley Cornelius, MSU Huntington, Waterways Management, U.S. Coast Guard; telephone 304–733–0198, email *Wesley.P.Cornelius@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
DHS Department of Homeland Security
FR Federal Register
NPRM Notice of proposed rulemaking
§ Section
U.S.C. United States Code
MM Mile Marker

II. Background Information and Regulatory History

The Coast Guard is issuing this temporary rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because it is impracticable and contrary to the public interest. It is impracticable and contrary to the public interest to publish an NPRM because we must establish the zone by October 24, 2019, to ensure the safety of the public during the fireworks display and lack sufficient time to request comments and respond to those comments before the zone must be established.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register,** Delaying the effective date of this rule would be impracticable and contrary to the public interest because immediate action is needed to provide for public safety and mitigation of potential hazards associated with the firework display.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70034 (previously 33 U.S.C. 1231). The Captain of the Port Ohio Valley has determined that potential hazards associated with University of Charleston fireworks display on October 24, 2019, will be a safety concern for anyone from Mile Marker (MM) 59.5 to MM 60.5 on the Kanawha River. This rule is needed to protect personnel, vessels, and the marine environment in the navigable waters within the safety zone before, during, and after the fireworks display.

IV. Discussion of the Rule

This rule establishes a safety zone from 6:15 p.m. through 7:15 p.m. on October 24, 2019. The safety zone will cover all navigable waters on the Kanawha River from MM 59.5 to MM 60.5. The duration of the zone is intended to protect personnel, vessels, and the marine environment in these navigable waters before, during, and after the fireworks display. No vessel or person will be permitted to enter the safety zone without obtaining permission from the Captain of the Port Ohio Valley or a designated representative.

V. Regulatory Analyses

We developed this rule after considering numerous statutes and Executive orders related to rulemaking. Below we summarize our analyses based on a number of these statutes and Executive orders, and we discuss First Amendment rights of protestors.

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. Executive Order 13771 directs agencies to control regulatory costs through a budgeting process. This rule has not been designated a ''significant regulatory action,'' under Executive Order 12866. Accordingly, this rule has not been reviewed by the Office of Management and Budget (OMB), and pursuant to OMB guidance it is exempt from the requirements of Executive Order 13771.

This regulatory action determination is based on size, location, and duration of the safety zone. The safety zone will impact a one-mile stretch of the Kanawha River for 1 hour when vessel traffic is normally low. Moreover the Coast Guard will issue a Broadcast Notice to Mariners via VHF–FM marine channel 16 about the zone and a Local Notice to Mariners.

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 rule will not have a significant economic impact on a substantial number of small entities.

While some owners or operators of vessels intending to transit the safety zone may be small entities, for the reasons stated in section V.A above, this rule will not have a significant economic impact on any vessel owner or operator.

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 rule. If the 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.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to

the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

C. Collection of Information

This rule will 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 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 rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does 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 rule has implications for federalism or Indian tribes, please call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section above.

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 rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this rule under Department of Homeland Security Directive 023–01 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 determined 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 rule involves a safety zone lasting 1 hour that will prohibit entry into the safety zone from MM 59.5 to MM 60.5 on the Kanawha River It is categorically excluded from further review under paragraph L60(a) in Table 3–1 of U.S. Coast Guard Environmental Planning Implementing Procedures. A Record of Environmental Consideration supporting this determination is available in the docket where indicated under **ADDRESSES**.

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.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 continues to read as follows:

Authority: 46 U.S.C. 70034, 70051; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add § 165.T08–0814 to read as follows:

§ 165.T08–0814 Safety Zone; Kanawha River, Charleston, WV.

(a) *Location.* The following area is a safety zone: All navigable waters on the Kanawha River from MM 59.5 to MM 60.5.

(b) *Enforcement period.* This section will be enforced from 6:15 p.m. through 7:15 p.m. on October 24, 2019.

(c) *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 Captain of the Port Ohio Valley in the enforcement of the safety zone.

(d) *Regulations.* Under the general safety zone regulations in subpart C of this part, you may not enter the safety zone described in paragraph (a) of this section unless authorized by the Captain of the Port Sector Ohio Valley or a designated representative. Persons or vessels desiring to enter into or pass through the zone must request permission from the Captain of the Port Ohio Valley or a designated representative. They may be contacted on VHF–FM radio channel 16 or phone at 1–800–253–7465.

Dated: October 10, 2019.

A.M. Beach,

Captain, U.S. Coast Guard, Captain of the Port Sector Ohio Valley.

[FR Doc. 2019–22547 Filed 10–16–19; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2019–0741]

RIN 1625–AA00

Safety Zone; Wando Terminal Crane Movement; Charleston, SC

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary moving safety zone in the Port of Charleston, SC around the vessel ZHEN HUA 28. This temporary safety zone is necessary to provide for the safety of waterway users and the M/V ZHEN HUA 28 during the vessel's transit into the Port of Charleston, its stay at Columbus Street Terminal, and its transit to, and stay at, Wando Terminal. Entry of vessels or persons into this zone is prohibited unless specifically authorized by the Captain of the Port Charleston.

DATES: This rule is effective on October 16, 2019 through October 28, 2019.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *https://www.regulations.gov,* type USCG–2019–0741 in the ''SEARCH'' box and click ''SEARCH.'' Click on Open Docket

Folder on the line associated with this rule.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Lieutenant Chad Ray, Sector Charleston Office of Waterways Management, Coast Guard; telephone (843) 740–3184, email *Chad.L.Ray@uscg.mil*.

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
DHS Department of Homeland Security
FR Federal Register
NPRM Notice of proposed rulemaking
§ Section
U.S.C. United States Code

II. Background Information and Regulatory History

The Coast Guard is issuing this temporary rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because it is impractical. We must establish this safety zone by October 16, and lack sufficient time to provide a reasonable comment period and then consider those comments before issuing the rule because the details of the event were not provided to the Coast Guard until September 27, 2019. It is also contrary to the public interest as it would delay the planning and implementation of safety measures necessary to protect the public and mariners from the hazards associated with the transit of the M/V ZHEN HUA 28.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Delaying the effective date of this rule would be contrary to public interest because immediate action is needed to respond to the potential safety hazards associated with the transit of the M/V ZHEN HUA 28.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70034 (previously 33 U.S.C. 1231). The Captain of the Port (COTP) Charleston has determined that potential hazards associated with navigation and dockside operations of the M/V ZHEN HUA 28 starting October 16, 2019, will be a safety concern for anyone within a 100-yard radius of the M/V ZHEN HUA 28. Due to the size of the cranes aboard the vessel and the vessel's limited ability to maneuver, this rule is necessary to protect persons and vessels within the safety zone.

IV. Discussion of the Rule

This rule establishes a temporary moving safety zone upon the arrival of the vessel ZHEN HUA 28 in the Charleston Harbor on October 16, 2019 through October 28, 2019, encompassing all navigable waters from the surface to the sea floor within a 100-yard radius of the M/V ZHEN HUA 28 while the vessel is underway, moored, or anchored in the Sector Charleston Captain of the Port (COTP) Zone. No vessel or person is permitted to enter the safety zone without first obtaining permission from the COTP or a designated representative. Sector Charleston may be contacted on VHF–FM radio channel 16 or via telephone at (843) 740–7050.

V. Regulatory Analyses

We developed this rule after considering numerous statutes and Executive Orders related to rulemaking. Below we summarize our analyses based on a number of these statutes and Executive orders, and we discuss First Amendment rights of protestors.

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. Executive Order 13771 directs agencies to control regulatory costs through a budgeting process. This rule has not been designated a ''significant regulatory action,'' under Executive Order 12866. Accordingly, this rule has not been reviewed by the Office of Management and Budget (OMB), and pursuant to OMB guidance it is exempt from the requirements of Executive Order 13771.

This regulatory action determination is based on the size, location, and duration of the safety zone. The size of the zone is limited to a 100-yard radius—the minimum size necessary to provide adequate protection for personnel and vessels in the area. The temporary safety zone is limited in duration as it will only be in place while the vessel is transiting, moored or anchored within the Sector Charleston COTP Zone. Once the vessel departs the Sector Charleston COTP Zone, the rule will no longer be enforced.

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 rule will not have a significant economic impact on a substantial number of small entities.

While some owners or operators of vessels intending to transit the safety zone may be small entities, for the reasons stated in section V.A above, this rule will not have a significant economic impact on any vessel owner or operator.

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 rule. If the 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.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

C. Collection of Information

This rule will 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 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 rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does 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 rule has implications for federalism or Indian tribes, please call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section above.

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 rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this rule under Department of Homeland Security Directive 023–01 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 determined 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 rule involves a temporary safety zone that will prohibit entry within a 100-yard radius of the vessel, M/V ZHEN HUA 28, during the vessel's transit, mooring and anchoring in the Sector Charleston COTP Zone. It is categorically excluded from further review under paragraph L60(a) in Table 3–1 of U.S. Coast Guard Environmental Planning Implementing Procedures. A Record of Environmental Consideration supporting this determination is available in the docket where indicated under **ADDRESSES**.

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.

List of Subjects in 33 CFR Part 165

Marine Safety, Navigation (water), Reporting and recordkeeping requirements, Waterways.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 continues to read as follows:

Authority: 46 U.S.C. 70034, 70051; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add § 165.T07–0741 to read as follows:

§ 165.T07–0741 Safety Zone; Wando Terminal Crane Movement; Charleston, SC.

(a) *Regulated area.* The following regulated area is a moving safety zone: All waters of the Charleston Harbor, Cooper River, and Wando River in Charleston, SC within a 100-yard radius around the outer most points of the M/V ZHEN HUA 28 while the vessel is underway, moored or anchored.

(b) *Definition.* As used in this section, ''designated representative'' means Coast Guard Patrol Commanders, including Coast Guard coxswains, petty officers, and other officers operating Coast Guard vessels, and Federal, state, and local officers designated by or assisting the COTP Charleston in the enforcement of the regulated areas.

(c) *Regulations.* (1) Under the general safety zone regulations in subpart C of this part, you may not enter the safety zone described in paragraph (a) of this section unless authorized by the COTP or the COTP's designated representative.

(2) To seek permission to enter the safety zone, contact the COTP or the COTP's designated representative by telephone at (843) 740–7050 or on VHF–FM radio channel 16. Those in the safety zone must comply with all lawful orders or directions given to them by the COTP or the COTP's designated representative.

(3) The Coast Guard will provide notice of the regulated area by Marine Safety Information Bulletin, Local Notice to Mariners, Broadcast Notice to Mariners, and on-scene designated representatives.

(d) *Enforcement periods.* This section is effective beginning upon the arrival of the vessel ZHEN HUA 28 in the Charleston Harbor on October 16, 2019, through October 28, 2019. This rule will be enforced while M/V ZHEN HUA 28 is underway, moored, or anchored in the Sector Charleston Captain of the Port Zone.

Dated: October 10, 2019.

J.W. Reed,

Captain, U.S. Coast Guard, Captain of the Port Charleston.

[FR Doc. 2019–22566 Filed 10–16–19; 8:45 am]

BILLING CODE 9110–04–P

POSTAL SERVICE

39 CFR Part 111

Domestic Competitive Products Pricing and Mailing Standards Changes

AGENCY: Postal Service™.

ACTION: Final rule.

SUMMARY: The Postal Service is amending *Mailing Standards of the United States Postal Service,* Domestic Mail Manual (DMM®), to reflect changes to prices and mailing standards for competitive products.

DATES: *Effective Date:* January 26, 2020.

FOR FURTHER INFORMATION CONTACT: Tom Foti at (202) 268–2931 or Garry Rodriguez at (202) 268–7281.

SUPPLEMENTARY INFORMATION: This final rule describes new prices and product features for competitive products, by class of mail, established by the Governors of the United States Postal Service®. New prices are available under Docket Number CP2020–5 on the Postal Regulatory Commission PRC website at *http://www.prc.gov,* and on the Postal Explorer® website at *http://pe.usps.com.*

The Postal Service will revise *Mailing Standards of the United States Postal Service,* Domestic Mail Manual (DMM), to reflect changes to prices and mailing standards for the following competitive products:

- Priority Mail Express®.
- Priority Mail®.
- First-Class Package Service®.
- Parcel Select®.
- USPS Retail Ground®.
- Extra Services.
- Return Services.
- Mailer Services.
- Recipient Services.
- Other.

Competitive product prices and changes are identified by product as follows:

Priority Mail Express

Prices

Overall, Priority Mail Express prices will increase 3.5 percent. Priority Mail Express will continue to offer zoned and Flat Rate Retail, Commercial Base®, and Commercial Plus® pricing.

Retail prices will increase an average of 3.8 percent. The Flat Rate Envelope price will increase to $26.35, the Legal Flat Rate Envelope will increase to $26.50, and the Padded Flat Rate Envelope will increase to $26.95.

Commercial Plus prices were matched to the Commercial Base prices in the 2016 price change and will continue to be matched in 2020. Commercial Base and Commercial Plus prices will increase an average of 2.2 percent.

Priority Mail

Prices

Overall, Priority Mail prices will increase 4.1 percent. Priority Mail will continue to offer zoned and Flat Rate Retail, Commercial Base, and Commercial Plus pricing.

Retail prices will increase an average of 4.9 percent. The Flat Rate Envelope price will increase to $7.75, the Legal Flat Rate Envelope will increase to $8.05, and the Padded Flat Rate Envelope will increase to $8.40. The Small Flat Rate Box price will increase to $8.30 and the Medium Flat Rate Boxes will increase to $15.05. The Large Flat Rate Box will increase to $21.10 and the APO/FPO/DPO Large Flat Rate Box will increase to $19.60.

Commercial Base prices offer lower prices to customers who use authorized postage payment methods. Commercial Base prices will increase an average of 2.8 percent.

The Commercial Plus price category offers price incentives to large volume customers who have a customer commitment agreement with USPS®. Commercial Plus prices as a whole will increase 3.0 percent.

First-Class Package Service

Prices

Overall, First-Class Package Service—Retail prices will increase 3.9 percent.

Overall, First-Class Package Service—Commercial prices will increase 2.2 percent.

Parcel Select

Prices

The prices for Parcel Select Destination Entry increase an average of 2.5 percent. Parcel Select Ground prices will increase an average of 3.9 percent. The prices for Parcel Select Lightweight® will increase an average of 4.2 percent.

USPS Retail Ground

Overall, USPS Retail Ground prices will increase an average of 3.9 percent.

Dimensional Weight Pricing

The Postal Service is implementing Dimensional Weight (DIM) pricing for USPS Retail Ground parcels. Postage for USPS Retail Ground parcels addressed for delivery to Zones 1 through 9 and exceeding 1 cubic foot (1,728 cubic inches) will be based on the actual weight or the dimensional weight, whichever is greater.

USPS Retail Ground DIM weight pricing will be calculated using one of two formulas, rectangular or nonrectangular, with a DIM divisor of 166.

USPS Retail Ground—Limited Overland Route pricing will not be subject to DIM pricing.

Balloon Pricing

As a result of the implementation of DIM pricing for USPS Retail Ground parcels in zones 1 through 9, the Postal Service will eliminate balloon pricing.

USPS Retail Ground—Limited Overland Route pricing will continue to be subject to balloon pricing.

Extra Services

Adult Signature Service

Adult Signature Required and Adult Signature Restricted Delivery service prices are increasing 3.9 percent. The price for Adult Signature Required will increase to $6.65 and Adult Signature Restricted Delivery will increase to $6.90.

Return Services

Parcel Return Service

Overall, Parcel Return Service prices will increase an average of 4.9 percent.

Return Sectional Center Facility (RSCF) prices will increase an average of 4.9 percent and Return Delivery Unit (RDU) prices will increase an average of 4.9 percent.

Mailer Services

Pickup on Demand Service

The Pickup on Demand® service fee will increase 4.3 percent to $24.00.

Premium Data Retention and Retrieval Services

The Postal Service is introducing ''Premium Data Retention and Retrieval'' service. Premium Data Retention and Retrieval service allows a customer to request that the Postal Service retain: (1) Scan data or (2) scan and signature data for the customer's packages beyond the Postal Service's standard data retention period, for up to ten years. Premium Data Retention service is available for packages shipped via Priority Mail Express, Priority Mail, First-Class Package Service, Parcel Select, and packages with Adult Signature Services. For Scan and Signature Retention on products other than Priority Mail Express, the customer must have purchased an underlying signature service, such as Signature Confirmation™ service. Customers can request Premium Data Retention and Retrieval service online at USPS.com or through a Shipping Services File.

Recipient Services

Post Office Box Service

The competitive Post Office Box™ service prices will increase an average of 10.4 percent within the existing price ranges.

Premium Forwarding Service

Premium Forwarding Service® (PFS®) prices will increase between 0.9 and 5.3 percent depending on the specific price element. The enrollment fee paid at the retail counter for PFS-Residential will increase to $21.90 and the PFS-Residential, PFS-Commercial, and PFS-Local enrollment fee paid online will increase to $20.10 per application. The price of the weekly shipment charge for PFS-Residential and per container charge for PFS-Local will increase to $21.90.

USPS Package Intercept

The USPS Package Intercept® fee will increase 3.9 percent to $14.65.

Other

Address Enhancement Service

Address Enhancement Service competitive product prices will increase between 0.4 and 3.8 percent.

Small Parcel Forwarding Fee

The small parcel forwarding fee, an optional service first offered in January 2019, will increase 4.9 percent to $4.75.

eVS Unmanifested Fee

The Postal Service is introducing an ''eVS Unmanifested'' fee to discourage unmanifested eVS eligible pieces, reduce occurrences of lower postage assessments, and offset additional reconciliation, manual processes, and operational costs. The fee will apply to Priority Mail Express, Priority Mail,

First-Class Package Service, and Parcel Select, commercial pieces.

Resources

The Postal Service provides additional resources to assist customers with this price change for competitive products. These tools include price lists, downloadable price files, and **Federal Register** Notices, which may be found on the Postal Explorer® website at *http://pe.usps.com.*

The Postal Service adopts the following changes to *Mailing Standards of the United States Postal Service,* Domestic Mail Manual (DMM), incorporated by reference in the *Code of Federal Regulations.* See 39 CFR 111.1.

List of Subjects in 39 CFR Part 111

Administrative practice and procedure, Postal Service.

Accordingly, 39 CFR part 111 is amended as follows:

PART 111—[AMENDED]

■ 1. The authority citation for 39 CFR part 111 continues to read as follows:

Authority: 5 U.S.C. 552(a); 13 U.S.C. 301–307; 18 U.S.C. 1692–1737; 39 U.S.C. 101, 401, 403, 404, 414, 416, 3001–3011, 3201–3219, 3403–3406, 3621, 3622, 3626, 3632, 3633, and 5001.

■ 2. Revise *Mailing Standards of the United States Postal Service,* Domestic Mail Manual (DMM) as follows:

***Mailing Standards of the United States Postal Service,* Domestic Mail Manual (DMM)**

* * * * *

100 Retail Mail Letters, Cards, Flats, and Parcels

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150 Retail Mail USPS Retail Ground

153 Prices and Eligibility

1.0 Prices and Fees

1.1 Price Eligibility

USPS Retail Ground prices are calculated based on the zone to which the parcel is addressed and the weight of the parcel. USPS Retail Ground prices are available as follows:

* * * * *

[Revise the text of item d to read as follows:]

d. USPS Retail Ground—Limited Overland Routes parcels that weigh less than 20 pounds but measure more than 84 inches (but not more than 108 inches) in combined length and girth are charged the applicable price for a 20-pound parcel (balloon price).

* * * * *

[Add new section 1.4, Dimensional Weight Price for Low-Density Parcels to Zones 1–9, to read as follows:]

1.4 Dimensional Weight Price for Low-Density Parcels to Zones 1–9

Except for USPS Retail Ground—Limited Overland Routes parcels under 1.3, postage for parcels addressed for delivery to Zones 1–9 and exceeding 1 cubic foot (1,728 cubic inches) is based on the actual weight or the dimensional weight (as calculated in 1.4.1 or 1.4.2), whichever is greater.

1.4.1 Determining Dimensional Weight for Rectangular Parcels

Follow these steps to determine the dimensional weight for a rectangular parcel:

a. Measure the length, width, and height in inches. Round off (see 604.7.0) each measurement to the nearest whole inch.

b. Multiply the length by the width by the height.

c. If the result exceeds 1,728 cubic inches, divide the result by 166 and round up (see 604.7.0) to the next whole number to determine the dimensional weight in pounds.

d. If the dimensional weight exceeds 70 pounds, the customer pays the 70-pound price.

1.4.2 Determining Dimensional Weight for Nonrectangular Parcels

Follow these steps to determine the dimensional weight for a nonrectangular parcel:

a. Measure the length, width, and height in inches at their extreme dimensions. Round off (see 604.7.0) each measurement to the nearest whole inch.

b. Multiply the length by the width by the height.

c. Multiply the result by an adjustment factor of 0.785.

d. If the final result exceeds 1,728 cubic inches, divide the result by 166 and round up (see 604.7.0) to the next whole number to determine the dimensional weight in pounds.

e. If the dimensional weight exceeds 70 pounds, the customer pays the 70-pound price.

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200 Commercial Mail Letters, Flats, and Parcels

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210 Commercial Mail Priority Mail Express

213 Prices and Eligibility

1.0 Prices and Fees

* * * * *

[Add new section 1.9, eVS Unmanifested Fee, to read as follows:]

1.9 eVS Unmanifested Fee

Eligible eVS Priority Mail Express pieces omitted from the eVS manifest are subject to the eVS Unmanifested fee (see Notice 123—Price List), unless the piece is subject to the IMpb noncompliance fee under 3.2.

* * * * *

220 Priority Mail

213 Prices and Eligibility

1.0 Prices and Fees

* * * * *

[Add new section 1.11, eVS Unmanifested Fee, to read as follows:]

1.11 eVS Unmanifested Fee

Eligible eVS Priority Mail pieces omitted from the eVS manifest are subject to the eVS Unmanifested piece fee (see Notice 123—Price List), unless the piece is subject to the IMpb noncompliance fee under 3.2.

* * * * *

250 Parcel Select

253 Prices and Eligibility

1.0 Prices and Fees

* * * * *

[Add new section 1.5, eVS Unmanifested Fee, to read as follows:]

1.5 eVS Unmanifested Fee

Eligible eVS Parcel Select pieces omitted from the eVS manifest are subject to the eVS Unmanifested fee (see Notice 123—Price List), unless the piece is subject to the IMpb noncompliance fee under 3.3.

* * * * *

280 Commercial Mail First-Class Package Service—Commercial

283 Prices and Eligibility

1.0 Prices and Fees

* * * * *

[Add new section 1.4, eVS Unmanifested Piece Fee, to read as follows:]

1.4 eVS Unmanifested Fee

Eligible eVS First-Class Package Service-Commercial pieces omitted from the eVS manifest are subject to the eVS Unmanifested fee (see Notice 123—Price List), unless the piece is subject to the IMpb noncompliance fee under 3.4.

* * * * *

500 Additional Mailing Services

* * * * *

507 Mailer Services

* * * * *

[Add new section 11.0, Premium Data Retention and Retrieval Service, to read as follows:]

11.0 Premium Data Retention and Retrieval Service

Premium Data Retention and Retrieval service allows a customer to request that the Postal Service retain: (1) Scan data or (2) scan and signature data for the customer's packages beyond the Postal Service's standard data retention period, for up to ten years. Premium Data Retention and Retrieval service is available for commercial packages shipped via Priority Mail Express, Priority Mail, First-Class Package Service, Parcel Select, and commercial packages with Adult Signature Services. For Scan and Signature Retention on products other than Priority Mail Express, the customer must have purchased an underlying signature service, such as Signature Confirmation service (see Notice 123—Price List). Customers can request Premium Data Retention and Retrieval service online at USPS.com or through a Shipping Services File.

* * * * *

Notice 123 (Price List)

[Revise competitive prices as applicable.]

* * * * *

Quick Service Guides (QSGs)

[Revise Quick Service Guides as applicable.]

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We will publish an appropriate amendment to 39 CFR part 111 to reflect these changes.

Joshua J. Hofer,

Attorney, Federal Compliance.

[FR Doc. 2019–22640 Filed 10–16–19; 8:45 am]

BILLING CODE 7710–12–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 635

[Docket No. 180117042–8884–02]

RIN 0648–XT026

Atlantic Highly Migratory Species; Atlantic Bluefin Tuna Fisheries

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

ACTION: Temporary rule; closure.

SUMMARY: NMFS closes the Atlantic bluefin tuna (BFT) General category fishery for the October through November subquota period until the General category reopens on December 1, 2019. The intent of this closure is to prevent overharvest of the adjusted October through November subquota.

DATES: Effective 11:30 p.m., local time, October 13, 2019, through November 30, 2019.

FOR FURTHER INFORMATION CONTACT: Sarah McLaughlin or Nicholas Velseboer, 978–281–9260, or Larry Redd, 301–427–8503.

SUPPLEMENTARY INFORMATION: Regulations implemented under the authority of the Atlantic Tunas Convention Act (ATCA; 16 U.S.C. 971 *et seq.*) and the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act; 16 U.S.C. 1801 *et seq.*) governing the harvest of BFT by persons and vessels subject to U.S. jurisdiction are found at 50 CFR part 635. Section 635.27 subdivides the U.S. BFT quota recommended by the International Commission for the Conservation of Atlantic Tunas (ICCAT) among the various domestic fishing categories, per the allocations established in the 2006 Consolidated Highly Migratory Species Fishery Management Plan (2006 Consolidated HMS FMP) (71 FR 58058, October 2, 2006) and amendments.

NMFS is required, under regulations at § 635.28(a)(1), to file a closure notice for publication with the Office of the Federal Register when a BFT quota (or subquota) is reached or is projected to be reached. On and after the effective date and time of such notification, for the remainder of the fishing year or for a specified period as indicated in the notification, retaining, possessing, or landing BFT under that quota category is prohibited until the opening of the subsequent quota period or until such date as specified in the notice.

The current baseline General category quota is 555.7 mt. See § 635.27(a). Each of the General category time periods (January, June through August, September, October through November, and December) is allocated a ''subquota'' or portion of the annual General category quota. The baseline subquotas for each time period are as follows: 29.5 mt for January; 277.9 mt for June through August; 147.3 mt for September; 72.2 mt for October through November; and 28.9 mt for December. Any unused General category quota rolls forward within the fishing year, which coincides with the calendar year, from one time period to the next, and is available for use in subsequent time periods. To date for 2019, NMFS has taken seven actions that resulted in adjustments to the Reserve category, leaving 65.3 mt of quota currently available (84 FR 3724, February 13, 2019; 84 FR 6701, February 28, 2019; 84 FR 35340, July 23, 2019; 84 FR 47440, September 10, 2019; 84 FR 48566, September 16, 2019; and 84 FR 52806, October 3, 2019).

Closure of the October Through November 2019 General Category Fishery

NMFS previously adjusted the subquota for the October through November time period to 172.2 mt (84 FR 52806, October 3, 2019). Based on the best available bluefin tuna General category landings information (*i.e.,* 147.5 mt landed as of October 10, 2019) as well as average catch rates and anticipated fishing conditions, NMFS projects that the adjusted General category October through November subquota will be reached by October 13, 2019, and that the fishery should be closed. Through this action, we are closing the General category bluefin tuna fishery effective 11:30 p.m., October 13, 2019, through November 30, 2019. Therefore, retaining, possessing, or landing large medium or giant BFT by persons aboard vessels permitted in the Atlantic tunas General and HMS Charter/Headboat categories must cease at 11:30 p.m. local time on October 13, 2019. The General category will reopen automatically on December 1, 2019, for the December 2019 subquota period. This action applies to those vessels permitted in the General category, as well as to those HMS Charter/Headboat permitted vessels with a commercial sale endorsement when fishing commercially for BFT. For information regarding the HMS Charter/Headboat commercial sale endorsement, see 82 FR 57543, December 6, 2017. The intent of this closure is to prevent overharvest of the available General category October through November BFT subquota.

Fishermen may catch and release (or tag and release) BFT of all sizes, subject to the requirements of the catch-and-release and tag-and-release programs at § 635.26. All BFT that are released must be handled in a manner that will maximize their survival, and without removing the fish from the water, consistent with requirements at § 635.21(a)(1). For additional information on safe handling, see the ''Careful Catch and Release'' brochure available at *www.nmfs.noaa.gov/sfa/hms/.*

Although NMFS previously adjusted the quota for the December 2019 subquota period to 9.4 mt in an inseason

quota transfer to the January 2019 subquota period, NMFS would consider a potential quota transfer from the Reserve to the General category for the December subquota period, prior to December 1, after reviewing the best available 2019 landings information to date.

Monitoring and Reporting

NMFS will continue to monitor the BFT fishery closely. Dealers are required to submit landing reports within 24 hours of a dealer receiving BFT. Late reporting by dealers compromises NMFS' ability to timely implement actions such as quota and retention limit adjustment, as well as closures, and may result in enforcement actions. Additionally, and separate from the dealer reporting requirement, General and HMS Charter/Headboat category vessel owners are required to report the catch of all BFT retained or discarded dead within 24 hours of the landing(s) or end of each trip, by accessing *hmspermits.noaa.gov,* using the HMS Catch Reporting app, or calling (888) 872–8862 (Monday through Friday from 8 a.m. until 4:30 p.m.).

Depending on the level of fishing effort and catch rates of BFT, NMFS may determine that additional action (*e.g.,* quota adjustment, daily retention limit adjustment, or closure) is necessary to ensure available subquotas are not exceeded or to enhance scientific data collection from, and fishing opportunities in, all geographic areas. If needed, subsequent adjustments will be published in the **Federal Register**. In addition, fishermen may call the Atlantic Tunas Information Line at (978) 281–9260, or access *hmspermits.noaa.gov,* for updates on quota monitoring and inseason adjustments.

Classification

The Assistant Administrator for NMFS (AA) finds that it is impracticable and contrary to the public interest to provide prior notice of, and an opportunity for public comment on, this action for the following reasons:

The regulations implementing the 2006 Consolidated HMS FMP and amendments provide for inseason quota transfers and fishery closures to respond to the unpredictable nature of BFT availability on the fishing grounds, the migratory nature of this species, and the regional variations in the BFT fishery. These fisheries are currently underway and the currently available quota for the subcategory is projected to be reached shortly. Affording prior notice and opportunity for public comment to implement the quota transfer is impracticable and contrary to the public interest as such a delay would likely result in exceedance of the General category October through November fishery subquota or earlier closure of the fishery while fish are available on the fishing grounds. Subquota exceedance may result in the need to reduce quota for the General category later in the year and thus could affect later fishing opportunities. Therefore, the AA finds good cause under 5 U.S.C. 553(b)(B) to waive prior notice and the opportunity for public comment. For all of the above reasons, there also is good cause under 5 U.S.C. 553(d) to waive the 30-day delay in effectiveness.

This action is being taken under §§ 635.27(a)(9) and 635.28(a)(1), and is exempt from review under Executive Order 12866.

Authority: 16 U.S.C. 971 *et seq.* and 1801 *et seq.*

Dated: October 10, 2019.

Jennifer M. Wallace,

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

[FR Doc. 2019–22601 Filed 10–11–19; 4:15 pm]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[Docket No. 180831813–9170–02]

RIN 0648–XY022

Fisheries of the Exclusive Economic Zone Off Alaska; Pacific Cod by Vessels Using Pot 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 pot gear in the Central Regulatory Area of the Gulf of Alaska (GOA). This action is necessary to prevent exceeding the 2019 Pacific cod total allowable catch apportioned to vessels using pot gear in the Central Regulatory Area of the GOA.

DATES: Effective 1200 hours, Alaska local time (A.l.t.), October 12, 2019, through 2400 hours, A.l.t., December 31, 2019.

FOR FURTHER INFORMATION CONTACT: Josh Keaton, 907–586–7228.

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. Regulations governing sideboard protections for GOA groundfish fisheries appear at subpart B of 50 CFR part 680.

The 2019 Pacific cod total allowable catch (TAC) apportioned to vessels using pot gear in the Central Regulatory Area of the GOA is 1,583 metric tons (mt), as established by the final 2019 and 2020 harvest specifications for groundfish of the GOA (84 FR 9416, March 14, 2019).

In accordance with § 679.20(d)(1)(i), the Administrator, Alaska Region, NMFS (Regional Administrator) has determined that the 2019 Pacific cod TAC apportioned to vessels using pot gear in the Central Regulatory Area of the GOA will soon be reached. Therefore, the Regional Administrator is establishing a directed fishing allowance of 1,573 mt and is setting aside the remaining 10 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 pot 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

This action responds to the best available information recently obtained from the fishery. The Assistant Administrator for Fisheries, NOAA (AA), finds good cause to waive the requirement to provide prior notice and opportunity for public comment pursuant to the authority set forth at 5 U.S.C. 553(b)(B) as such requirement is impracticable and contrary to the public interest. This requirement is 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 directed fishing closure of Pacific cod by vessels using pot 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 October 10, 2019.

The AA 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.

This action is required by § 679.20 and is exempt from review under Executive Order 12866.

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

Dated: October 11, 2019.

Jennifer M. Wallace,

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

[FR Doc. 2019–22634 Filed 10–11–19; 4:15 pm]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register
Vol. 84, No. 201
Thursday, October 17, 2019

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.

DEPARTMENT OF THE TREASURY

Office of the Comptroller of the Currency

12 CFR Part 30

[Docket No. ID OCC–2019–0013]

FEDERAL RESERVE SYSTEM

12 CFR Part 208

[Docket No. OP–1680]

FEDERAL DEPOSIT INSURANCE CORPORATION

12 CFR Part 364

RIN 3064–ZA10

NATIONAL CREDIT UNION ADMINISTRATION

12 CFR Part 741

RIN 3133–AF05

Interagency Policy Statement on Allowances for Credit Losses

AGENCY: Office of the Comptroller of the Currency (OCC), Treasury; Board of Governors of the Federal Reserve System (Board); Federal Deposit Insurance Corporation (FDIC); and National Credit Union Administration (NCUA).

ACTION: Proposed interagency policy statement; request for comment.

SUMMARY: The Office of the Comptroller of the Currency, the Board of Governors of the Federal Reserve System, the Federal Deposit Insurance Corporation (collectively, the banking agencies), and the National Credit Union Administration (collectively, the agencies) are inviting public comment on a proposed interagency policy statement on allowances for credit losses (ACLs). The agencies are issuing this proposed interagency policy statement in response to changes to U.S. generally accepted accounting principles (GAAP) as promulgated by the Financial Accounting Standards Board (FASB) in Accounting Standards Update (ASU) 2016–13, *Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments* and subsequent amendments issued since June 2016. These updates are codified in Accounting Standards Codification (ASC) Topic 326, *Financial Instruments—Credit Losses* (FASB ASC Topic 326).

This proposed interagency policy statement describes the measurement of expected credit losses under the current expected credit losses (CECL) methodology and the accounting for impairment on available-for-sale (AFS) debt securities in accordance with FASB ASC Topic 326; supervisory expectations for designing, documenting, and validating expected credit loss estimation processes, including the internal controls over these processes; maintaining appropriate ACLs; the responsibilities of boards of directors and management; and examiner reviews of ACLs.

DATES: Comments must be received by December 16, 2019.

ADDRESSES: Interested parties are invited to submit written comments to any or all of the agencies. All comments, which should refer to the ''Proposed Interagency Policy Statement on Allowances for Credit Losses,'' will be shared among the agencies.

OCC: Commenters are encouraged to submit comments through the Federal eRulemaking Portal or email, if possible. Please use the title ''Proposed Interagency Policy Statement on Allowances for Credit Losses'' to facilitate the organization and distribution of the comments. You may submit comments by any of the following methods:

- Federal eRulemaking Portal—*Regulations.gov* Classic or *Regulation.gov* Beta

Regulation.gov Classic: Go to *https://www.regulations.gov/.* Enter ''Docket ID OCC–2019–0013'' in the Search Box and click ''Search.'' Click on ''Comment Now'' to submit public comments. For help with submitting effective comments please click on ''View Commenter's Checklist.'' Click on the ''Help'' tab on the *Regulations.gov* home page to get information on using *Regulations.gov,* including instructions for submitting public comments.

Regulations.gov Beta: Go to *https://beta.regulations.gov/* or click ''Visit New *Regulations.gov* Site'' from the *Regulations.gov* classic homepage. Enter ''Docket ID OCC–2019–0013'' in the Search Box and click ''Search.'' Public comments can be submitted via the ''Comment'' box below the displayed document information or click on the document title and click the ''Comment'' box on the top-left side of the screen. For help with submitting effective comments please click on ''Commenter's Checklist.'' For assistance with the *Regulations.gov* Beta site please call (877) 378–5457 (toll free) or (703) 454–9859 Monday–Friday, 9 a.m.–5 p.m. ET or email to *regulations@erulemakinghelpdesk.com.*

- *Email: regs.comments@occ.treas.gov.*
- *Mail:* Chief Counsel's Office, Attention: Comment Processing, Office of the Comptroller of the Currency, 400 7th Street SW, Suite 3E–218, Washington, DC 20219.
- *Hand Delivery/Courier:* 400 7th Street SW, Suite 3E–218, Washington, DC 20219.
- *Fax:* (571) 465–4326.

Instructions: You must include ''OCC'' as the agency name and ''Docket ID OCC–2019–0013'' in your comment. In general, the OCC will enter all comments received into the docket and publish them on the *Regulations.gov* website without change, including any business or personal information that you provide such as name and address information, email addresses, or phone numbers. Comments received, including attachments and other supporting materials, are part of the public record and subject to public disclosure. Do not enclose any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure.

You may review comments and other related materials that pertain to this notice by any of the following methods:

- Viewing Comments Electronically—*Regulations.gov* Classic or *Regulations.gov* Beta

Regulations.gov Classic: Go to *https://www.regulations.gov/.* Enter ''Docket ID OCC–2019–0013'' in the Search box and click ''Search.'' Click on ''Open Docket Folder'' on the right side of the screen. Comments and supporting materials can be viewed and filtered by clicking on ''View all documents and comments in

this docket'' and then using the filtering tools on the left side of the screen. Click on the ''Help'' tab on the *Regulations.gov* home page to get information on using *Regulations.gov.* The docket may be viewed after the close of the comment period in the same manner as during the comment period.

Regulations.gov Beta: Go to *https://beta.regulations.gov/* or click ''Visit New *Regulations.gov* Site'' from the *Regulations.gov* classic homepage. Enter ''Docket ID OCC–2019–2013'' in the Search Box and click ''Search.'' Click on the ''Comments'' tab. Comments can be viewed and filtered by clicking on the ''Sort By'' drop-down on the right side of the screen or the ''Refine Results'' options on the left side of the screen. Supporting Materials can be viewed by clicking on the ''Documents'' tab and filtered by clicking on the ''Sort By'' drop-down on the right side of the screen or the ''Refine Results'' options on the left side of the screen.'' For assistance with the *Regulations.gov* Beta site please call (877) 378–5457 (toll free) or (703) 454–9859 Monday–Friday, 9 a.m.–5 p.m. ET or email to *regulations@erulemakinghelpdesk.com.*

The docket may be viewed after the close of the comment period in the same manner as during the comment period.

- *Viewing Comments Personally:* You may personally inspect comments at the OCC, 400 7th Street SW, Washington, DC 20219. For security reasons, the OCC requires that visitors make an appointment to inspect comments. You may do so by calling (202) 649–6700 or, for persons who are deaf or hearing impaired, TTY, (202) 649–5597. Upon arrival, visitors will be required to present valid government-issued photo identification and submit to security screening in order to inspect comments.

Board: You may submit written comments, identified by Docket No. OP–1680, by any of the following methods:

- *Agency Website: http://www.federalreserve.gov.* Follow the instructions for submitting comments at *http://www.federalreserve.gov/generalinfo/foia/ProposedRegs.cfm.*
- *Email: regs.comments@federalreserve.gov.* Include docket number in the subject line of the message.
- *Fax:* (202) 452–3819 or 202–452–3102.
- *Mail:* Ann E. Misback, Secretary, Board of Governors of the Federal Reserve System, 20th Street and Constitution Avenue NW, Washington, DC 20551.

All public comments will be made available on the Board's website at *http://www.federalreserve.gov/generalinfo/foia/ProposedRegs.cfm* as submitted, unless modified for technical reasons or to remove personally identifiable information at the commenter's request. Accordingly, comments will not be edited to remove any identifying or contact information. Public comments may also be viewed electronically or in paper form in Room 146, 1709 New York Avenue NW, Washington, DC 20006, between 9:00 a.m. and 5:00 p.m. on weekdays.

FDIC: You may submit comments, which should refer to ''Proposed Interagency Policy Statement on Allowances for Credit Losses,'' by any of the following methods:

- *Agency Website: https://www.fdic.gov/regulations/laws/federal/.* Follow the instructions for submitting comments on the FDIC's website.
- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments.
- *Email: Comments@fdic.gov.* Include ''Proposed Interagency Policy Statement on Allowances for Credit Losses'' in the subject line of the message.
- *Mail:* Robert E. Feldman, Executive Secretary, Attention: Comments, 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 550 17th Street Building (located on F Street) on business days between 7:00 a.m. and 5:00 p.m.

Public Inspection: All comments received will be posted without change to *https://www.fdic.gov/regulations/laws/federal/* including any personal information provided. Paper copies of public comments may be requested from the FDIC Public Information Center by telephone at (877) 275–3342 or (703) 562–2200.

NCUA: You may submit comments by any one of the following methods (please send comments by one method only):

- *Federal Rulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Email:* Address to *regcomments@ncua.gov.* Include ''[Your name]—Comments on Proposed Interagency Policy Statement on Allowances for Credit Losses'' in the email subject line.
- *Fax:* (703) 518–6319. Use the subject line described above for email.
- *Mail:* Address to Gerard Poliquin, Secretary of the Board, National Credit Union Administration, 1775 Duke Street, Alexandria, Virginia 22314–3428.
- *Hand Delivery/Courier:* Same as mail address.

Public Inspection: You can view all public comments on NCUA's website at *https://www.ncua.gov/regulation-supervision/rules-regulations/proposed-pending-and-recently-final-regulations* as submitted, except for those we cannot post for technical reasons. NCUA will not edit or remove any identifying or contact information from the public comments submitted. You may inspect paper copies of comments in NCUA's law library at 1775 Duke Street, Alexandria, Virginia 22314, by appointment weekdays between 9:00 a.m. and 3:00 p.m. To make an appointment, call (703) 518–6546 or send an email to *OGCMail@ncua.gov.*

FOR FURTHER INFORMATION CONTACT:

OCC: Amanda Freedle, Senior Accounting Policy Advisor, Office of the Chief Accountant, (202) 649–6280; or Kevin Korzeniewski, Counsel, Chief Counsel's Office, (202) 649–5490; or for persons who are hearing impaired, TTY, (202) 649–5597.

BOARD: Lara Lylozian, Assistant Chief Accountant—Supervision, (202) 475–6656; or Kevin Chiu, Accounting Policy Analyst, (202) 912–4608, Division of Supervision and Regulation; or David W. Alexander, Senior Counsel, (202) 452–2877; or Asad Kudiya, Senior Counsel, (202) 475–6358, Legal Division, Board of Governors of the Federal Reserve System, 20th and C Streets NW, Washington, DC 20551. For the hearing impaired only, Telecommunication Device for the Deaf (TDD), (202) 263–4869.

FDIC: Shannon Beattie, Chief, Accounting and Securities Disclosure Section, (202) 898–3952; or John Rieger, Deputy Chief Accountant, (202) 898–3602; or Andrew Overton, Examination Specialist (Bank Accounting), (202) 898–8922; Division of Risk Management Supervision; or Michael Phillips, Counsel, (202) 898–3581, Legal Division, Federal Deposit Insurance Corporation, 550 17th Street NW, Washington, DC 20429.

NCUA: Technical information: Alison Clark, Chief Accountant, Office of Examination and Insurance, at the above address or telephone (703) 518–6611 or *Legal information:* Ariel Pereira, Staff Attorney, Office of General Counsel, at (703) 548–2778.

SUPPLEMENTARY INFORMATION:

I. Background

FASB ASC Topic 326 introduces the CECL methodology, which replaces the incurred loss methodology for financial assets measured at amortized cost, net investments in leases, and certain off-balance-sheet credit exposures, and modifies the accounting for impairment on AFS debt securities. FASB ASC Topic 326 applies to all banks, savings

associations, credit unions, and financial institution holding companies (collectively, institutions), regardless of size, that file regulatory reports for which the reporting requirements conform to GAAP.[1] The agencies are maintaining conformance with GAAP and consistency with FASB ASC Topic 326 through their issuance of the proposed Interagency Policy Statement on Allowances for Credit Losses.

For FDIC-insured institutions, the banking agencies have issued guidelines establishing standards for safety and soundness, including operational and managerial standards that address such matters as internal controls and information systems, an internal audit system, loan documentation, credit underwriting, asset quality, and earnings and should be appropriate for an institution's size and the nature, scope, and risk of its activities.[2] The principles described in the proposed interagency policy statement are consistent with these guidelines.

The effective dates of FASB ASC Topic 326 vary for different institutions. Under GAAP as currently in effect, FASB ASC Topic 326 is effective for institutions that are public business entities (PBEs) and also are Securities and Exchange Commission (SEC) filers, as both terms are defined in GAAP, for fiscal years beginning after December 15, 2019, including interim periods within those fiscal years. For institutions that are PBEs but not SEC filers, FASB ASC Topic 326 is effective for fiscal years beginning after December 15, 2020, including interim periods within those fiscal years. For institutions that are not PBEs (non-PBEs), FASB ASC Topic 326 is effective for fiscal years beginning after December 15, 2021, including interim periods within those fiscal years.[3] Early application of FASB ASC Topic 326 is permitted for all institutions for fiscal years beginning after December 15, 2018, including interim periods within that fiscal year.

II. Overview of the Proposed Interagency Policy Statement on Allowances for Credit Losses

The agencies are issuing this proposed interagency policy statement on allowances for credit losses (ACLs) in response to the changes in accounting for credit losses in accordance with FASB ASC Topic 326. The proposed interagency policy statement would be effective at the time of each institution's adoption of FASB ASC Topic 326. The following policy statements would no longer be effective for an institution upon its adoption of FASB ASC Topic 326: The agencies' December 2006 Interagency Policy Statement on the Allowance for Loan and Lease Losses; the banking agencies' July 2001 Policy Statement on Allowance for Loan and Lease Losses Methodologies and Documentation for Banks and Savings Institutions; and the NCUA's May 2002 Interpretive Ruling and Policy Statement 02–3, Allowance for Loan and Lease Losses Methodologies and Documentation for Federally Insured Credit Unions (collectively, the ALLL policy statements). After FASB ASC Topic 326 is effective for all institutions, the agencies will rescind the ALLL policy statements.

This proposed interagency policy statement describes the CECL methodology for determining ACLs applicable to financial assets measured at amortized cost, including loans held-for-investment, net investments in leases, held-to-maturity (HTM) debt securities, and certain off-balance-sheet credit exposures in accordance with FASB ASC Topic 326. It also describes the estimation of an ACL for an impaired AFS debt security in accordance with FASB ASC Subtopic 326–30.

The proposed interagency policy statement also includes and updates concepts and practices detailed in the existing ALLL policy statements that remain relevant under FASB ASC Topic 326. These concepts and practices relate to management's responsibilities for the allowance estimation process, including the need to appropriately support and document the institution's allowance estimates; the board of directors' responsibilities for overseeing management's processes; and the role of examiners in reviewing the appropriateness of an institution's ACLs as part of their supervisory activities.

An attachment to the agencies' December 2006 Interagency Policy Statement on the Allowance for Loan and Lease Losses addresses concepts and practices related to loan review systems. Rather than updating the agencies' guidance on loan review systems as part of the proposed interagency policy statement on ACLs, the agencies are currently developing separate standalone guidance on supervisory expectations for effective credit risk review.

III. Request for Comment

The agencies request comments on all aspects of the proposed interagency policy statement, including but, not limited to those set forth below. The agencies will revise the Statement, if needed and as appropriate, after reviewing the comments received on the proposal.

(1) Does the proposed interagency policy statement clearly describe the measurement of expected credit losses under CECL in accordance with FASB ASC Topic 326? Why or why not? If not, what additional information is needed? What information should be omitted from the policy statement?

(2) Does the proposed interagency policy statement clearly describe the measurement of credit losses on impaired AFS debt securities in accordance with FASB ASC Topic 326? Why or why not? If not, what additional information is needed? What information should be omitted from the policy statement?

(3) Does the proposed interagency policy statement clearly communicate supervisory expectations for designing, documenting, and validating expected credit loss estimation processes, internal controls over ACLs, and maintaining appropriate ACLs?

(4) Has the proposed interagency policy statement appropriately included concepts and practices detailed in the existing ALLL policy statements that also are relevant under FASB ASC Topic 326? If not, what additional information should also be included?

IV. The Paperwork Reduction Act

In accordance with the requirements of the Paperwork Reduction Act of 1995

[1] *See* section 37(a) of the Federal Deposit Insurance Act and section 202(a) of the Federal Credit Union Act. Under these statutory provisions, the accounting principles applicable to reports or statements required to be filed by all insured depository institutions with the federal banking agencies or by all insured credit unions with assets of $10 million or more with the NCUA Board must be uniform and consistent with GAAP. Furthermore, regardless of asset size, all federally insured credit unions must comply with GAAP for certain financial reporting requirements relating to charges for loan losses. *See* 12 U.S.C. 1831n(a)(2)(A), 12 U.S.C. 1782(a)(6)(C), and 12 CFR 702.402(d).

[2] *See* Appendix A to 12 CFR part 30 (OCC), Appendix D to 12 CFR part 208 (Board), and Appendix A to 12 CFR part 364 (FDIC), which were adopted by the banking agencies pursuant to Section 39 of the Federal Deposit Insurance Act. *See* 12 U.S.C. 1831p–1. National credit unions should refer to Section 206(b)(1) of the Federal Credit Union Act (12 U.S.C. 1786) and 12 CFR 741.3.

[3] On July 17, 2019, the FASB Board decided to adopt a two-bucket approach to stagger effective dates for major accounting standards including FASB ASC Topic 326. The FASB Board decided that FASB ASC Topic 326 will be effective for SEC filers, excluding smaller reporting companies (SRCs) as currently defined by the SEC, for fiscal years beginning after December 15, 2019, including interim periods within those fiscal years. For all other entities, the FASB Board decided that FASB ASC Topic 326 will be effective for fiscal years beginning after December 15, 2022, including interim periods within those fiscal years.

(PRA),[4] the agencies may not conduct or sponsor, and the respondent is not required to respond to, an information collection unless it displays a currently valid Office of Management and Budget (OMB) control number.

The proposed interagency policy statement will not create any new or revise any existing collections of information under the PRA. Therefore, no information collection request will be submitted to the OMB for review.

V. Proposed Interagency Policy Statement

The text of the proposed interagency policy statement is as follows:

Interagency Policy Statement on the Allowances for Credit Losses Purpose

The Office of the Comptroller of the Currency (OCC), the Board of Governors of the Federal Reserve System (FRB), the Federal Deposit Insurance Corporation (FDIC), and the National Credit Union Administration (NCUA) (collectively, the agencies) are issuing this Interagency Policy Statement on Allowances for Credit Losses (hereafter, the policy statement) to promote consistency in the interpretation and application of Financial Accounting Standards Board (FASB) Accounting Standards Update 2016–13, *Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments,* as well as the amendments issued since June 2016.[5] These updates are codified in Accounting Standards Codification (ASC) Topic 326, *Financial Instruments—Credit Losses* (FASB ASC Topic 326). FASB ASC Topic 326 applies to all banks, savings associations, credit unions, and financial institution holding companies (collectively, institutions), regardless of size, that file regulatory reports for which the reporting requirements conform to U.S. generally accepted accounting principles (GAAP).[6] This policy statement describes the measurement of expected credit losses in accordance with FASB ASC Topic 326; supervisory expectations for designing, documenting, and validating expected credit loss estimation processes, including the internal controls over these processes; maintaining appropriate allowances for credit losses (ACLs); the responsibilities of boards of directors and management; and examiner reviews of ACLs.

This policy statement is effective at the time of each institution's adoption of FASB ASC Topic 326.[7] The following policy statements are no longer effective for an institution upon its adoption of FASB ASC Topic 326: The December 2006 Interagency Policy Statement on the Allowance for Loan and Lease Losses; the July 2001 Policy Statement on Allowance for Loan and Lease Losses Methodologies and Documentation for Banks and Savings Institutions; and the NCUA's May 2002 Interpretive Ruling and Policy Statement 02–3, Allowance for Loan and Lease Losses Methodologies and Documentation for Federally Insured Credit Unions (collectively, ALLL Policy Statements). After FASB ASC Topic 326 is effective for all institutions, the agencies will rescind the ALLL Policy Statements.

The principles described in this policy statement are consistent with GAAP, applicable regulatory reporting requirements,[8] safe and sound banking practices, and the agencies' codified guidelines establishing standards for safety and soundness.[9] The operational and managerial standards included in those guidelines, which address such matters as internal controls and information systems, an internal audit system, loan documentation, credit underwriting, asset quality, and earnings, should be appropriate for an institution's size and the nature, scope, and risk of its activities.

Contents

[4] 44 U.S.C. 3501–3521.

[5] The FASB issued *Accounting Standards Update (ASU) 2016–13* on June 16, 2016. The following updates were published after the issuance of ASU 2016–13: *ASU 2018–19—Codification Improvements to Topic 326, Financial Instruments—Credit Losses; ASU 2019–04—Codification Improvements to Topic 326, Financial Instruments—Credit Losses, Topic 815, Derivatives and Hedging, and Topic 825, Financial Instruments;* and *ASU 2019–05—Financial Instruments—Credit Losses (Topic 326): Targeted Transition Relief.* Additionally, institutions may refer to *FASB Staff Q&A-Topic 326, No. 1, Whether the Weighted-Average Remaining Maturity Method is an Acceptable Method to Estimate Expected Credit Losses,* and *FASB Staff Q&A-Topic 326, No. 2, Developing an Estimate of Expected Credit Losses on Financial Assets.*

[6] U.S. branches and agencies of foreign banking organizations may choose to, but are not required to, maintain ACLs on a branch or agency level. These institutions should refer to the instructions for the FFIEC 002, *Report of Assets and Liabilities of U. S. Branches and Agencies of Foreign Banks;* Supervision and Regulation (SR) Letter 95–4, *Allowance for Loan and Lease Losses for U. S. Branches and Agencies of Foreign Banking Organizations;* and SR Letter 95–42, *Allowance for Loan and Lease Losses for U.S. Branches and Agencies of Foreign Banking Organizations.*

[7] The effective date for FASB ASC Topic 326 is based on an institution's characteristics, including an institution's U.S. Securities and Exchange Commission (SEC) filing status, as described in Accounting Standards Codification (ASC) 326–10–65–1, with early adoption permitted only as of the beginning of an institution's fiscal year.

[8] For FDIC-insured depository institutions, Section 37(a) of the Federal Deposit Insurance Act (12 U.SC. 1831n(a)) states that, in general, the accounting principles applicable to the Consolidated Reports of Condition and Income (Call Report) ''shall be uniform and consistent with generally accepted accounting principles.'' Section 202(a)(6)(C) of the Federal Credit Union Act (12 U.S.C. 1782(a)(6)(C)) establishes the same standard for federally insured credit unions with assets of $10 million or greater, providing that, in general, the ''[a]ccounting principles applicable to reports or statements required to be filed with the [NCUA] Board by each insured credit union shall be uniform and consistent with generally accepted accounting principles.'' Furthermore, regardless of asset size, all federally insured credit unions must comply with GAAP for certain financial reporting requirements relating to charges for loan losses. *See* 12 CFR 702.402(d).

[9] FDIC-insured depository institutions should refer to the *Interagency Guidelines Establishing Standards for Safety and Soundness* adopted by their primary federal regulator pursuant to Section 39 of the Federal Deposit Insurance Act (12 U.S.C. 1831p–1) as follows: For national banks and federal savings associations, Appendix A to 12 CFR part 30; for state member banks, Appendix D to 12 CFR part 208; and for state nonmember banks, state savings associations, and insured state-licensed branches of foreign banks, Appendix A to 12 CFR part 364. Federal credit unions should refer to Section 206(b)(1) of the Federal Credit Union Act (12 U.S.C. 1786) and 12 CFR 741.3.

Scope

This policy statement describes the current expected credit losses (CECL) methodology for determining the ACLs applicable to loans held-for-investment, net investments in leases, and held-to-maturity debt securities accounted for at amortized cost.[10] It also describes the estimation of the ACL for an available-for-sale debt security in accordance with FASB ASC Subtopic 326–30. This policy statement does not address or supersede existing agency requirements or guidance regarding appropriate due diligence in connection with the purchase or sale of assets or determining whether assets are permissible to be purchased or held by institutions.[11]

The CECL methodology described in FASB ASC Topic 326 applies to financial assets measured at amortized cost, net investments in leases, and off-balance-sheet credit exposures (collectively, financial assets) including:

- Financing receivables such as loans held-for-investment;
- Overdrawn deposit accounts (*i.e.* overdrafts) that are reclassified as held-for-investment loans;
- Held-to-maturity debt securities;
- Receivables that result from revenue transactions within the scope of Topic 606 on revenue from contracts with customers and Topic 610 on other income, which applies, for example, to the sale of foreclosed real estate;
- Reinsurance recoverables that result from insurance transactions within the scope of Topic 944 on insurance;
- Receivables related to repurchase agreements and securities lending agreements within the scope of Topic 860 on transfers and servicing;
- Net investments in leases recognized by a lessor in accordance with Topic 842 on leases; and
- Off-balance-sheet credit exposures including off-balance-sheet loan commitments, standby letters of credit, financial guarantees not accounted for as insurance, and other similar instruments except for those within the scope of Topic 815 on derivatives and hedging.

The CECL methodology does not apply to the following financial assets:

- Financial assets measured at fair value through net income, including those assets for which the fair value option has been elected;
- Available-for-sale debt securities;[12]
- Loans held-for-sale;
- Policy loan receivables of an insurance entity;
- Loans and receivables between entities under common control; and
- Receivables arising from operating leases.

Measurement of ACLs for Loans, Leases, Held-to-Maturity Debt Securities, and Off-Balance-Sheet Credit Exposures

Overview of ACLs

An ACL is a valuation account that is deducted from, or added to, the amortized cost basis of financial assets to present the net amount expected to be collected over the contractual term[13] of the assets. In estimating the net amount expected to be collected, management should consider the effects of past events, current conditions, and reasonable and supportable forecasts on the collectibility of the institution's financial assets.[14] FASB ASC Topic 326 requires management to use relevant forward-looking information and expectations drawn from reasonable and supportable forecasts when estimating expected credit losses.

ACLs are evaluated as of the end of each reporting period. The methods used to determine ACLs generally should be applied consistently over time and reflect management's current expectations of credit losses. Changes to ACLs resulting from these periodic evaluations are recorded through increases or decreases to the related provisions for credit losses (PCLs). When available information confirms that specific loans, securities, other assets, or portions thereof, are uncollectible, these amounts should be promptly written off[15] against the related ACLs.

Estimating appropriate ACLs involves a high degree of management judgment and is inherently imprecise. An institution's process for determining appropriate ACLs may result in a range of estimates for expected credit losses. An institution should support and record its best estimate within the range of expected credit losses.

Collective Evaluation of Expected Losses

FASB ASC Topic 326 requires expected losses to be evaluated on a collective, or pool, basis when financial assets share similar risk characteristics. Financial assets may be segmented based on one characteristic, or a combination of characteristics.

Examples of risk characteristics relevant to this evaluation include, but are not limited to:

- Internal or external credit scores or credit ratings;
- Risk ratings or classifications;
- Financial asset type;

[10] FASB ASC Topic 326 defines the amortized cost basis of an asset as the amount at which a financing receivable or investment is originated or acquired, adjusted for applicable accrued interest, accretion, or amortization of premium, discount, and net deferred fees or costs, collection of cash, write-offs, foreign exchange, and fair value hedge accounting.

[11] See OCC Bulletin 2012–18, *Guidance on Due Diligence Requirements in Determining Whether Securities are Eligible for Investment* (for national banks and federal savings associations), 12 CFR part 1, *Investment Securities* (for national banks), and 12 CFR part 160, *Lending and Investment* (for federal savings associations). Federal credit unions should refer to 12 CFR part 703, *Investment and Deposit Activities*. Federally insured, state-chartered credit unions should refer to applicable state laws and regulations, as well as 12 CFR 741.219 (''investment requirements'').

[12] Refer to FASB ASC Subtopic 326–30, Financial Instruments—Credit Losses—Available-for-Sale Debt Securities (FASB ASC Subtopic 326–30).

[13] Consistent with FASB ASC Topic 326, an institution's determination of the contractual term should reflect the financial asset's contractual life adjusted for prepayments, renewal and extension options that are not unconditionally cancellable by the institution, and reasonably expected troubled debt restructurings. For more information, see the ''Contractual Term of a Financial Asset'' section in this policy statement.

[14] Recoveries are a component of management's estimation of the net amount expected to be collected for a financial asset. Expected recoveries of amounts previously written off or expected to be written off that are included in ACLs may not exceed the aggregate amounts previously written off or expected to be written off. In some circumstances, the ACL for a specific portfolio or loan may be negative because the amount expected to be collected, including expected recoveries, exceeds the financial asset's amortized cost basis.

[15] Consistent with FASB ASC Topic 326, this policy statement uses the verbs ''write off'' and ''written off'' and the noun ''write-off.'' These terms are used interchangeably with ''charge off,'' ''charged off,'' and ''charge-off,'' respectively, in the agencies' regulations, guidance, and regulatory reporting instructions.

- Collateral type;
- Size;
- Effective interest rate;
- Term;
- Geographical location;
- Industry of the borrower; and
- Vintage.

Other risk characteristics that may be relevant for segmenting held-to-maturity debt securities include issuer, maturity, coupon rate, yield, payment frequency, source of repayment, bond payment structure, and embedded options.

FASB ASC Topic 326 does not prescribe a process for segmenting financial assets for collective evaluation. Therefore, management should exercise judgment when establishing appropriate segments or pools. Management should evaluate financial asset segmentation on an ongoing basis to determine whether the financial assets in the pool continue to share similar risk characteristics. If a financial asset ceases to share risk characteristics with other assets in its segment, it should be moved to a different segment with assets sharing similar risk characteristics if such a segment exists.

If a financial asset does not share similar risk characteristics with other assets, expected credit losses for that asset should be evaluated individually. Individually evaluated assets should not be included in a collective assessment of expected credit losses.

Estimation Methods for Expected Credit Losses

FASB ASC Topic 326 does not require the use of a specific loss estimation method for purposes of determining ACLs. Various methods may be used to estimate the expected collectibility of financial assets, with those methods generally applied consistently over time. The same loss estimation method does not need to be applied to all financial assets. Management is not precluded from selecting a different method when it determines the method will result in a better estimate of ACLs.

Management may use a loss-rate method,[16] probability of default/loss given default (PD/LGD) method, roll-rate method, discounted cash flow method, a method that uses aging schedules, or another reasonable method to estimate expected credit losses. The selected method(s) should be appropriate for the financial assets being evaluated, consistent with the institution's size and complexity.

[16] Various loss-rate methods may be used to estimate expected credit losses under the CECL methodology. These include the weighted-average remaining maturity (WARM) method, vintage analysis, and the snapshot or open pool method.

Contractual Term of a Financial Asset

FASB ASC Topic 326 requires an institution to measure estimated expected credit losses over the contractual term of its financial assets, considering expected prepayments. Renewals, extensions, and modifications are excluded from the contractual term of a financial asset for purposes of estimating the ACL unless there is a reasonable expectation of executing a troubled debt restructuring (TDR) or the renewal and extension options are part of the original or modified contract and are not unconditionally cancellable by the institution. If such renewal or extension options are present, management must evaluate the likelihood of a borrower exercising those options when determining the contractual term.

Historical Loss Information

Historical loss information generally provides a basis for an institution's assessment of expected credit losses. Historical loss information may be based on internal information, external information, or a combination of both. Management should consider whether the historical loss information may need to be adjusted for differences in current asset specific characteristics such as differences in underwriting standards, portfolio mix, or when historical asset terms do not reflect the contractual terms of the financial assets being evaluated as of the reporting date.

Management should then consider whether further adjustments to historical loss information are needed to reflect the extent to which current conditions and reasonable and supportable forecasts differ from the conditions that existed during the historical loss period. Adjustments to historical loss information may be quantitative or qualitative in nature and should reflect changes to relevant data (such as changes in unemployment rates, delinquency, or other factors associated with the financial assets).

Reasonable and Supportable Forecasts

When estimating expected credit losses, FASB ASC Topic 326 requires management to consider forward-looking information that is both reasonable and supportable and relevant to assessing the collectibility of cash flows. Reasonable and supportable forecasts may extend over the entire contractual term of a financial asset or a period shorter than the contractual term. FASB ASC Topic 326 does not prescribe a specific method for determining reasonable and supportable forecasts nor does it include bright lines for establishing a minimum or maximum length of time for reasonable and supportable forecast period(s). Judgment is necessary in determining an appropriate period(s) for each institution. Reasonable and supportable forecasts may vary by portfolio segment or individual forecast input. These forecasts may include data from internal sources, external sources, or a combination of both. Management is not required to search for all possible information nor incur undue cost and effort to collect data for its forecasts. However, reasonably available and relevant information should not be ignored in assessing the collectibility of cash flows. Management should evaluate the appropriateness of the reasonable and supportable forecast period(s) each reporting period, consistent with other inputs used in the estimation of expected credit losses.

Institutions may develop reasonable and supportable forecasts by using one or more economic scenarios. FASB ASC Topic 326 does not require the use of multiple economic scenarios, however, institutions are not precluded from considering multiple economic scenarios when estimating expected credit losses.

Reversion

When the contractual term of a financial asset extends beyond the reasonable and supportable period, FASB ASC Topic 326 requires reverting to historical loss information, or an appropriate proxy, for those periods beyond the reasonable and supportable forecast period (often referred to as the reversion period). Management may revert to historical loss information for each individual forecast input or based on the entire estimate of loss.

FASB ASC Topic 326 does not require the application of a specific reversion technique or use of a specific reversion period. Reversion to historical loss information may be immediate, occur on a straight-line basis, or use any systematic, rational method. Management may apply different reversion techniques depending on the economic environment or the financial asset portfolio. Reversion techniques are not accounting policy elections and should be evaluated for appropriateness each reporting period, consistent with other inputs used in the estimation of expected credit losses.

FASB ASC Topic 326 does not specify the historical loss information that is used in the reversion period. This historical loss information may be based on long-term average losses or on losses that occurred during a particular historical period(s). Management may

use multiple historical periods that are not sequential. Management should not adjust historical loss information for existing economic conditions or expectations of future economic conditions for periods beyond the reasonable and supportable period. However, management should consider whether the historical loss information may need to be adjusted for differences in current asset specific characteristics such as differences in underwriting standards, portfolio mix, or when historical asset terms do not reflect the contractual terms of the financial assets being evaluated as of the reporting date.

Qualitative Factor Adjustments

The estimation of ACLs should reflect consideration of all significant factors relevant to the expected collectibility of the institution's financial assets as of the reporting date. Management may begin the expected credit loss estimation process by determining its historical loss information or obtaining reliable and relevant historical loss proxy data for each segment of financial assets with similar risk characteristics. Historical credit losses (or even recent trends in losses) generally do not, by themselves, form a sufficient basis to determine the appropriate levels for ACLs.

Management should consider the need to qualitatively adjust expected credit loss estimates for information not already captured in the loss estimation process. These qualitative factor adjustments may increase or decrease management's estimate of expected credit losses. Adjustments should not be made for information that has already been considered and included in the loss estimation process.

Management should consider the qualitative factors that are relevant to the institution as of the reporting date, which may include, but are not limited to:

- The nature and volume of the institution's financial assets;
- The existence, growth, and effect of any concentrations of credit;
- The volume and severity of past due financial assets, the volume of nonaccrual assets, and the volume and severity of adversely classified or graded assets; [17]
- The value of the underlying collateral for loans that are not collateral-dependent; [18]
- The institution's lending policies and procedures, including changes in underwriting standards and practices for collections, write-offs, and recoveries;
- The quality of the institution's credit review function;
- The experience, ability, and depth of the institution's lending, investment, collection, and other relevant management and staff;
- The effect of other external factors such as the regulatory, legal and technological environments; competition; and events such as natural disasters; and
- Actual and expected changes in international, national, regional, and local economic and business conditions and developments [19] in which the institution operates that affect the collectibility of financial assets.

Management may consider the following additional qualitative factors specific to debt securities as of the reporting date: [20]

- The effect of recent changes in investment strategies and policies;
- The existence and effect of loss allocation methods, the definition of default, the impact of performance and market value triggers, and credit and liquidity enhancements associated with debt securities;
- The effect of structural subordination and collateral deterioration on tranche performance of debt securities;
- The quality of underwriting for any collateral backing debt securities; and
- The effect of legal covenants associated with debt securities.

Changes in the level of an institution's ACLs may not always be directionally consistent with changes in the level of qualitative factor adjustments due to the incorporation of reasonable and supportable forecasts in estimating expected losses. For example, if improving credit quality trends are evident throughout an institution's portfolio in recent years, but management's evaluation of reasonable and supportable forecasts indicates expected deterioration in credit quality of the institution's financial assets during the forecast period, the ACL as a percentage of the portfolio may increase.

Collateral-Dependent Financial Assets

FASB ASC Topic 326 describes a collateral-dependent asset as a financial asset for which the repayment is expected to be provided substantially through the operation or sale of the collateral when the borrower, based on management's assessment, is experiencing financial difficulty as of the reporting date. For regulatory reporting purposes, the ACL for a collateral-dependent loan is measured using the fair value of collateral, regardless of whether foreclosure is probable.[21]

When estimating the ACL for a collateral-dependent loan, FASB ASC Topic 326 requires the fair value of collateral to be adjusted to consider estimated costs to sell if repayment or satisfaction of the loan depends on the sale of the collateral. ACL adjustments for estimated costs to sell are not appropriate when the repayment of a collateral-dependent loan is expected from the operation of the collateral.

The fair value of collateral securing a collateral-dependent loan may change over time. If the fair value of the collateral as of the ACL evaluation date has decreased since the previous ACL evaluation date, the ACL should be increased to reflect the additional deterioration in the fair value of the collateral. Likewise, if the fair value of the collateral has increased as of the ACL evaluation date, the increase in the fair value of the collateral is reflected through a reduction in the ACL. Any negative ACL that results is capped at

[17] For banks and savings associations, adversely classified or graded loans are loans rated ''substandard'' (or its equivalent) or worse under the institution's loan classification system. For credit unions, adversely graded loans are loans included in the more severely graded categories under the institution's credit grading system, *i.e.,* those loans that tend to be included in the credit union's ''watch lists.'' Criteria related to the classification of an investment security may be found in the interagency policy statement *Uniform Agreement on the Classification and Appraisal of Securities Held by Depository Institutions* issued by the FDIC, Board, and OCC in October 2013.

[18] See the ''Collateral-Dependent Financial Assets'' section of this policy statement for more information on collateral-dependent loans.

[19] Changes in economic and business conditions and developments included in qualitative factor adjustments are limited to those that affect the collectibility of an institution's financial assets and are relevant to the institution's financial asset portfolios. For example, an economic factor for current or forecasted unemployment at the national or state level may indicate a strong job market based on low national or state unemployment rates, but a local unemployment rate, which may be significantly higher, for example, because of the actual or forecasted loss of a major local employer may be more relevant to the collectibility of an institution's financial assets.

[20] This list is not all-inclusive and all of the factors listed may not be relevant to all institutions.

[21] The agencies, at times, prescribe specific regulatory reporting requirements that fall within a range of acceptable practice under GAAP. These specific reporting requirements, such as the requirement for institutions to apply the practical expedient in ASC 326–20–35–5 for collateral-dependent loans, regardless of whether foreclosure is probable, have been adopted to achieve safety and soundness and other public policy objectives and to ensure comparability among institutions. The regulatory reporting requirement to apply the practical expedient for collateral-dependent financial assets is consistent with the agencies' longstanding practice for collateral-dependent loans, and it continues to be limited to collateral-dependent loans. It does not apply to other financial assets such as held-to-maturity debt securities that are collateral-dependent.

the amount previously written off. Changes in the fair value of collateral described herein should be supported and documented through recent appraisals or evaluations.[22]

Troubled Debt Restructurings[23]

Expected credit losses on financial assets modified in TDRs or reasonably expected to be modified in TDRs (collectively, TDRs) are estimated under the same CECL methodology that is applied to other financial assets measured at amortized cost. Expected credit losses are evaluated on a collective basis, or, if a TDR does not share similar risk characteristics with other financial assets, on an individual basis.

FASB ASC Topic 326 allows an institution to use any appropriate loss estimation method to estimate ACLs for TDRs. However, there are circumstances when specific measurement methods are required. If a TDR, or a financial asset for which a TDR is reasonably expected, is collateral-dependent, the ACL is estimated using the fair value of collateral.

In addition, when management has a reasonable expectation of executing a TDR or if a TDR has been executed, the expected effect of the modification (*e.g.,* term extension or interest rate concession) is included in the estimate of the ACLs. Management should determine, support, and document how it identifies and estimates the effect of a reasonably expected TDR and estimates the related ACL. The estimated effect of reasonably expected TDRs may be included in an institution's qualitative factor adjustments.

Purchased Credit-Deteriorated Assets

FASB ASC Topic 326 introduces the concept of purchased credit-deteriorated (PCD) assets. PCD assets are acquired financial assets that, at acquisition, have experienced more-than-insignificant deterioration in credit quality since origination. FASB ASC Topic 326 does not provide a prescriptive definition of more-than-insignificant credit deterioration. The acquiring institution's management should establish and document a reasonable process to consistently determine what constitutes a more-than-insignificant deterioration in credit quality.

When recording the acquisition of PCD assets, the amount of expected credit losses as of the acquisition date is added to the purchase price of the financial assets rather than recording these losses through PCLs. This establishes the amortized cost basis of the PCD assets. Any difference between the unpaid principal balance of the PCD assets and the amortized cost basis of the assets as of the acquisition date is the non-credit discount or premium. The initial ACL and non-credit discount or premium determined on a collective basis at that acquisition date are allocated to the individual PCD assets.

After acquisition, ACLs for PCD assets should be adjusted at each reporting date with a corresponding debit or credit to the PCLs to reflect management's current estimate of expected credit losses. The non-credit discount recorded at acquisition will be accreted into interest income over the remaining life of the PCD assets on a level-yield basis.

Financial Assets With Collateral Maintenance Agreements

Institutions may have financial assets that are secured by collateral (such as debt securities) and are subject to collateral maintenance agreements requiring the borrower to continuously replenish the amount of collateral securing the asset. If the fair value of the collateral declines, the borrower is required to provide additional collateral as specified by the agreement.

FASB ASC Topic 326 includes a practical expedient for financial assets with collateral maintenance agreements where the borrower is required to provide collateral greater than or equal to the amortized cost basis of the asset and is expected to continuously replenish the collateral. In those cases, management may elect the collateral maintenance practical expedient and measure expected credit losses for these qualifying assets based on the fair value of the collateral.[24] If the fair value of the collateral is greater than the amortized cost of the financial asset and management expects the borrower to replenish collateral as needed, management may record an ACL of zero for the financial asset when the collateral maintenance practical expedient is applied. Similarly, if the fair value of the collateral is less than the amortized cost basis of the financial asset and management expects the borrower to replenish collateral as needed, the ACL is limited to the difference between the fair value of the collateral and the amortized cost basis of the asset as of the reporting date when applying the collateral maintenance practical expedient.

Accrued Interest Receivable

FASB ASC Topic 326 includes accrued interest receivable in the amortized cost basis of a financial asset. As a result, accrued interest receivable is included in the amounts for which ACLs are estimated. Generally, any accrued interest receivable that is not collectible is written off against the related ACL.

FASB ASC Topic 326 permits a series of independent accounting policy elections related to accrued interest receivable that alter the accounting treatment described in the preceding paragraph. These elections are made upon adoption of FASB ASC Topic 326 and may differ by financial asset portfolio. The available accounting policy elections[25] are:

- Management may elect not to measure ACLs for accrued interest receivable if uncollectible accrued interest is written off in a timely manner. Management should define and document its definition of a timely write-off.
- Management may elect to write off accrued interest receivable by either reversing interest income, recognizing the loss through PCLs, or through a combination of both methods.
- Management may elect to separately present accrued interest receivable from the associated financial asset in its

[22] For more information on regulatory expectations related to the use of appraisals and evaluations, see the *Interagency Appraisal and Evaluation Guidelines* published on December 10, 2010. Insured depository institutions should also refer to the interagency regulations on appraisals adopted by their primary federal regulator as follows: For national banks and federal savings associations, Subpart C of 12 CFR part 34; for state member banks, 12 CFR parts 208 and 225; for state nonmember banks, state savings associations, and insured state-licensed branches of foreign banks, 12 CFR part 323; and for national credit unions, 12 CFR part 722.

[23] A troubled debt restructuring is defined in ASC Subtopic 310–40, Receivables—Troubled Debt Restructurings by Creditors. The October 24, 2013, Interagency Supervisory Guidance Addressing Certain Issues Related to Troubled Debt Restructurings provides more information on TDRs including, but not limited to, accrual status, regulatory credit risk grade, classification and write-off treatment, and capitalized costs. This interagency supervisory guidance remains applicable, unless affected by FASB ASC Topic 326. Information on the reporting of a subsequent restructuring of a TDR may be found in the instructions for the Call Report.

[24] For example, an institution enters into a reverse repurchase agreement with a collateral maintenance agreement. Management may not need to record the expected credit losses at each reporting date as long as the fair value of the security collateral is greater than the amortized cost basis of the reverse repurchase agreement. Refer to ASC 326–20–55–46 for more information.

[25] The accounting policy elections related to accrued interest receivable that are described in this paragraph also apply to accrued interest receivable for an available-for-sale debt security that, for purposes of identifying and measuring an impairment, exclude the applicable accrued interest from both the fair value and amortized cost basis of the securities.

regulatory reports and financial statements, if applicable. The accrued interest receivable is presented net of ACLs (if any).

Financial Assets With Zero Credit Loss Expectations

There may be certain financial assets for which the expectation of credit loss is zero after evaluating historical loss information, making necessary adjustments for current conditions and reasonable and supportable forecasts, and considering any collateral or guarantee arrangements that are not free-standing contracts. Factors to consider when evaluating whether expectations of zero credit loss are appropriate may include, but are not limited to:

- A long history of zero credit loss;
- A financial asset that is fully secured by cash or cash equivalents;
- High credit ratings from rating agencies with no expected future downgrade; [26]
- Principal and interest payments that are guaranteed by the U.S. government;
- The issuer, guarantor, or sponsor can print its own currency and the currency is held by other central banks as reserve currency; and
- The interest rate on the security is recognized as a risk-free rate.

A loan that is fully secured by cash or cash equivalents, such as certificates of deposit issued by the lending institution, would likely have zero credit loss expectations. Similarly, the guaranteed portion of a U.S. Small Business Administration (SBA) loan or security purchased on the secondary market through the SBA's fiscal and transfer agent would likely have zero credit loss expectations because these financial assets are unconditionally guaranteed by the U.S. government. Examples of held-to-maturity debt securities that may result in expectations of zero credit loss include U.S. Treasury securities as well as mortgage-backed securities issued and guaranteed by the Government National Mortgage Association, the Federal Home Loan Mortgage Corporation, and the Federal National Mortgage Association. Assumptions related to zero credit loss expectations should be included in the institution's ACL documentation.

Estimated Credit Losses for Off-Balance-Sheet Credit Exposures

FASB ASC Topic 326 requires that an institution estimate expected credit losses for off-balance-sheet credit exposures within the scope of FASB ASC Topic 326 over the contractual period during which the institution is exposed to credit risk. The estimate of expected credit losses should take into consideration the likelihood that funding will occur as well as the amount expected to be funded over the estimated remaining contractual term of the off-balance-sheet credit exposures. Management should not record an estimate of expected credit losses for off-balance-sheet exposures that are unconditionally cancellable by the issuer.

Management must evaluate expected credit losses for off-balance-sheet credit exposures as of each reporting date. While the process for estimating expected credit losses for these exposures is similar to the one used for on-balance-sheet financial assets, these estimated credit losses are not recorded as part of the ACLs because cash has not yet been disbursed to fund the contractual obligation to extend credit. Instead, these loss estimates are recorded as a liability, separate and distinct from the ACLs.[27] The amount needed to adjust the liability for expected credit losses on off-balance-sheet credit exposures is reported as an other noninterest expense rather than being reported as part of the PCLs.[28]

Measurement of the ACL for Available-for-Sale Debt Securities

FASB ASC Subtopic 326–30, *Financial Instruments—Credit Losses—Available-for-Sale Debt Securities* (FASB ASC Subtopic 326–30) describes the accounting for expected credit losses associated with available-for-sale debt securities. Credit losses for available-for-sale debt securities are evaluated as of each reporting date when the fair value is less than amortized cost. FASB ASC Subtopic 326–30 requires credit losses to be calculated individually, rather than collectively, using a discounted cash flow method, through which management compares the present value of expected cash flows with the amortized cost basis of the security. An ACL is established, with a charge to the PCL, to reflect the credit loss component of the decline in fair value below amortized cost. If the fair value of the security increases over time, any ACL that has not been written off may be reversed through a credit to the PCL. The ACL for an available-for-sale debt security is limited by the amount that the fair value is less than the amortized cost, which is referred to as the fair value floor.

If management intends to sell an available-for-sale debt security or will more likely than not be required to sell the security before recovery of the amortized cost basis, the security's ACL should be written off and the amortized cost basis of the security should be written down to its fair value at the reporting date with any incremental impairment reported in income.

A change during the reporting period in the non-credit component of any decline in fair value below amortized cost on an available-for-sale debt security is reported in other comprehensive income, net of applicable income taxes.[29]

When evaluating impairment for available-for-sale debt securities, management may evaluate the amortized cost basis including accrued interest receivable, or may evaluate the accrued interest receivable separately from the remaining amortized cost basis. If evaluated separately, accrued interest receivable is excluded from both the fair value of the available-for-sale debt security and its amortized cost basis.[30]

Documentation Standards

For financial and regulatory reporting purposes, ACLs and PCLs must be determined in accordance with GAAP. ACLs and PCLs should be well documented, with clear explanations of the supporting analyses and rationale. Sound policies, procedures, and control systems should be appropriately tailored to an institution's size and complexity, organizational structure, business environment and strategy, risk appetite, financial asset characteristics, loan administration procedures,

[26] Management should not rely solely on credit rating agencies but should also make its own assessment based on third party research, default statistics, and other data that may indicate a decline in credit rating.

[27] The ACL associated with off-balance-sheet credit exposures is included in the ''Allowance for credit losses on off-balance-sheet credit exposures'' in *Schedule RC–G—Other Liabilities* in the Call Report and in the *Liabilities* schedule in NCUA Call Report Form 5300.

[28] Provisions for credit losses on off-balance-sheet credit exposures are included as part of ''Other noninterest expense'' in *Schedule RI—Income Statement* in the Call Report and in ''Credit Loss Expense—Off-Balance-Sheet Credit Exposures'' in the *Statement of Income and Expense* in NCUA Call Report Form 5300.

[29] Non-credit impairment on an available-for-sale debt security that is not required to be recorded through the ACL should be reported in other comprehensive income as described in ASC 326–30–35–2.

[30] The accounting policy elections described in the ''Accrued Interest Receivable'' section of this policy statement apply to accrued interest receivable recorded for an available-for-sale debt security if an institution excludes applicable accrued interest receivable from both the fair value and amortized cost basis of the security for purposes of identifying and measuring impairment.

investment strategy, and management information systems.[31] Maintaining, analyzing, supporting, and documenting appropriate ACLs and PCLs in accordance with GAAP is consistent with safe and sound banking practices.

The policies and procedures governing an institution's ACL processes and the controls over these processes should be designed, implemented, and maintained to reasonably estimate expected credit losses for financial assets and off-balance-sheet credit exposures as of the reporting date. The policies and procedures should describe management's processes for evaluating the credit quality and collectibility of financial asset portfolios, including reasonable and supportable forecasts about changes in the credit quality of these portfolios, through a disciplined and consistently applied process that results in an appropriate estimate of the ACLs. Management should review and, as needed, revise the institution's ACL policies and procedures at least annually, or more frequently if necessary.

An institution's policies and procedures for the systems, processes, and controls necessary to maintain appropriate ACLs should address, but not be limited to:

- Processes that support the determination and maintenance of appropriate levels for ACLs that are based on a comprehensive, well-documented, and consistently applied analysis of an institution's financial asset portfolios and off-balance-sheet credit exposures. The analyses and loss estimation processes used should consider all significant factors that affect the credit risk and collectibility of the financial asset portfolios;
- The roles, responsibilities, and segregation of duties of the institution's senior management and other personnel who provide input into ACL processes, determine ACLs, or review ACLs. These departments and individuals may include accounting, financial reporting, treasury, investment management, lending, special asset or problem loan workout teams, retail collections and foreclosure groups, credit review, model risk management, internal audit, and others, as applicable. Individuals with responsibilities related to the estimation of ACLs should be competent and well-trained, with the ability to escalate material issues;
- Processes for determining the appropriate historical period(s) to use as the basis for estimating expected credit losses and approaches for adjusting historical credit loss information to reflect differences in asset specific characteristics, as well as current conditions and reasonable and supportable forecasts that are different from conditions existing in the historical period(s);
- Processes for determining and revising the appropriate techniques and periods to revert to historical credit loss information when the contractual term of a financial asset or off-balance-sheet credit exposure extends beyond the reasonable and supportable forecast period(s);
- Processes for segmenting financial assets for estimating expected credit losses and periodically evaluating the segments to determine whether the assets continue to share similar risk characteristics;
- Data capture and reporting systems that supply the quality and breadth of relevant and reliable information necessary, whether obtained internally or externally, to support and document the estimates of appropriate ACLs for regulatory reporting requirements and, if applicable, financial statement and disclosure requirements;
- The description of the institution's systematic and logical loss estimation process(es) for determining and consolidating expected credit losses to ensure that the ACLs are recorded in accordance with GAAP and regulatory reporting requirements. This may include, but is not limited to:
  - Management's judgments, accounting policy elections, and application of practical expedients in determining the amount of expected credit losses;
  - The process for determining when a loan is collateral-dependent;
  - The process for determining the fair value of collateral, if any, used as an input when estimating the ACL, including the basis for making any adjustments to the market value conclusion and how costs to sell, if applicable, are calculated;
  - The process for determining when a financial asset has zero credit loss expectations;
  - The process for determining expected credit losses when a financial asset has a collateral maintenance provision; and
  - A description of and support for qualitative factors that affect collectibility of financial assets;
- Procedures for validating and independently reviewing the loss estimation process as well as any changes to the process from prior periods;
- Policies and procedures for the prompt write-off of financial assets, or portions of financial assets, when available information confirms the assets to be uncollectible, consistent with regulatory reporting requirements; and
- The systems of internal controls used to confirm that the ACL processes are maintained and periodically adjusted in accordance with GAAP and interagency guidelines establishing standards for safety and soundness.

Internal control systems for the ACL estimation processes should:

- Provide reasonable assurance regarding the relevance, reliability, and integrity of data and other information used in estimating expected credit losses;
- Provide reasonable assurance of compliance with laws, regulations, and the institution's policies and procedures;
- Provide reasonable assurance that the institution's financial statements are prepared in accordance with GAAP, and the institution's regulatory reports are prepared in accordance with the applicable instructions;
- Include a well-defined and effective loan review and grading process that is consistently applied and identifies, measures, monitors, and addresses asset quality problems in an accurate, sound and timely manner. The loan review process should respond to changes in internal and external factors affecting the level of credit risk in the portfolio; and
- Include a well-defined and effective process for monitoring credit quality in the debt securities portfolio.

Analyzing and Validating the Overall Measurement of ACLs

To ensure that ACLs are presented fairly, in accordance with GAAP and regulatory reporting requirements, and are transparent for regulatory examinations, management should document its measurements of the amounts of ACLs reported in regulatory reports and financial statements, if applicable, for each type of financial asset (*e.g.,* loans, held-to-maturity debt securities, and available-for-sale debt securities) and for off-balance-sheet credit exposures. This documentation should include ACL calculations, qualitative adjustments, and any adjustments to the ACLs that are required as part of the internal review and challenge process. The board of directors, or a committee thereof, should review management's assessments of and justifications for the reported amounts of ACLs.

[31] Management often documents policies, procedures, and controls related to ACLs in accounting or credit risk management policies, or a combination thereof.

Various techniques are available to assist management in analyzing and evaluating the ACLs. For example, comparing estimates of expected credit losses to actual write-offs in aggregate, and by portfolio, may enable management to assess whether the institution's loss estimation process is sufficiently designed.[32] Further, comparing the estimate of ACLs to actual write-offs at the financial asset portfolio level allows management to analyze changing portfolio characteristics, such as the volume of assets or increases in write-off rates, which may affect future forecast adjustments. Techniques applied in these instances do not have to be complex to be effective, but, if used, should be commensurate with the institution's size and complexity.

Ratio analysis may also be useful for evaluating the overall reasonableness of ACLs. Ratio analysis assists in identifying divergent or emerging trends in the relationship of ACLs to other factors such as adversely classified or graded loans, past due and nonaccrual loans, total loans, historical gross write-offs, net write-offs, and historic delinquency and default trends for securities.

Comparing the institution's ACLs to those of peer institutions may provide management with limited insight into management's own ACL estimates. Management should apply caution when performing peer comparisons as there may be significant differences among peer institutions in the mix of financial asset portfolios, reasonable and supportable forecast period assumptions, reversion techniques, the data used for historical loss information, and other factors.

When used prudently, comparisons of estimated expected losses to actual write-offs, ratio analysis, and peer comparisons can be helpful as a supplemental check on the reasonableness of management's assumptions and analyses. Because appropriate ACLs are institution-specific estimates, the use of comparisons does not eliminate the need for a comprehensive analysis of financial asset portfolios and the factors affecting their collectibility.

When an appropriate expected credit loss framework has been used to estimate expected credit losses, it is inappropriate for the board of directors or management to make further adjustments to ACLs for the sole purpose of reporting ACLs that correspond to a peer group median, a target ratio, or a budgeted amount.

After analyzing ACLs, management should periodically validate the loss estimation process, and any changes to the process, to confirm that the process remains appropriate for the institution's size, complexity, and risk profile. The validation process should include procedures for review by a party with appropriate knowledge, technical expertise, and experience who is independent of the institution's credit approval and ACL estimation processes. A party who is independent of these processes could be from internal audit staff, a risk management unit of the institution independent of management supervising these processes, or a contracted third-party. One party need not perform the entire analysis as the validation may be divided among various independent parties.[33]

Responsibilities of the Board of Directors

The board of directors, or a committee thereof, is responsible for overseeing management's significant judgments and estimates used in determining appropriate ACLs. Evidence of the board of directors' oversight activities is subject to review by examiners. These activities should include, but are not limited to:

- Retaining experienced and qualified management to oversee all ACL and PCL activities;
- Reviewing and approving the institution's written loss estimation policies, including any revisions thereto, at least annually;
- Reviewing management's assessment of the loan review system and management's conclusion and support for whether the system is sound and appropriate for the institution's size and complexity;
- Reviewing management's assessment of the effectiveness of processes and controls for monitoring the credit quality of the investment portfolio;
- Reviewing management's assessments of and justifications for the estimated amounts reported each period for the ACLs and the PCLs;
- Requiring management to periodically validate, and, when appropriate, revise loss estimation methods;
- Approving the internal and external audit plans for the ACLs, as applicable; and
- Reviewing any identified audit findings and monitoring resolution of those items.

Responsibilities of Management

Management is responsible for maintaining ACLs at appropriate levels and for documenting its analyses in accordance with the concepts and requirements set forth in GAAP, regulatory reporting requirements, and this policy statement. Management should evaluate the ACLs reported on the balance sheet as of the end of each period (and for credit unions, prior to paying dividends), and debit or credit the related PCLs to bring the ACLs to an appropriate level as of each reporting date. The determination of the amounts of the ACLs and the PCLs should be based on management's current judgments about the credit quality of the institution's financial assets and should consider known and expected relevant internal and external factors that significantly affect collectibility over reasonable and supportable forecast periods for the institution's financial assets as well as appropriate reversion techniques applied to periods beyond the reasonable and supportable forecast periods. Management's evaluations are subject to review by examiners.

In carrying out its responsibility for maintaining appropriate ACLs, management should adopt and adhere to written policies and procedures that are appropriate to the institution's size and the nature, scope, and risk of its lending and investing activities. These policies and procedures should address the processes and activities described in the ''Documentation Standards'' section of this policy statement.

Management fulfills other responsibilities that aid in the maintenance of appropriate ACLs. These activities include, but are not limited to:

- Establishing and maintaining appropriate governance activities for the loss estimation process(es). These activities may include reviewing and challenging the assumptions used in estimating expected credit losses and designing and executing effective internal controls over the credit loss estimation method(s);
- Periodically performing procedures that compare credit loss estimates to actual write-offs, at the portfolio level and in aggregate, to confirm that

[32] Institutions using models in the loss estimation process may incorporate a qualitative factor adjustment in the estimate of expected credit losses to capture the variance between modeled credit loss expectations and actual historical losses when the model is still considered predictive and fit for use. Institutions should monitor this variance, as well as changes to the variance, to determine if the variance is significant or material enough to warrant further changes to the model.

[33] Engaging the institution's external auditor to perform the validation process described in this paragraph may impair the auditor's independence under applicable auditor independence standards and prevent the auditor from performing an independent audit of the institution's financial statements.

amounts recorded in the ACLs were sufficient to cover actual credit losses. This analysis supports that appropriate ACLs were recorded and provides insight into the loss estimation process's ability to estimate expected credit losses. This analysis is not intended to reflect the accuracy of management's economic forecasts;

- Periodically validating the loss estimation process(es), including changes, if any, to confirm it is appropriate for the institution; and
- Engaging in sound risk management of third-parties involved [34] in ACL estimation process(es), if applicable, to ensure that the loss estimation processes are commensurate with the level of risk, the complexity of the third-party relationship and the institution's organizational structure.

Additionally, if an institution uses loss estimation models in determining expected credit losses, management should evaluate the models before they are employed and modify the model logic and assumptions, as needed, to help ensure that the resulting loss estimates are consistent with GAAP and regulatory reporting requirements.[35] To demonstrate such consistency, management should document its evaluations and conclusions regarding the appropriateness of estimating credit losses with models. When used for multiple purposes within an institution, models should be specifically adjusted and validated for use in ACL loss estimation processes. Management should document and support any adjustments made to the models, the outputs of the models, and compensating controls applied in determining the estimated expected credit losses.

[34] Guidance on third party service providers may be found in SR Letter 13–19/Consumer Affairs Letter 13–21, *Guidance on Managing Outsourcing Risk* (FRB); Financial Institution Letter (FIL) 44–2008, *Guidance for Managing Third Party Risk* (FDIC); Supervisory Letter No. 07–01, *Evaluating Third Party Relationships* (NCUA); and OCC Bulletin 2013–29, *Third Party Relationships: Risk Management Guidance,* OCC Bulletin 2017–7, *Third Party Relationships: Supplemental Examination Procedures,* and OCC Bulletin 2017–21, *Third Party Relationships: Frequently Asked Questions to Supplement OCC Bulletin 2013–29.*

[35] See the interagency statement titled, *Supervisory Guidance on Model Risk Management,* published by the Board in SR Letter 11–7 and OCC Bulletin 2011–12 on April 4, 2011. The statement also addresses the incorporation of vendor products into an institution's model risk management framework following the same principles relevant to in-house models. The FDIC adopted the interagency statement on June 7, 2017. Institutions supervised by the FDIC should refer to FIL 22–2017, *Adoption of Supervisory Guidance on Model Risk Management,* including the statement of applicability in the FIL.

Examiner Review of ACLs

Examiners are expected to assess the appropriateness of management's loss estimation processes and the appropriateness of the institution's ACL balances as part of their supervisory activities. The review of ACLs, including the depth of the examiner's assessment, should be commensurate with the institution's size, complexity, and risk profile. As part of their supervisory activities, examiners generally assess the credit quality and credit risk of an institution's financial asset portfolios, the adequacy of the institution's credit loss estimation processes, the adequacy of supporting documentation, and the appropriateness of the reported ACLs and PCLs in the institution's regulatory reports and financial statements, if applicable. Examiners may consider the significant factors that affect collectibility, including the value of collateral securing financial assets and any other repayment sources. Supervisory activities may include evaluating management's effectiveness in assessing credit risk for debt securities (both prior to purchase and on an on-going basis). In reviewing the appropriateness of an institution's ACLs, examiners may:

- Evaluate the institution's ACL policies and procedures and assess the loss estimation method(s) used to arrive at overall estimates of ACLs, including the documentation supporting the reasonableness of management's assumptions, valuations, and judgments. Supporting activities may include, but, are not limited to:
  - Evaluating whether management has appropriately considered historical loss information, current conditions, and reasonable and supportable forecasts, including significant qualitative factors that affect the collectibility of the financial asset portfolios;
  - Assessing loss estimation techniques, including loss estimation models, if applicable, as well as the incorporation of qualitative adjustments to determine whether the resulting estimates of expected credit losses are in conformity with GAAP and regulatory reporting requirements; and
  - Evaluating the adequacy of the documentation and the effectiveness of the controls used to support the measurement of the ACLs;
- Assess the effectiveness of board oversight as well as management's effectiveness in identifying, measuring, monitoring, and controlling credit risk. This may include, but is not limited to, a review of underwriting standards and practices, portfolio composition and trends, credit risk review functions, risk rating systems, credit administration practices, investment securities management practices, and related management information systems and reports;
- Review the appropriateness and reasonableness of the overall level of the ACLs relative to the level of credit risk, the complexity of the institution's financial asset portfolios, and available information relevant to assessing collectibility, including consideration of current conditions and reasonable and supportable forecasts. Examiners may include a quantitative analysis (*e.g.,* using management's results comparing expected write-offs to actual write-offs as well as ratio analysis) to assess the appropriateness of the ACLs. This quantitative analysis may be used to determine the reasonableness of management's assumptions, valuations, and judgments and understand variances between actual and estimated credit losses. Loss estimates that are consistently and materially over or under predicting actual losses may indicate a weakness in the loss forecasting process;
- Review the ACLs reported in the institution's regulatory reports and in any financial statements and other key financial reports to determine whether the reported amounts reconcile to the institution's estimate of the ACLs. The consolidated loss estimates determined by the institution's loss estimation method(s) should be consistent with the final ACLs reported in its regulatory reports and financial statements, if applicable;
- Verify that models used in the loss estimation process, if any, are subject to initial and ongoing validation activities. Validation activities include evaluating and concluding on the conceptual soundness of the model, including developmental evidence, performing ongoing monitoring activities, including process verification and benchmarking, and analyzing model output.[36] Examiners may review model validation findings, management's response to those findings, and applicable action plans to remediate any concerns, if applicable. Examiners may also assess the adequacy of the institution's processes to implement changes in a timely manner; and
- Review the effectiveness of the institution's third-party risk management framework associated with the estimation of ACLs, if applicable, to assess whether the processes are commensurate with the level of risk, the complexity and nature of the

[36] See footnote 35.

relationship, and the institution's organizational structure. Examiners may determine whether management monitors material risks and deficiencies in third-party relationships, and takes appropriate action as needed.[37]

When assessing the appropriateness of ACLs, examiners should recognize that the processes, loss estimation methods, and underlying assumptions an institution uses to calculate ACLs require the exercise of a substantial degree of management judgment. Even when an institution maintains sound procedures, controls, and monitoring activities, an estimate of expected credit losses is not a single precise amount and may result in a range of acceptable outcomes for these estimates. This is a result of the flexibility FASB ASC Topic 326 provides institutions in selecting loss estimation methods and the wide range of qualitative and forecasting factors that are considered.

Management's ability to estimate expected credit losses should improve over the contractual term of financial assets as substantive information accumulates regarding the factors affecting repayment prospects. Examiners generally should accept an institution's ACL estimates and not seek adjustments to the ACLs, when management has provided adequate support for the loss estimation process employed, and the ACL balances and the assumptions used in the ACL estimates are in accordance with GAAP and regulatory reporting requirements. It is inappropriate for examiners to seek adjustments to ACLs for the sole purpose of achieving ACL levels that correspond to a peer group median, a target ratio, or a benchmark amount when management has used an appropriate expected credit loss framework to estimate expected credit losses.

If the examiner concludes that an institution's reported ACLs are not appropriate or determines that its ACL evaluation processes or loss estimation method(s) are otherwise deficient, these concerns should be noted in the report of examination and communicated to the board of directors and senior management.[38] Additional supervisory action may be taken based on the magnitude of the shortcomings in ACLs, including the materiality of any errors in the reported amounts of ACLs.

Dated: October 1, 2019.

Joseph M. Otting,

Comptroller of the Currency.

By order of the Board of Governors of the Federal Reserve System, October 9, 2019.

Ann E. Misback,

Secretary of the Board.

Federal Deposit Insurance Corporation.

By order of the Board of Directors.

Dated at Washington, DC, on August 20, 2019.

Valerie J. Best,

Assistant Executive Secretary.

By the National Credit Union Administration Board on September 3, 2019.

Gerard Poliquin,

Secretary of the Board.

[FR Doc. 2019–22655 Filed 10–16–19; 8:45 am]

BILLING CODE 4810–33–P; 7590–01 P; 6741–01–P; 6210–01–P

[37] See footnote 34.

[38] Each agency has formal and informal communication channels for sharing supervisory information with the board of directors and management depending on agency practices and the nature of the information being shared. These channels may include, but are not limited to, institution specific supervisory letters, letters to the industry, transmittal letters, visitation findings summary letters, targeted review conclusion letters, or official examination or inspection reports.

DEPARTMENT OF AGRICULTURE

Forest Service

36 CFR Part 294

RIN 0596–AD37

Special Areas; Roadless Area Conservation; National Forest System Lands in Alaska

AGENCY: Forest Service, USDA.

ACTION: Notice of proposed rulemaking; request for comment.

SUMMARY: The United States Department of Agriculture (USDA) is proposing to exempt the Tongass National Forest from the 2001 Roadless Area Conservation Rule, which prohibits tree harvest and road construction/reconstruction within inventoried roadless areas with certain limited exceptions. In addition, the proposed rule would provide an administrative procedure for correcting and modifying inventoried roadless area boundaries on the Chugach National Forest. The USDA invites written comments on the proposed rule and the draft environmental impact statement (DEIS). The proposed rule would not directly authorize any ground-disturbing activities. Substantive comments received during the comment period will be considered in developing the final rule and final environmental impact statement (FEIS). The final rule will be published in the **Federal Register**.

DATES: Comments must be received in writing by December 16, 2019.

ADDRESSES: Comments may be submitted electronically to *www.fs.usda.gov/project/?project=54511*. Written comments can be sent hard copy to: Alaska Roadless Rule, USDA Forest Service, P.O. Box 21628, Juneau, Alaska 99802–1628. All comments, including names and addresses, are placed in the record and are available for public inspection and copying. The public may inspect comments received at *www.fs.usda.gov/project/?project=54511*.

FOR FURTHER INFORMATION CONTACT: Ken Tu, Interdisciplinary Team Leader, at 202–403–8991 or *akroadlessrule@usda.gov*. Individuals using telecommunication devices for the deaf (TDD) may call the Federal Information Relay Services at 1–800–877–8339 between 8 a.m. and 8 p.m. Eastern Time, Monday through Friday.

SUPPLEMENTARY INFORMATION:

Background

The USDA Forest Service (hereafter Forest Service) manages National Forest System (NFS) lands to maintain and enhance the quality of the environment to meet the Nation's current and future needs. Forest Service land management supports recreation, water, timber, fish, wildlife, wilderness, aesthetic values and a variety of resource development activities for current and future generations. As a leader in natural resource conservation, the Forest Service provides direction for the management and use of the Nation's forests, rangeland, and aquatic ecosystems under its jurisdiction.

On January 12, 2001, the USDA promulgated the Roadless Area Conservation Rule (hereafter 2001 Roadless Rule) (66 FR 3244), establishing nationwide prohibitions on timber harvest, road construction, and road reconstruction within inventoried roadless areas with certain limited exceptions. The intent of the 2001 Roadless Rule is to provide lasting protection for inventoried roadless areas within the National Forest System in the context of multiple-use land management. Based on the State of Alaska's Roadless Rule Petition (described below) and a review of public comment, USDA analyzed rulemaking alternatives addressing whether and how the national prohibitions on timber harvesting, road construction, and road reconstruction should apply on the Tongass National Forest.

In 2001, the State of Alaska filed a complaint challenging the USDA's promulgation of the 2001 Roadless Rule and its application in Alaska. *State of*

Alaska v. *USDA,* A01–039 CV (JKS) (D. Alaska). The USDA and the State of Alaska reached a settlement in 2003, and the USDA subsequently issued a rule temporarily exempting the Tongass National Forest from the 2001 Roadless Rule. In 2011, a federal court set aside the Tongass Exemption and reinstated, with clarifying instructions, the 2001 Roadless Rule on the Tongass National Forest. The district court's ruling was initially reversed by a three-judge panel of the Ninth Circuit, but was ultimately upheld in a 6–5 *en banc* ruling in 2015. Consequently, the 2001 Roadless Rule (as provided for in the district court's Judgment) remains in effect in Alaska and the Forest Service continues to apply the 2001 Roadless Rule to both the Tongass and Chugach National Forests.

Currently there are over 21.9 million acres of national forest in the State of Alaska, of which approximately 14.7 million acres (67%) are considered inventoried roadless areas as defined by the 2001 Roadless Rule, including both the Tongass and Chugach National Forests. The Tongass National Forest, in particular, is approximately 16.7 million acres of which approximately 9.2 million (55%) acres are designated inventoried roadless areas. This rulemaking focuses on the Tongass National Forest roadless areas, along with a boundary modification and correction provision that would apply to the Chugach National Forest.

State of Alaska Petition

In January 2018, Governor Bill Walker submitted a petition on behalf of the State of Alaska to Secretary of Agriculture Sonny Perdue pursuant to the Administrative Procedure Act. The petition requested the USDA consider creation of a state-specific rule to exempt the Tongass National Forest from the 2001 Roadless Rule. In June 2018, the Secretary of Agriculture agreed to address the State's concerns on roadless area management and economic development opportunities in Southeast Alaska through a rulemaking process. The Secretary directed the Forest Service to begin working with representatives from the State of Alaska concerning a state-specific roadless rule. On August 2, 2018, the State of Alaska and the USDA Forest Service signed a memorandum of understanding concerning the development of the state-specific rule. The Forest Service initiated its environmental analysis process with the publication in the **Federal Register** of a notice of intent to prepare an environmental impact statement on August 30, 2018 (83 FR 44252).

On September 6, 2018, Governor Walker issued Administrative Order 299 to establish the Alaska Roadless Rule Citizen Advisory Committee (the Committee) to provide an opportunity for Southeast Alaskans to advise the State of Alaska on the future management of roadless areas in the Tongass National Forest. The Committee's report identifies that it was comprised of 13 members, appointed by Governor Walker, intended to represent a diversity of perspectives, including Alaska Native Corporations and tribes, fishing, timber, conservation, tourism, utilities, mining, transportation, local government, and the Alaska Division of Forestry. The Committee's specific task was to present a written report on the rulemaking process to the Governor and State Forester, which included options for a state-specific roadless rule. The Committee met for three in-person meetings during the fall of 2018 (October 2–3 in Juneau; October 24–26 in Ketchikan; and November 6–8 in Sitka). Meetings were open to the public and each meeting included an opportunity for public comment. The Committee's Report was submitted to the Governor and State Forester in late November 2018 and recommendations from the Committee informed the State of Alaska input, as a cooperating agency, to the Forest Service in the development of the alternatives. The final Committee report can be found at: *http://bit.ly/akroadlessreport.*

Proposed Alaska Roadless Rule

The proposed rule exempts the Tongass National Forest from the 2001 Roadless Rule, is responsive to the State of Alaska's petition, and is based on Alternative 6 of the DEIS. Removing the regulatory designation of roadless areas on the Tongass National Forest would not authorize any ground disturbing activities. Instead, the proposed rule would return decision-making authority to the Forest Service, allowing decisions concerning timber harvest, road construction, and roadless area management on the Tongass National Forest to be made by local officials on a case-by-case basis.

The 2001 Roadless Rule would remain applicable to the Chugach National Forest. However new administrative provisions for correcting and modifying inventoried roadless area boundaries would be applied to the Chugach National Forest to allow for limited adjustments to remedy clerical errors, improvements in mapping technology, conformance to statutory changes, or incorporation of changes due to land adjustments.

Rationale for the Proposed Rule

The Secretary of Agriculture has broad authority to protect and administer the National Forest System through regulation as provided by the Organic Administration Act of 1897 (the Organic Act), the Multiple-Use Sustained Yield Act of 1960 (MUSYA), and the National Forest Management Act of 1976 (NFMA). These statutes provide the Secretary with discretion to determine the proper uses within any area, including the appropriate resource emphasis and mix of uses. For decades, USDA has worked with States, Tribes, local communities and collaborative groups toward land management solutions for roadless areas. Sometimes solutions have been found nationally. Sometimes a state-by-state approach has been the best option. Often, the solutions are found forest by forest, or even area by area. USDA remains committed to working closely with States, Tribes, and others toward shared stewardship of National Forest System lands and resources.

In selecting the proposed rule among the several alternatives considered, the Department has given substantial weight to the State's policy preferences as expressed in the incoming Petition. The State's preference to emphasize rural economic development opportunities is consistent with the findings of the Interagency Task Force on Agriculture and Rural Prosperity established by Executive Order 13790 (issued Apr. 25, 2017). *See* Report to the President of the United States from the Task Force on Agriculture and Rural Prosperity (Oct. 21, 2017), *https://www.usda.gov/sites/default/files/documents/rural-prosperity-report.pdf.* USDA recognizes that ensuring rural Americans can achieve a high quality of life is one of the foundations of prosperity. *See id.* at 2, 21–25; *see also id.* at 26–29, 35–42 (calls to action for supporting a rural workforce and developing the rural economy). The State's views on how to balance economic development and environmental protection offer valuable insight when making management decisions concerning NFS lands within Alaska.

The USDA is acutely aware of the heightened sense of expectation concerning adjustments to administration and management of roadless areas on the Tongass National Forest. See *Organized Village of Kake* v. *State of Alaska,* 795 F.3d 956 (9th Cir 2015) (*en banc*). USDA's consideration of whether or how to apply the original 2001 Roadless Rule on the Tongass National Forest itself substantially evolved during the 2001 rulemaking,

culminating in the identification of four different policy preferences as described in the 2001 final rule, including the alternative proposed here. *See generally* 66 FR 3244, 3262–63 (Jan. 12, 2001) (final 2001 Roadless Rule); *see id.* at 3263 (''The Tongass Exempt alternative did not apply a national prohibition to the Tongass National Forest. It allowed road construction and reconstruction on the Tongass to continue subject to existing land management plan prescriptions. Future proposals for road activities in inventoried roadless areas would be considered on a case-by-case basis.''); *see id.* at 3266 (giving one-sentence explanation for rejection of Tongass Exempt alternative); *id.* at 3254–55 (lengthier discussion). Similarly, the 2003 Tongass Exemption rulemaking reflected not so much a change of underlying facts or circumstance but instead reflected a different policy perspective on the roadless policy question. These sorts of normative policy preferences and judgments are inherent in the Department's authority to manage National Forest System lands and resources.

USDA has listened carefully to the many divergent views and interests concerning the appropriate policy approach for these roadless areas, and, as is further explained below and in the DEIS, USDA has considered the factual and normative considerations at issue in past rulemakings concerning this matter, including the original 2001 Roadless Rule rulemaking, *see, e.g.,* 66 FR at 3254–55, as well as more recent factual and legal developments. There is broad agreement that the circumstances of the Tongass National Forest are unique in a number of respects. The Tongass differs from other national forests with respect to size, percentage of roadless areas, amount of NFS lands and dependency of 32 communities on federal lands, among other Alaska- and Tongass-specific statutory considerations (*e.g.,* the Alaska National Interest Lands Conservation Act and the Tongass Timber Reform Act). There is not consensus over how to manage the Forest given those unique features. The key factual issues (further discussed below and in the DEIS) are generally well understood by a wide range of stakeholders; but ultimately these stakeholders' good faith disagreements over preferred outcomes are rooted in value judgments and normative preferences.

In part because of such sharply divided policy priorities (for example, differing value judgments and normative preferences concerning rural prosperity, competing economic interests, environmental tradeoffs-), the Department believes that the national rule's one-size-fits-all approach to roadless area management is not the best approach for roadless area management on the Tongass National Forest. Instead, the circumstances of the Tongass National Forest appear to be best managed through the local planning processes, as is generally true for forest management pursuant to the Organic Act, MUSYA, and NFMA. The Forest Service's 40 years of experience with the forest planning system under NFMA, which includes forest plans subject to periodic review and adjustment, routinely demonstrates that system's capacity to provide durable and widely accepted solutions providing for balanced multiple use and sustained yield of the many goods and services provided by the National Forest System.

The analysis set out in the DEIS indicates that removal of regulatory roadless designations and prohibitions on the Tongass National Forest would not cause a substantial loss of roadless protection. The proposed rule would effectively bring only 185,000 acres (~2%) out of 9.2 million designated as inventoried roadless areas on the Tongass National Forest into the set of lands that may be considered for timber harvest. When examined in 2016, the Forest Service projected that only 17,000 acres of old-growth and 11,800 acres of young-growth might be harvested over the next 100 years. That modest addition of suitable timber lands would allow local managers greater flexibility in the selection and design of future timber sale areas. This improved flexibility could, in turn, improve the Forest Service's ability to offer economic timber sales that better meet the needs of the timber industry and contribute to rural economies. Despite the proposed regulatory exemption, the remaining 9 million acres would not be scheduled or expected to be subject to timber harvest activities. Of course, any proposed timber harvest or road construction would be individually reviewed and environmental impacts minimized through the protective measures set out in the Tongass Forest Plan and other conservation requirements.

Notably, approximately 3.6 million acres in key watersheds (defined in the 2016 Forest Plan as Tongass 77 Watersheds and The Nature Conservancy/Audubon Conservation Areas) are managed for no old-growth timber harvest, thus minimizing adverse impacts to fisheries. In addition, the Tongass Timber Reform Act (Pub. L. 101–626, Title II, Section 201) and the National Defense Authorization Act for Fiscal Year 2015 (Pub. L. 113–291, 128 Stat. 3729, Section 3720(f)) designated approximately 856,000 acres as Land Use Designation (LUD) II areas, which are managed in a roadless state to retain their wildland character.

Aside from the flexibility that would be attained for timber harvest activities, the proposed exemption would allow forest plan direction to guide other access needs that support isolated rural communities in the unique island archipelago environment of the Tongass National Forest. Specifically, the proposed rule would promote clarity and remove doubt concerning standards for the construction of roads that may be needed for access to municipal water and wastewater utility systems, Alaska Native cultural sites, micro and small timber sales, aquaculture facilities, and administrative access to designated experimental forests.

The proposed rule is a deregulatory action, consistent with the goals of Executive Order 13771, Reducing Regulation and Controlling Regulatory Costs. The proposed rule would create an incremental reduction in the cost of conducting compliance reviews of permissible projects proposed in designated inventoried roadless areas on the Tongass National Forest, thus reducing expenditure of taxpayer dollars. Though usually prompt, internal compliance reviews can take months to complete. Although a few months may not represent a substantial burden, it could impact businesses through additional costs, thus reducing the attractiveness to investors.

The overarching goal of the proposed rule is to reach a long-term, durable approach to roadless area management that accommodates the unique biological, social, and economic situation found in and around the Tongass National Forest. The proposed rule provides local forest managers an avenue for a long-term durable approach for managing the Tongass National Forest, unencumbered by the 2001 Roadless Rule, through the local forest planning process. The existing Forest Plan and other conservation measures would continue to provide protections that allow roadless area values to prevail on the Tongass National Forest.

2016 Tongass National Forest Land and Resource Management Plan

The 2001 Roadless Rule was largely not operational on the Tongass until 2011, leading to the creation of so called ''roaded roadless'' areas, which are areas designated as inventoried roadless areas by the 2001 Roadless Rule that have been subsequently harvested and/or

roaded. The Tongass Land and Resource Management Plan (Forest Plan) was amended in 2008 and again in 2016. Both amendments, particularly the 2016 amendment, substantially accelerated the Forest Service's movement toward a timber harvest program that would focus on second growth harvests. While estimating long-term market demand for Tongass timber is inherently uncertain and there are differences in opinion regarding long-term forecasts of market demand, the Record of Decision for the 2016 Tongass Forest Plan concluded that 46 million board feet (MMBF) of timber a year was reasonable, conservative, and based on the best available information. Subsequent review of the analysis completed for the Forest Plan indicates that there is no data supporting the conclusion that circumstances have changed or are likely to change with regard to the market demand for Tongass timber in the near- or long-term future due to overall limited competitiveness of Tongass timber in domestic and export markets. Therefore, the DEIS for the proposed Alaska Roadless Rule assumes that the harvest levels projected in the Tongass Forest Plan will remain the same, and that the changes to roadless area management in any Alaska Roadless Rule will provide more flexibility for those timber harvest opportunities.

The 2016 Forest Plan (*https://www.fs.usda.gov/internet/FSE_DOCUMENTS/fseprd527907.pdf*) was the product of an extensive, collaborative effort with members of the public and the Tongass Advisory Committee—a committee organized under the Federal Advisory Committee Act. The proposed Alaska Roadless Rule would not alter the Forest Plan's management area designations, harvest levels, substantive requirements (goals, objectives, standards, and guidelines), or the young-growth transition strategy, except for the administrative changes noted below concerning suitable lands determinations specifically issued to implement the 2001 Roadless Rule. Possible impacts from this rulemaking are discussed in the Regulatory Impact Assessment and DEIS in terms of the baseline conditions described in the 2016 Forest Plan.

The proposed rule does not change the projected timber sale quantity or timber demand projections set out in the Tongass Forest Plan. The Tongass National Forest, in compliance with the Tongass Timber Reform Act (1990), seeks to provide an annual supply of timber to meet market demand to the extent consistent with providing for multiple use and sustained yield of all renewable forest resources, and other requirements. While projected harvest levels are not expected to be materially different under any of the alternatives under consideration, the various alternatives considered in the DEIS for the roadless rule can influence the potential location or likelihood of future timber harvesting. In other words, the alternatives examine different mixes of land areas and timber restrictions that would incrementally increase management flexibility for how the forest plan's timber harvest goals can be achieved, but does not fundamentally alter the plan's underlying goals or projected outcomes.

Relationship of the Proposed Rule to the Forest Plan

The National Forest Management Act of 1976 (NFMA) requires the Forest Service to develop, maintain and, as appropriate, revise land and resource management plans (forest plans) for units of the National Forest System. Forest plans provide a framework for integrated resource management and for guiding project and activity decision making, but plans do not authorize projects or activities or commit the Forest Service to take action. A revised Tongass Forest Plan was issued in 1997, and amended in 2008 and 2016. Forest planning is a distinct and separate process from USDA's various roadless rulemakings. *See Kootenai Tribe of Idaho* v. *Veneman,* 313 F.2d 1094 (9th Cir. 2002); and *State of Wyoming* v. *USDA,* 661 F.3d 1209 (10th Cir. 2011).

All forest plans must conform to existing laws and regulations as well as new laws and regulations. See 36 CFR 219.1(f) and 219.13(c). All of USDA's previous roadless rules, national and state-specific, have directed that: (1) No amendment or revision of any forest plan was compelled by promulgation of such rules, (2) subsequent forest planning decisions could not revise the Secretary's regulatory instructions, and (3) line officers were to conform project decisions to the prohibitions and exceptions set forth in the applicable rules. The proposed rule would continue this approach with one minor exception.

The proposed rule would direct the Tongass Forest Supervisor to provide notice of an administrative change (36 CFR 219.13(c)) concerning lands that were deemed unsuitable in the 2016 Tongass Forest Plan (See Tongass Forest Plan, Appendix A: Identification of Lands Suitable for Timber Production and Limitations on Timber Harvest) solely due to the application of the 2001 Roadless Rule. Similarly, an administrative change addressing timber suitability would occur for other alternatives that alter the underlying assumptions of the 2016 plan's identification of suitable lands. Any such lands would be appropriately returned to the suitable timber base via the administrative change provision of the planning regulations. All other aspects of the Tongass Forest Plan would remain operational under the proposed rule including the goals, objectives, management prescriptions, standards, guidelines, projected timber sale quantity, projected wood sale quantity, and young-growth transition strategy. This includes standards and guidelines for non-timber resources (for example, riparian management standards and guidelines, which provide protection for fisheries with subsistence and commercial importance). All timber harvest, including any timber harvesting in areas formerly designated as inventoried roadless areas, would be compelled to adhere to these resource standards and guidelines (fisheries, water quality, air, recreation, etc.), thus providing continuation of 2016 Forest Plan protections under all the regulatory alternatives.

Although the Forest Service has broad discretion during forest plan revision to modify management direction, any change would need to be consistent with applicable law, regulation, and policies, including any final Alaska Roadless Rule. Similarly, the Tongass Timber Reform Act directs the Forest Service to seek to provide a supply of timber from the Tongass National Forest that meets annual market demand and the market demand for each planning cycle to the extent consistent with providing for the multiple-use and sustained-yield of all renewable resources and other applicable requirements, including the NFMA. The current Forest Plan anticipates sufficient timber availability to meet projected demand as described in the 2016 Tongass Forest Plan Amendment Final EIS and Record of Decision. In addition, the 2016 Tongass Forest Plan provides guidance to conduct annual monitoring and review of current timber demand. Similarly, the Tongass Timber Reform Act provides for protection of riparian habitats and the multiple use and sustained yield of all renewable surface resources. Watershed protection measures, such as riparian buffers and application of watershed conservation measures, will be provided for during future plan revisions or amendments in conformance with all applicable laws, including the Clean Water Act, Magnuson–Stevens Fishery

Conservation and Management Act, and Alaska's Department of Environmental Conservation Water Quality Standards.

Alternatives Considered in Detail

In addition to Alternative 6, the proposed rule and preferred alternative, the DEIS analyzes five other alternatives for managing roadless areas on the Tongass National Forest. Alternative 1 is the no action alternative and would result in the continued implementation of the 2001 Roadless Rule as prescribed in the Alaska District Court's Judgement. Alternative 2 increases the geographic scope of roadless area designation by adding an additional 133,000 acres as Alaska Roadless Areas while removing areas where roadless characteristics have already been substantially altered, (commonly referred to as ''roaded roadless'') primarily by road development and/or timber harvest.

Alternative 3 would increase the available land base from which timber harvest opportunities could occur by making timber harvest, road construction, and road reconstruction permissible in areas where roadless characteristics have already been substantially altered and areas immediately adjacent to existing roads and past harvest areas. Adjacent areas are considered to be the logical extensions of the existing road and/or harvest systems, which would remove approximately 376,000 acres from the roadless classification system. The adjacent areas represent the most likely locations where future timber harvest could occur and have the least environmental impacts to overall roadless characteristics while providing for additional timber opportunities.

Alternative 3 also establishes a Community Priority category which allows for small-scale timber harvest and associated road construction and reconstruction. In addition, it allows for infrastructure development to connect and support local communities, recreation opportunities, and traditional Alaska Native cultural uses. Alternative 3 also includes the Watershed Priority category, applied to approximately 3.2 million acres identified in the 2016 Forest Plan as the Tongass 77 Watersheds and The Nature Conservancy/Audubon Conservation Priority Areas (T77 and TNC/Audubon Conservation Areas). Approximately 90% of those 3.2 million acres fall within roadless area boundaries identified in Alternative 3. To provide heightened balance and integrity of watershed protections and establish management continuity across these high priority watersheds, Alternative 3 would also include a prohibition on old-growth timber harvesting on the portion of the T77 and TNC/Audubon Conservation Areas that extend beyond roadless areas boundaries established by Alternative 3.

In addition to the roaded roadless and adjacent areas being removed from the roadless classification system, approximately 828,000 acres designated as LUD II areas would be removed from the roadless classification system in Alternative 3. LUD II areas are statutory land use designations managed in a roadless state to retain their wildland character as defined in the Tongass Timber Reform Act (Pub. L. 101–626, Title II, Section 201) and the National Defense Authorization Act for Fiscal Year 2015 (Pub. L. 113–291, 128 Stat. 3729, Section 3720(f)). These areas are proposed for removal from regulatory roadless classification because having two layers of protection (statutory and regulatory direction) that are substantially similar but slightly different does not make a meaningful difference to the level of protection provided and can create confusion for land managers, stakeholder groups, and the public. Removal of the LUD II areas from regulatory roadless classification is an attempt to eliminate that confusion while remaining consistent with the congressionally established management regime established for the LUD II areas. The statutory direction for LUD II areas would remain in place regardless of which alternative is selected.

Alternative 4 provides additional lands from which timber harvest opportunities could occur while maintaining protections for areas designated as roadless and defined in the 2016 Tongass Forest Plan as Scenic Viewsheds, T77 Watersheds, and The Nature Conservancy/Audubon Conservation Priority Areas. Additional timber opportunities are provided by removing approximately 376,000 acres of roaded roadless areas and adjacent extensions, as described in Alternative 3, from roadless classification. In addition, timber opportunities are provided by managing approximately 749,000 acres of Timber Development and Modified Landscape Land Use Designations, as defined in the 2016 Tongass Forest Plan, in a roadless management category called Timber Priority, which allows for timber harvest, road construction, and road reconstruction.

Alternative 4 adds approximately 32,000 acres not included in the 2001 roadless inventory which are designated as LUD II areas. These areas in addition to the LUD II areas included in the 2001 roadless inventory amount to about 856,000 total acres that would be managed as roadless with regulatory direction mirroring the statutory direction.

The remaining 7,252,000 acres of Alaska Roadless Areas in Alternative 4 would be managed as a roadless management category called Roadless Priority, which is similar to the 2001 Roadless Rule, but less restrictive and addresses Alaska-specific concerns for infrastructure development to connect and support local communities and access to renewable energy and leasable minerals.

Alternative 5 maximizes the land base from which timber harvest opportunities could occur by removing 2.3 million acres from roadless area designation. Taken together, the six alternatives represent the spectrum of management regimes identified to the Forest Service through public comments, public meetings, and cooperating agency input.

The table below displays the acreage changes from the 2001 Roadless Rule to acreages that would be designated under each of the six alternatives displayed in the DEIS.

	Alternatives					
	1	2	3	4	5	6 Proposed rule
Total Roadless Acres	9,200,000	9,220,000	8,103,000	8,857,000	6,905,000	0
Roadless Acres Removed	0	113,000	1,202,000	375,000	2,298,000	9,200,000
Roadless Acres Added	0	133,000	105,000	32,000	3,000	0
Net Acre Change	0	20,000	−1,098,000	−343,000	−2,295,000	−9,200,000

Public Participation

The August 30, 2018, publication of the notice of intent initiated a 45-day public comment period. The Forest Service received about 144,000 responses (approximately 32,500 form letters, 110,000 petition signatures, and 1,400 unique letters). During the comment period, the Forest Service held 17 public meetings throughout Southeast Alaska, Anchorage, and Washington, DC. Public comments received during the comment period and information from the public meetings helped inform the development of the alternatives to the proposed rule. In addition, the State of Alaska and six federally-recognized tribes agreed to participate as cooperating agencies (Angoon Community Association, Central Council of Tlingit and Haida Indian Tribes of Alaska, Hoonah Indian Association, Hydaburg Cooperative Association, Organized Village of Kake, and Organized Village of Kasaan) and provided input on the DEIS, which informed the development of the alternatives.

The Forest Service invites comments on all aspects of this rulemaking, including the alternatives analyzed in the DEIS, the expected economic costs and benefits, and any additional costs and benefits. Comments received during the 60-day comment period on the proposed rule and DEIS will be considered in development of a final rule and supporting analyses. Public meetings are planned to be held during the 60-day comment period and tentative public meeting locations include Anchorage, Angoon, Craig, Gustavus, Hoonah, Hydaburg, Juneau, Kake, Kasaan, Ketchikan, Petersburg, Point Baker, Sitka, Tenakee Springs, Thorne Bay, Wrangell, Yakutat, and Washington, DC. Additional information on meeting times and specific locations will be provided through the project website (*www.fs.usda.gov/project/?project=54511*) and local media.

Regulatory Certifications

Regulatory Planning and Review

The Office of Management and Budget (OMB) determined this rulemaking to be a significant regulatory action as it may raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in Executive Order 12866. The agency has prepared a regulatory requirements analysis of impacts and discussion of benefits and costs of the proposed rule.

The proposed rule exempting the Tongass National Forest from the 2001 Roadless Rule will provide additional opportunities for timber harvest and road construction to occur; however, it does not materially affect the quantity of timber expected to be harvested or the miles of new roads constructed. As to timber harvest activities, the proposed rule would increase the flexibility for land managers to locate and design timber sales. Improved flexibility could, in turn, improve the Forest Service's ability to offer economic sales that meets timber industry needs and contribute to rural economies. While many factors can influence the cost of timber harvest, areas along existing roads or those using marine access facilities are typically more economically efficient, followed by areas where existing roads can be easily extended. The most expensive harvesting costs are associated with areas without existing road or marine access facilities. Estimated harvest cost savings (felling, yarding, loading, etc.) range from $1 to $2 million dollars per year depending on the level of harvest (24 MMBF or one standard deviation less than the average annual harvest on the Tongass National Forest over the last 16 years or the harvest ceiling under the 2016 Forest Plan of 46 MMBF).

Cost savings from improved flexibility for timber harvest activities would accrue alongside other benefits, including reduced costs for leasable mineral availability, renewable energy development potential, and potential for development of state roads and other transportation projects. Cost savings are anticipated to outweigh estimated lost revenue to outfitters and guides, by a factor of 10 ($77,000 travel and guided related expenses), and across all industries in Southeast Alaska by a factor of 3 ($319,000 in total expenditures across all recreation industries in Southeast Alaska including outfitters and guides) from visitors potentially displaced from annual harvest of suitable young- and old-growth. Expenses incurred by visitors are not necessarily lost but subject to displacement related changes. While some businesses may lose revenue if visitors choose not to travel to Southeast Alaska, others may see increases in revenue if visitors choose to stay longer or travel to substitute sites within Southeast Alaska.

Regulatory Flexibility Act and Consideration of Small Entities

The USDA certifies that the proposed rule, if promulgated, will not have a significant economic impact on a substantial number of small entities as determined in the Regulatory Flexibility Analysis because the proposed rule does not directly subject small entities to regulatory requirements. Therefore, notification to the Small Business Administration's Chief Council for Advocacy is not required pursuant to Executive Order 13272. A number of small and large entities may experience time or money savings as a result of flexibility provided by the proposed rule, or otherwise benefit from activities on National Forest System lands under the proposed rule. The agency is interested in receiving specific input regarding the anticipated effects of the proposed rule to small businesses.

Paperwork Reduction Act

This proposed rule does not require any additional record keeping, reporting requirement, or other information collection requirements as defined in 5 CFR part 1320 that are not already approved for use and, therefore, imposes no additional paperwork on the public. Accordingly, the review provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) and its implementing regulations at 5 CFR part 1320 do not apply.

Regulatory Risk Assessment

A risk assessment is only required under 7 U.S.C. 2204e for a ''major'' proposed rule, the primary purpose of which is to regulate issues of human health, human safety, or the environment. The statute (Pub. L. 103–354, Title III, Section 304) defines ''major'' as any regulation the Secretary of Agriculture estimates is likely to have an impact on the economy of the United States of $100 million or more as measured in 1994 dollars. Economic effects of the proposed rule are estimated to be less than $100 million per year.

Reducing Regulation and Controlling Regulatory Costs

Executive Order 13771, Reducing Regulation and Controlling Regulatory Costs, issued January 30, 2017, requires significant new regulations shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations.

The proposed rule has been reviewed in accordance with Executive Order 13771 on reducing regulation and controlling regulatory costs and is considered an Executive Order 13771 deregulatory action.

Federalism

The USDA has considered the proposed rule in context of Executive Order 13132, Federalism, issued August 4, 1999. The USDA has determined that the proposed rule conforms with

Federalism principles set out in Executive Order 13132; would not impose any compliance costs on any State; and would not have substantial direct effects on States, on the relationship between the national government and the State of Alaska or any other State, nor on the distribution of power and responsibilities among the various levels of government. Therefore, the USDA concludes that this proposed rule does not have Federalism implications. The proposed rule is based on a petition submitted by the State of Alaska under the Administrative Procedure Act (5 U.S.C. 553(e)) and pursuant to Department of Agriculture regulations at 7 CFR 1.28. The proposed rule responds to the State's petition, considers public comment received during the Forest Service's public scoping process, and considers input received from cooperating agencies. The State of Alaska is a cooperating agency pursuant to 40 CFR 1501.6 of the Council on Environmental Quality regulations for implementing the procedural provisions of the National Environmental Policy Act.

Consultation With Indian Tribal Governments

On July 30, 2018, the Forest Service initiated government-to-government consultation with 32 Alaska federally-recognized tribes and 27 Alaska Native corporations, and invited them to participate as cooperating agencies during the rulemaking process. Six tribes agreed to become a cooperating agency including Angoon Community Association, Central Council Tlingit and Haida Indian Tribes of Alaska, Hoonah Indian Association, Hydaburg Cooperative Association, Organized Village of Kake, and Organized Village of Kasaan. Biweekly cooperating agency meetings are occurring that include the six cooperating agency tribal governments. Furthermore, additional government-to-government consultations will occur by request of any of the 19 tribal governments across Southeast Alaska.

The proposed 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 policies that have tribal implications, including regulations, legislative comments or proposed legislation, and 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.

The USDA's Office of Tribal Relations has assessed the impact of this rule on Indian tribes and determined that this rule has tribal implications that require continued outreach efforts to determine if tribal consultation under Executive Order 13175 is required. To date, as part of their regulatory review process noted above, Forest Service detailed in their proposed rule various outreach efforts to American Indian and Alaska Native tribes, villages, and corporations regarding the development of this proposed rule, and the ongoing tribal cooperation in this process.

If a tribe requests consultation, Forest Service will work with the Office of Tribal Relations to ensure meaningful consultation is provided where changes, additions, and modifications identified herein are not expressly mandated by Congress.

No Takings Implications

The USDA has considered the proposed rule in context with the principles and criteria contained in Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights, issued March 15, 1988. The USDA has determined that the proposed rule does not pose the risk of a taking of private property because it only applies to management of National Forest System lands and contains exemptions that prevent the taking of constitutionally protected private property.

Civil Justice Reform

The USDA reviewed the proposed rule in context of Executive Order 12988. The USDA has not identified any State or local laws or regulations that are in conflict with the proposed rule or would impede full implementation of the rules. However, if the rule is adopted, (1) all State and local laws and regulations that conflict with this rule or would impede full implementation of this rule would be preempted; (2) no retroactive effect would be given to this rule; and (3) the proposed rule would not require the use of administrative proceedings before parties could file suit in court.

Unfunded Mandates

Pursuant to Title II of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538), signed into law on March 22, 1995, the USDA has assessed the effects of the proposed rule on State, local, and Tribal governments and the private sector. The proposed rule does not compel the expenditure of $100 million or more by any State, local, or Tribal government, or anyone in the private sector. Therefore, a statement under section 202 of the Act is not required.

Energy Effects

The USDA has considered the proposed rule in context of Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use, issued May 18, 2001. The USDA has determined the proposed rule does not constitute a significant energy action as defined in Executive Order 13211. Therefore, a statement of energy effects is not required.

E-Government Act

The USDA is committed to complying with the E-Government Act, to promote 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 Subject in 36 CFR Part 294

National Forests, Recreation areas, Navigation (air), roadless area management.

For the reasons set forth in the preamble, the USDA proposes to amend part 294 of Title 36 of the Code of Federal Regulations by adding subpart E to read as follows:

PART 294—SPECIAL AREAS

Subpart E—Alaska Roadless Areas Management

Sec.

Authority: 16 U.S.C. 472, 529, 551, 1608, 1613; 23 U.S.C. 201, 205.

Subpart E—Alaska Roadless Areas Management

§ 294.50 Tongass National Forest.

(a) The 2001 Roadless Area Conservation Rule (see 36 CFR part 294, subpart B, revised as of July 1, 2001) shall not apply to the Tongass National Forest.

§ 294.51 Chugach National Forest.

(a) Administrative correction or modification of inventoried roadless area designations on the Chugach National Forest may be made as follows:

(1) Administrative corrections to boundaries. The Regional Forester for the Alaska Region may issue administrative corrections to the boundaries of an Inventoried Roadless

Area after a 30-day public notice and opportunity to comment period. Administrative corrections are limited to adjustments that remedy clerical errors, typographical errors, mapping errors, improvements in mapping technology, conformance to statutory or regulatory changes, or incorporation of changes due to land exchanges.

(2) Administrative modifications to Classifications and Boundaries. The Regional Forester for the Alaska Region may issue modifications to the classifications and boundaries of an Inventoried Roadless Area after a 45-day public notice and opportunity to comment period.

Dated: October 11, 2019.

Sonny Perdue,

Secretary of Agriculture.

[FR Doc. 2019–22638 Filed 10–16–19; 8:45 am]

BILLING CODE 3411–15–P

POSTAL SERVICE

39 CFR Part 111

New Mailing Standards for Domestic Mailing Services Products

AGENCY: Postal Service™.

ACTION: Proposed rule.

SUMMARY: On October 9, 2019, the Postal Service (USPS®) filed a notice of mailing services price adjustments with the Postal Regulatory Commission (PRC), effective January 26, 2020. This proposed rule contains the revisions to *Mailing Standards of the United States Postal Service,* Domestic Mail Manual (DMM®) that we would adopt to implement the changes coincident with the price adjustments.

DATES: Submit comments on or before November 18, 2019.

ADDRESSES: Mail or deliver written comments to the Manager, Product Classification, U.S. Postal Service, 475 L'Enfant Plaza SW, Room 4446, Washington, DC 20260–5015. If sending comments by email, include the name and address of the commenter and send to *ProductClassification@usps.gov,* with a subject line of ''January 2020 Domestic Mailing Services Proposal.'' Faxed comments are not accepted.

Confidentiality

All submitted comments and attachments are part of the public record and subject to disclosure. Do not enclose any material in your comments that you consider to be confidential or inappropriate for public disclosure.

You may inspect and photocopy all written comments, by appointment only, at USPS® Headquarters Library, 475 L'Enfant Plaza SW, 11th Floor North, Washington, DC 20260. These records are available for review on Monday through Friday, 9 a.m.–4 p.m., by calling 202–268–2906.

FOR FURTHER INFORMATION CONTACT: Jacqueline Erwin at (202) 268–2158, or Dale Kennedy at (202) 268–6592.

SUPPLEMENTARY INFORMATION: Proposed prices will be available under Docket No. R2020–1 on the Postal Regulatory Commission's website at *www.prc.gov.*

The Postal Service's proposed rule includes: Changes to prices, mail classification updates, product simplification efforts, and a few minor revisions to the DMM.

Permit Simplification

Currently, mailers are required to pay annual presort and destination entry fees for certain mailings.

The Postal Service is proposing to simplify permits in order to better serve customers and to utilize current and new technologies that have eliminated prior operational costs for permit creation, payment, and maintenance. The simplification would allow auto-finalization for Seamless Acceptance mailings without presort fees being paid. The annual presort fee will be required to be paid for any mailing not eligible for Seamless Acceptance.

P.O. Box Fee Group Reassignments

In Docket No. R2020–1, the Postal Service is proposing to reassign some ZIP Codes to the next higher-priced fee group based on market characteristics, such as occupancy and growth rates. Consistent with this proposal, the Postal Service plans to add more substantive standards to the authorizing language in DMM 508.4.4.2, specifying the basis upon which such reassignments to more appropriate fee groups might be made.

Full-Service Exemption Calculation Change

Currently, mailers who present automation mailings of First-Class Mail cards, letters, and flats, USPS Marketing Mail letters and flats, or Bound Printed Matter flats that contain 90 percent or more of their presort eligible pieces at full-service automation prices are exempt from paying annual presort mailing or destination entry fees, as applicable, for qualified full-service mailings. USPS Marketing Mail Saturation and EDDM flats are eligible for presort rates but ineligible for full-service incentives. Saturation and EDDM flats are included in the denominator of the calculation, but not the numerator.

The Postal Service is proposing to change the full-service fee exemption calculation to exempt annual presort and destination entry fees for those customers who enter 90 percent or more full-service eligible volume as full-service. Additionally, at least 75 percent of all the mailer's volume must be full-service eligible. The new formula excludes USPS Marketing Mail Saturation flats (including EDDM) and EDDM letter mailings from the denominator. This change would allow more mailers to qualify for an exemption from paying annual mailing fees.

Although exempt from the notice and comment requirements of the Administrative Procedure Act (5 U.S.C. 553(b), (c)) regarding proposed rulemaking by 39 U.S.C. 410(a), the Postal Service invites public comments on the following proposed revisions to *Mailing Standards of the United States Postal Service,* Domestic Mail Manual (DMM), incorporated by reference in the Code of Federal Regulations. *See* 39 CFR 111.1.

We will publish an appropriate amendment to 39 CFR part 111 to reflect these changes.

List of Subjects in 39 CFR Part 111

Administrative practice and procedure, Postal Service.

Accordingly, 39 CFR part 111 is proposed to be amended as follows:

PART 111—[AMENDED.]

■ 1. The authority citation for 39 CFR part 111 continues to read as follows:

Authority: 5 U.S.C. 552(a); 13 U.S.C. 301–307; 18 U.S.C. 1692–1737; 39 U.S.C. 101, 401, 403, 404, 414, 416, 3001–3011, 3201–3219, 3403–3406, 3621, 3622, 3626, 3632, 3633, and 5001.

■ 2. Revise the *Mailing Standards of the United States Postal Service,* Domestic Mail Manual (DMM) as follows:

Mailing Standards of the United States Postal Service, Domestic Mail Manual (DMM)

* * * * *

200 Commercial Mail

* * * * *

230 First-Class Mail

233 Prices and Eligibility

1.0 Prices and Fees

* * * * *

1.5 Presort Mailing Fee

[Revise the second sentence of 1.5; to read as follows:]

* * * Payment of this fee does not apply to qualified full-service mailings (under 705.23.3.1a).* * *

* * * * *

240 Commercial Mail USPS Marketing Mail

243 Prices and Eligibility

1.0 Prices and Fees

* * * * *

1.4 Fees

1.4.1 Presort Mailing Fee

[Revise the second sentence of 1.4.1; to read as follows:]

* * * Payment of this fee does not apply to mailers who present qualified full-service mailings (under 705.23.3.1a).* * *

* * * * *

260 Commercial Mail Bound Printed Matter

263 Prices and Eligibility

1.0 Prices and Fees

* * * * *

1.2 Presorted and Carrier Route Bound Printed Matter

* * * * *

1.2.5 Destination Entry Mailing Fee

[Revise the last sentence of 1.2.5; to read as follows:]

* * * Payment of this fee does not apply to mailers who present only qualified full-service flat-size mailings (under 705.23.3.1a).

* * * * *

500 Additional Services

* * * * *

508 Recipient Services

* * * * *

4.0 Post Office Box Service

* * * * *

4.4 Basis of Fees and Payment

* * * * *

4.4.2 Fee Changes

[Revise the second sentence of 4.4.2; to read as follows:]

* * * In addition, the USPS may assign a fee group to a new ZIP Code, may reassign one or more 5-digit ZIP Codes to the next higher or lower fee group based on the ZIP Codes' cost and market characteristics, or may regroup 5-digit ZIP Codes.* * *

* * * * *

5.0 Caller Service

* * * * *

5.5 Basis of Fees and Payment

* * * * *

5.5.3 Fee Changes

[Revise the text of 5.5.3 by adding new last sentence; to read as follows:]

* * * In addition, the USPS may assign a fee group to a new ZIP Code, may reassign one or more 5-digit ZIP Codes to the next higher or lower fee group based on the ZIP Codes' cost and market characteristics, or may regroup 5-digit ZIP Codes.

* * * * *

700 Special Standards

* * * * *

705 Advanced Preparation and Special Postage Payment Systems

* * * * *

22.0 Seamless Acceptance Program

* * * * *

22.3 Basic Standards

[Revise the introductory text of 22.3, by adding new second and third sentences to read as follows:]

* * * Any permits used in a Seamless acceptance mailing will not prevent that mailing from being finalized regardless of if an annual fee is due on that permit. However, the first time the permit is used for a non-seamless mailing the mailer will have to pay the permit fee if they do not meet the requirements for a fee waiver.* * *

* * * * *

23.0 Full-Service Automation Option

* * * * *

23.2 General Eligibility Standards

[Revise the first sentence of the introductory text of 23.2; to read as follows:]

First-Class Mail (FCM), Periodicals, and USPS Marketing Mail, cards (FCM only), letters (except letters using simplified address format) and flats meeting eligibility requirements for automation or carrier route prices (except for USPS Marketing Mail ECR saturation flats), and Bound Printed Matter presorted or carrier route barcoded flats, are potentially eligible for full-service incentives.* * *

23.3 Fees

[Revise the title of 23.3.1; to read as follows:]

23.3.1 Eligibility for Exception to Payment of Annual Fees and Waiver of Deposit of Permit Imprint Mail Restrictions

[Revise the introductory text of 23.3.1; to read as follows:]

Mailers who present automation or presort mailings (of First-Class Mail cards, letters, and flats, USPS Marketing Mail letters and flats, or Bound Printed Matter flats) that contain 90 percent or more full-service eligible mail as full-service, and 75 percent of their total mail is eligible for full-service incentives, are eligible for the following exception to standards:

[Revise the text of item 23.3.1a; to read as follows:]

a. Annual presort mailing or destination entry fees, as applicable, do not apply to mailings entered by mailers who meet both the 90 percent and 75 percent full-service thresholds, for qualified full-service mailings, as specified in 23.3.1.* * *

* * * * *

Notice 123 (Price List)

[Revise prices as applicable.]

* * * * *

We will publish an appropriate amendment to 39 CFR part 111 to reflect these changes.

Joshua J. Hofer,

Attorney, Federal Compliance.

[FR Doc. 2019–22635 Filed 10–16–19; 8:45 am]

BILLING CODE 7710–12–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Parts 223, 224, and 226

[Docket No. 190925–0039 and 190829–0020]

RIN 0648–BI06, 0648–BH95

Endangered and Threatened Wildlife and Plants: Proposed Rule To Designate Critical Habitat for the Central America, Mexico, and Western North Pacific Distinct Population Segments of Humpback Whales and Proposed Rule To Revise Critical Habitat for the Southern Resident Killer Whale Distinct Population Segment, Public Hearings

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

ACTION: Notification of public hearings.

SUMMARY: We, NMFS, will hold five public hearings related to our proposed rule to designate critical habitat for the Western North Pacific distinct population segment (DPS), the Central America DPS, and the Mexico DPS of humpback whales (*Megaptera novaeangliae*) under the Endangered

Species Act (ESA). We will also hold three public hearings related to our proposed rule to revise the critical habitat designation for the Southern Resident killer whale DPS (*Orcinus orca*) under the ESA. Three of the public hearings will be joint hearings that address both of these proposed rules.

DATES: Public hearings will be held from 4 to 7 p.m. (local time) on the following dates: November 4, 2019, in Santa Cruz, California; November 5, 2019, in Newport, Oregon; November 6, 2019, in Seattle, Washington; November 7, 2019, in Juneau, Alaska; and December 3, 2019, in Anchorage, Alaska.

ADDRESSES: The November 4th hearing will be held in conference Room 188 at the NMFS Southwest Fisheries Science Center, Santa Cruz Laboratory on the University of California Santa Cruz's Coastal Science Campus, 110 McAllister Way, Santa Cruz, CA 95060.

The November 5th hearing will be held in the Hennings Auditorium at the Hatfield Marine Science Center Visitor Center, 2030 SE Marine Science Drive, Newport, OR 97365.

The November 6th hearing will be held in the Alder Auditorium at the University of Washington, 1310 NE 40th Street, Seattle, WA 98105. (The auditorium entrance is located on NE 40th Street between Brooklyn Avenue NE and University Way NE.)

The November 7th hearing will be held in the Egan Lecture Hall (Room 112), University of Alaska Southeast, 11066 Auke Lake Way, Juneau, Alaska 99801.

The December 3rd hearing will be held in the Wilda Marston Theater in Z.J. Loussac Public Library, 3600 Denali St., Anchorage, AK 99503.

FOR FURTHER INFORMATION CONTACT: Lisa Manning, NMFS, Office of Protected Resources 301–427–8466; or Nancy Young, NMFS West Coast Region, 206–526–4297.

SUPPLEMENTARY INFORMATION:

Background

On September 19, 2019, we published a proposed rule to revise existing critical habitat for endangered Southern Resident killer whales (84 FR 49214) under the ESA. This rule proposes to revise the critical habitat by designating six new marine areas along the U.S. West Coast. The specific new areas proposed for designation extend along the U.S. West Coast from the U.S. international border with Canada, south to Point Sur, California. Based on consideration of national security impacts, we are proposing to exclude from the designation one area off the coast of Washington. We are soliciting public comment on this proposed rule through December 18, 2019.

On October 9, 2019, we published a proposed rule to designate critical habitat for the endangered Western North Pacific DPS, the endangered Central America DPS, and the threatened Mexico DPS of humpback whales under the ESA (84 FR 54354). Areas proposed as critical habitat include specific marine areas located off the coasts of California, Oregon, Washington, and Alaska. Based on consideration of national security and economic impacts, we are also proposing to exclude multiple areas from the designation for each DPS. We are soliciting comments on the proposed humpback whale critical habitat designations through December 9, 2019.

Public Hearings

Each of the public hearings will be conducted in the same manner. The hearings will begin with a brief presentation by NMFS that gives an overview of critical habitat under the ESA and a summary of the relevant proposed critical habitat designation(s). Following the presentation, members of the public will have the opportunity to provide oral comments on the record regarding the proposed designations. Members of the public will also have the opportunity to submit written comments at the hearing. Written comments may also be submitted at any time during the relevant public comment period via the Federal e-Rulemaking Portal. To do the latter, go to *www.regulations.gov*; and for Southern Resident killer whale critical habitat search on the docket ID ''NOAA–NMFS–2014–0041''; for humpback whale critical habitat search on docket ID ''NOAA–NMFS–2019–0066''; click the ''Comment Now!'' icon; then complete the required fields and enter or attach your comments. Note that all comments received are a part of the public record and will generally be posted for public viewing on *www.regulations.gov* without change. All personal identifying information (*e.g.,* name, address, *etc.*), confidential business information, or otherwise sensitive information submitted voluntarily by the commenter will be publicly accessible. NMFS will accept anonymous comments (enter ''N/A'' in the required fields if you wish to remain anonymous). Attachments to electronic comments will be accepted in Microsoft Word, Excel, or Adobe PDF file formats only.

Reasonable Accommodations

People needing accommodations so that they may attend and participate at the public hearings should submit a request for reasonable accommodations as soon as possible, and no later than 7 business days prior to the hearing date, by contacting Lisa Manning or Nancy Young (see **FOR FURTHER INFORMATION CONTACT**).

Authority: 16 U.S.C. 1531 *et seq.*

Dated: October 9, 2019.

Samuel D. Rauch III,

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

[FR Doc. 2019–22445 Filed 10–16–19; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 622

[Docket No. 191004–0056]

RIN 0648–BI32

Fisheries of the Caribbean, Gulf of Mexico, and South Atlantic; Snapper-Grouper Fishery of the South Atlantic Region; Regulatory Amendment 27

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

ACTION: Proposed rule; request for comments.

SUMMARY: NMFS proposes to implement management measures described in Vision Blueprint Commercial Regulatory Amendment 27 (Regulatory Amendment 27) to the Fishery Management Plan (FMP) for the Snapper-Grouper Fishery of the South Atlantic Region (Snapper-Grouper FMP), as prepared and submitted by the South Atlantic Fishery Management Council (Council). If implemented, this proposed rule would modify commercial fishing seasons, trip limits, and minimum size limits for selected snapper-grouper species in the South Atlantic exclusive economic zone (EEZ). The purpose of this proposed rule is to improve equitable access for commercial fishermen in the snapper-grouper fishery, minimize discards to the extent practicable, and improve marketability within the snapper-grouper fishery.

DATES: Written comments on the proposed rule must be received by November 18, 2019.

ADDRESSES: You may submit comments on the proposed rule, identified by ''NOAA–NMFS–2019–0059,'' by either of the following methods:

• *Electronic submission:* Submit all electronic comments via the Federal e-Rulemaking Portal. Go to *http://www.regulations.gov/docket?D=NOAA-NMFS-2019-0059, click the* ''*Comment Now!*'' icon, complete the required fields, and enter or attach your comments.

• *Mail:* Submit written comments to Mary Vara, NMFS Southeast Regional Office, 263 13th Avenue South, St. Petersburg, FL 33701.

Instructions: Comments sent by any other method, to any other address or individual, or received after the end of the comment period, may not be considered by NMFS. All comments received are a part of the public record and will generally be posted for public viewing on *www.regulations.gov* without change. All personal identifying information (*e.g.,* name, address, etc.), confidential business information, or otherwise sensitive information submitted voluntarily by the sender will be publicly accessible. NMFS will accept anonymous comments (enter ''N/A'' in required fields if you wish to remain anonymous).

Electronic copies of Regulatory Amendment 27 may be obtained from *www.regulations.gov* or the Southeast Regional Office website at *https://www.fisheries.noaa.gov/action/regulatory-amendment-27-vision-blueprint-commercial-measures* includes an environmental assessment, regulatory impact review, and Initial Regulatory Flexibility Analysis (IRFA).

FOR FURTHER INFORMATION CONTACT: Mary Vara, NMFS Southeast Regional Office, telephone: 727–824–5305, or email: *mary.vara@noaa.gov.*

SUPPLEMENTARY INFORMATION: The snapper-grouper fishery in the South Atlantic region is managed under the Snapper-Grouper FMP and includes blueline tilefish, snowy grouper, greater amberjack, red porgy, vermilion snapper, almaco jack, other jacks complex (lesser amberjack, almaco jack, and banded rudderfish), queen snapper, silk snapper, blackfin snapper, and gray triggerfish, along with other snapper-grouper species. The Snapper-Grouper FMP was prepared by the Council and is implemented by NMFS through regulations at 50 CFR part 622 under the authority of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act).

Background

During a series of stakeholder meetings in 2014, the Council gathered input from commercial fishermen throughout the South Atlantic region to develop a long-term strategic plan for managing the snapper-grouper fishery. Based on that input, the Council developed the 2016–2020 Vision Blueprint for the Snapper-Grouper Fishery (Vision Blueprint). The Vision Blueprint identified the goals, objectives, strategies, and actions that support the Council's vision for the snapper-grouper fishery and centers around four goal areas: Science, Management, Communication, and Governance. In 2015, the Council prioritized action items in the Vision Blueprint that would be addressed through amendments to the Snapper-Grouper FMP over the next 5 years. As part of this prioritization, the Council chose to focus on actions that would address the seasonality of access to certain snapper-grouper species and measures to lengthen fishing seasons to better utilize existing annual catch limits (ACLs) in the snapper-grouper fishery. To accomplish this, the Council began development of two regulatory amendments to the Snapper-Grouper FMP to address the commercial and recreational sectors, respectively. Regulatory Amendment 27 includes modifications to the commercial sector management measures in the snapper-grouper fishery based on stakeholder input. The purpose of Regulatory Amendment 27 is to enable equitable access for commercial fishermen participating in the snapper-grouper fishery, and to minimize discards to the extent practicable, while improving marketability for some snapper-grouper species. Vision Blueprint Recreational Regulatory Amendment 26 to the Snapper-Grouper FMP, which would revise recreational management measures in the fishery, has been submitted to NMFS by the Council, and NMFS is developing a proposed rule.

Management Measures Contained in This Proposed Rule

This proposed rule would modify the commercial trip limits for blueline tilefish, greater amberjack, red porgy, and vermilion snapper; establish commercial split seasons for snowy grouper, greater amberjack, and red porgy; and establish a commercial trip limit for the other jacks complex. For the commercial sector, this proposed rule would also establish a minimum size limit for almaco jack, remove the minimum size limits for silk snapper, queen snapper, and blackfin snapper, and reduce the minimum size limit for gray triggerfish in the EEZ off the east coast of Florida. The management measures in this proposed rule would apply on board a vessel for which a Federal commercial permit for South Atlantic snapper-grouper has been issued. Unless otherwise noted, all weights in this proposed rule are described in gutted weight.

Commercial Trip Limit for Blueline Tilefish

Currently, the commercial trip limit for blueline tilefish is 300 lb (136 kg) during the January through December fishing year. In Regulatory Amendment 27, the Council determined that management measures for blueline tilefish should be more consistent with snowy grouper management measures since the two species co-occur in parts of the Council's jurisdiction. Blueline tilefish and snowy grouper are both target species for fishermen north of Cape Hatteras, North Carolina, but access to these species in that area is limited early in the fishing year (during January through May) as a result of poor weather conditions. However, blueline tilefish are mostly an incidental catch during commercial harvest of snowy grouper occurring south of Cape Hatteras, North Carolina, through approximately Cape Canaveral, Florida. South of Cape Hatteras, commercial fishermen targeting snowy grouper tend to continue fishing for blueline tilefish after they have reached their snowy grouper trip limit and they report that this practice results in increased discards of snowy grouper. Access to the blueline tilefish by the commercial sector has been further limited over the past few years, because the commercial sector for blueline tilefish has closed before the end of the fishing year as a result of reaching the commercial quota.

This proposed rule would modify the 300-lb (136-kg) commercial trip limit for blueline tilefish throughout the South Atlantic EEZ. During January 1 through April 30 each year, the commercial trip limit would be reduced to 100 lb (45 kg), and during May 1 through December 31 each year, the commercial trip limit would continue to be 300 lb (136 kg). The Council determined that a lower 100-lb (45-kg) commercial trip limit of blueline tilefish each year from January through April would help reduce snowy grouper discards by commercial fishermen operating south of Cape Hatteras, North Carolina, because the commercial trip limit for blueline tilefish would be met more quickly on a trip. This proposed rule would maintain the current 300-lb (136-kg) trip limit for blueline tilefish from May through December when good weather conditions are more likely to allow commercial fishermen in the northern portion of the Council's area of jurisdiction to have greater access to the resource and optimize their harvest through an extended fishing season.

Commercial Split Season for Snowy Grouper

During the Council's development of the Vision Blueprint, stakeholders requested that the Council address regional differences in access to the snapper-grouper resource, including snowy grouper, and implement management approaches that would minimize discards. Commercial fishermen and other stakeholders notified the Council to an increase in snowy grouper discards when fishermen attempt to harvest the commercial trip limit of blueline tilefish, a co-occurring species, after reaching the commercial trip limit for snowy grouper. In addition, stakeholders stated the importance of snowy grouper in the commercial market during the early months of the year (January through April), when the harvest of shallow-water groupers is closed. Currently, the fishing year for snowy grouper is January 1 through December 31 and there is a single fishing season to harvest the commercial ACL (equivalent to the commercial quota) of 153,935 lb (69,824 kg), gutted weight, or 181,644 lb (82,392 kg), round weight.

After reviewing stakeholder input, the Council determined that allocating the majority (70 percent) of the commercial quota to a January through June fishing season would ensure availability of snowy grouper when it is most valuable at the market and optimize access to this species for the majority of commercial fishermen in the South Atlantic. The Council also decided that allocating 30 percent of the commercial quota of snowy grouper for a July through December fishing season allows for the incidental harvest of snowy grouper when North Carolina commercial fishermen are targeting blueline tilefish. The Council determined that the longer grouper species are available in the marketplace, the more this benefits fishermen and communities in the South Atlantic.

This proposed rule would establish two commercial fishing seasons for snowy grouper of January 1 through June 30 (Season 1) and July 1 through December 31 (Season 2) within the current fishing year. This proposed rule would allocate the commercial quotas as 70 percent to Season 1, 107,754 lb (48,876 kg), and 30 percent to Season 2, 46,181 lb (20,947 kg). Any remaining commercial quota from Season 1 would be transferred to Season 2. Any remaining commercial quota from Season 2 would not be carried forward into the next fishing year.

Commercial Split Season and Trip Limit for Greater Amberjack

Currently, the commercial ACL (equivalent to the commercial quota) for greater amberjack is 769,388 lb (348,989 kg), the fishing year is March 1 through the end of February, and the commercial trip limit is 1,200 lb (544 kg) and applies in either round or gutted weight. During April of each year, the commercial harvest and possession limit for greater amberjack (equivalent to a commercial trip limit) is one fish per person per day or one fish per person per trip, whichever is more restrictive. Also during April each year, the sale and purchase of greater amberjack in or from the South Atlantic EEZ is prohibited on board a vessel for which a Federal commercial permit for South Atlantic snapper-grouper has been issued.

During the development of Regulatory Amendment 27, the Council determined that recent commercial harvests of yellowtail snapper have influenced the commercial harvest of greater amberjack. In 2017 and 2018, the commercial sector for yellowtail snapper closed 2 months prior to the end of that species' fishing year. The early closures of commercial yellowtail snapper resulted in commercial fishermen in Florida targeting greater amberjack more heavily, leading to earlier commercial closures of greater amberjack and price fluctuations that affect resource users throughout the South Atlantic. The Council expects that dividing the commercial quota for South Atlantic greater amberjack between two seasons and reducing the commercial trip limit for the latter half of the fishing year would lengthen the greater amberjack commercial season and allow for a more equitable distribution and price stability of the greater amberjack resource throughout the South Atlantic.

Regulatory Amendment 27 and this proposed rule would specify two commercial fishing seasons for greater amberjack. The two seasons would be March 1 through August 31 (Season 1) and September 1 through the end of February (Season 2). The commercial quotas would be allocated as 60 percent to Season 1, 461,633 lb (209,393 kg), and 40 percent to Season 2, 307,755 lb (139,595 kg). Any remaining commercial quota from Season 1 would be added to the commercial quota in Season 2. Any remaining quota from Season 2 would not be carried forward into the next fishing year.

Additionally, Regulatory Amendment 27 and this proposed rule would modify the commercial trip limit for greater amberjack. During Season 1, the commercial trip limit would be 1,200 lb (544 kg) in round or gutted weight, and during Season 2, the commercial trip limit would be 1,000 lb (454 kg) in round or gutted weight. However, during April each year, the commercial sale and purchase of greater amberjack would continue to be prohibited, and the harvest and possession limit would continue to be one fish per person per day or one fish per person per trip, whichever is more restrictive.

Commercial Split Season and Trip Limit for Red Porgy

Currently, the fishing year for red porgy is January 1 through December 31, and the commercial ACL (equivalent to the commercial quota) is 157,692 lb (71,528 kg), gutted weight, or 164,000 lb (74,389 kg), round weight. During January through April each year, the commercial sale and purchase of red porgy is prohibited on board a vessel for which a Federal commercial permit for South Atlantic snapper-grouper has been issued, and the commercial harvest and possession limit for red porgy (equivalent to a commercial trip limit) is three fish per person per day or three fish per person per trip, whichever is more restrictive. The commercial trip limit for red porgy is 120 fish from May 1 through December 31.

In the South Atlantic, red porgy spawn from January through May and spawning activity peaks from January through March. The current January through April prohibition on sale and purchase of red porgy and restrictive harvest and possession limit encompasses the majority of the spawning season, and provides direct benefits to the stock by reducing fishing pressure on the spawning stock. However, during January through April commercial fishermen target two co-occurring species, vermilion snapper and gray triggerfish, while reporting discards of red porgy. Therefore, these discards of red porgy reduce the benefits of a spawning season closure for the stock when commercial fishermen target other co-occurring species. The Council determined that a commercial trip limit of 60 fish and a lower portion of the commercial quota during January through April would continue to constrain harvest to protect spawning fish, while allowing commercial fishermen to retain a sufficient amount of red porgy when targeting co-occurring species, thereby reducing discards of red porgy.

Regulatory Amendment 27 and this proposed rule would establish two commercial fishing seasons for red porgy. The first season would be

January 1 through April 30 (Season 1), and the second season would be May 1 through December 31 (Season 2). The current fishing year would not change. The commercial quotas would be allocated as 30 percent to Season 1, 47,308 lb (21,459 kg) gutted weight, 49,200 lb (22,317 kg), round weight; and 70 percent to Season 2, 110,384 lb (50,069 kg) gutted weight, 114,800 lb (52,072 kg), round weight. Any remaining commercial quota from Season 1 would be added to the commercial quota in Season 2. Any remaining quota from Season 2 would not be carried forward into the next fishing year. The proposed rule would remove the current commercial sale and purchase prohibition and the possession limit of three fish per person per day or three fish per person per trip, whichever is more restrictive, during January 1 through April 30.

Additionally, Regulatory Amendment 27 and this proposed rule would modify the commercial trip limits for red porgy during the Season 1 to be 60 fish. During Season 2, the commercial trip limit for red porgy would continue to be 120 fish.

Commercial Trip Limit for Vermilion Snapper

Currently, the commercial fishing year for vermilion snapper is from January 1 through December 31. The commercial ACL (equivalent to the commercial quota) is divided equally between two commercial fishing seasons as January 1 through June 30 (Season 1) and July 1 through December 31 (Season 2). Any remaining commercial quota from Season 1 is added to the commercial quota for Season 2. Any remaining commercial quota from Season 2 is not carried forward into the next fishing year. During both Season 1 and Season 2, the commercial trip limit for vermilion snapper is 1,000 lb (454 kg). Additionally, if NMFS estimates that 75 percent of the vermilion snapper commercial quota during either season is met or is projected to be met, NMFS will publish a notice in the **Federal Register** to reduce the commercial trip limit to 500 lb (227 kg).

Fishermen requested that the Council consider reducing the commercial trip limit in Season 2, as many more snapper-grouper species are available for harvest during that time and a reduced commercial trip limit would be expected to extend the fishing season for vermilion snapper. In addition, Abbreviated Framework Amendment 2 to the Snapper-Grouper FMP was recently implemented (84 FR 14021, April 9, 2019) that increased the total ACL for vermilion snapper based on the results of the latest stock assessment in 2018. Therefore, the Council determined that there is no longer a need to have a trip limit reduction for vermilion snapper. Also, as described in Regulatory Amendment 27, maintaining the current commercial trip limit would ensure economic profitability and efficient use of the vermilion snapper resource.

Regulatory Amendment 27 and this proposed rule would remove the trip limit reduction for vermilion snapper from both seasons but retain the 1,000 lb (454 kg) commercial trip limit. Any remaining commercial quota from Season 1 would continue to be added to the commercial quota for Season 2, and any remaining commercial quota from Season 2 would not be carried forward into the next fishing year.

Minimum Size Limit for Almaco Jack

There is currently no commercial minimum size limit for almaco jack. This proposed rule would establish a commercial minimum size limit of 20 inches (50.8 cm), fork length (FL), in the South Atlantic EEZ. Fishermen with Federal commercial permits for South Atlantic snapper-grouper reported their concerns to the Council about the small size, and resulting poor commercial value, of some of the almaco jack being landed. The minimum size limit for the commercial sector of 20 inches (50.8 cm), FL, would allow more individual almaco jack to reach reproductive activity before being susceptible to harvest, and is projected to increase the average size and the corresponding average weight of fish harvested.

Commercial Trip Limit for the Other Jacks Complex

Currently, there is not a commercial trip limit for species in the other jacks complex, which includes lesser amberjack, almaco jack, and banded rudderfish. Regulatory Amendment 27 and this proposed rule would establish a commercial trip limit for the other jacks complex of 500 lb (227 kg). In 2014, stakeholders told the Council that almaco jack, which typically dominate commercial landings of species in the other jacks complex, are an incidental catch on trips targeting vermilion snapper. The Council determined that commercial fishermen would benefit from being able to profit from those incidental catches of almaco jack if they were to achieve a higher price per fish, since the market value of almaco jack (and the other species in the other jacks complex) is increasing. Because the commercial sector for the other jacks complex has historically closed before the end of the fishing year, fishermen told the Council that a 500-lb (227-kg) commercial trip limit for the other jacks complex would still allow them to make a profitable trip, and the proposed commercial trip limit would enable fishermen to have the added benefit of an extended commercial season for the other jacks complex. In addition, Council members noted that banded rudderfish are commercially important in the springtime, particularly in April when the commercial harvest of greater amberjack is closed. Although some commercial trips can land over 1,000 lb (454 kg) of banded rudderfish during certain times of the year, the Council determined it would be more equitable for commercial fishermen, and better for the long-term sustainability of the other jacks complex resource, to establish a 500-lb (227-kg) commercial trip limit for this species complex.

Minimum Size Limit for Queen Snapper, Silk Snapper, and Blackfin Snapper

Queen snapper, silk snapper, and blackfin snapper are part of the deep-water complex. Currently, the commercial minimum size limit for queen snapper, silk snapper, and blackfin snapper is 12 inches (30.5 cm) total length (TL), but the remaining species in the deep-water complex do not have a specified minimum size limit requirement. The 12-inch (30.5-cm) TL commercial minimum size limit was implemented for queen snapper, blackfin snapper, and silk snapper early in the management of the snapper-grouper fishery, before estimates of discard mortality were available, and before the creation of the various species complexes by the Council. All of the species in the deep-water complex (yellowedge grouper, silk snapper, misty grouper, queen snapper, sand tilefish, and blackfin snapper) are typically associated with a high discard mortality. The Council determined that removing the commercial minimum size limit for queen snapper, silk snapper, and blackfin snapper would reduce discards and discard mortality for these species. Therefore, Regulatory Amendment 27 and this proposed rule would remove the commercial minimum size limit for queen snapper, silk snapper, and blackfin snapper.

Minimum Size Limit for Gray Triggerfish

The current commercial minimum size limit for gray triggerfish in the South Atlantic EEZ is 14 inches (35.6 cm) FL off the east coast of Florida and 12 inches (30.5 cm) FL off North Carolina, South Carolina, and Georgia. Regulatory Amendment 27 and this proposed rule would reduce the

commercial minimum size limit to 12 inches (30.5 cm) FL in the EEZ off the east coast of Florida. In 2015, the 12-inch (30.5-cm) FL commercial minimum size limit was implemented for gray triggerfish in the EEZ off North Carolina, South Carolina, and Georgia, and a commercial minimum size limit of 14 inches (35.6 cm) FL was implemented in the EEZ off the east coast of Florida (80 FR 30947, June 1, 2015). This was a precautionary action taken by the Council in response to their concerns about the status of the South Atlantic gray triggerfish stock, to align Federal regulations off the east coast of Florida with those in the Gulf of Mexico, and achieve consistency between state and Federal regulations off the east coast of Florida. However, after the commercial minimum size limit went into effect on July 1, 2015, stakeholders in Florida expressed concern to the Florida Fish and Wildlife Conservation Commission (FWC) regarding increasing discards of gray triggerfish in south Florida where the average size of gray triggerfish is less than that off northeast Florida. In response to that concern, the FWC reduced the recreational minimum size limit of gray triggerfish in state waters to 12 inches (30.5 cm) FL in 2017, and requested that the Council develop consistent size limit regulations in Federal waters for gray triggerfish. Therefore, reducing the commercial minimum size limit to 12 inches (30.5 cm) FL would make these state and Federal regulations for gray triggerfish consistent off the east coast of Florida, off the other South Atlantic states, and in Federal waters throughout the Council's jurisdiction.

Classification

Pursuant to section 304(b)(1)(A) of the Magnuson-Stevens Act, the NMFS Assistant Administrator has determined that this proposed rule is consistent with Regulatory Amendment 27, the Snapper-Grouper FMP, other provisions of the Magnuson-Stevens Act, and other applicable laws, subject to further consideration after public comment.

This proposed rule has been determined to be not significant for purposes of Executive Order 12866. This rule is expected to be an Executive Order 13771 deregulatory action.

The Magnuson-Stevens Act provides the statutory basis for this proposed rule. No duplicative, overlapping, or conflicting Federal rules have been identified.

NMFS prepared an initial regulatory flexibility analysis (IRFA) for this proposed rule, as required by section 603 of the RFA, 5 U.S.C. 603. The IRFA describes the economic impact this proposed rule, if adopted, would have on small entities. A description of this proposed rule, why it is being considered, and the purposes of this proposed rule are contained in the preamble and in the **SUMMARY** section of the preamble. A copy of the full analysis is available from NMFS (see **ADDRESSES**). A summary of the IRFA follows.

The objective of this proposed rule is to improve management of the commercial sector of the snapper-grouper fishery to better achieve optimum yield, while minimizing, to the extent practicable, the adverse socio-economic effects of regulations on commercial fishing entities in the South Atlantic.

This proposed rule, if implemented, would make the following changes to the regulations for the commercial snapper-grouper fishing industry in the South Atlantic region. This proposed rule would reduce the commercial trip limit for blueline tilefish from 300 lb (136 kg) to 100 lb (45 kg) from January 1 through April 30. For snowy grouper, this proposed rule would establish two commercial fishing seasons of January 1 through June 30 (Season 1) and July 1 through December 31 (Season 2), rather than a single season within the fishing year, allocate 70 percent of the commercial quota to Season 1 and 30 percent to Season 2, and transfer any remaining commercial quota from Season 1 to Season 2 only. For greater amberjack, this proposed rule would establish two commercial fishing seasons of March 1 through August 31 (Season 1) and September 1 through the end of February (Season 2), rather than a single season within the March through February fishing year; allocate 60 percent of the commercial quota to Season 1 and 40 percent to Season 2, and add any remaining commercial quota from Season 1 to Season 2 only; and reduce the commercial trip limit from 1,200 lb (545 kg) in round or gutted weight to 1,000 lb (454 kg) in round or gutted weight for Season 2. For red porgy, this proposed rule would remove the sale and purchase prohibition, and the possession limit of three fish per person per day or three fish per person per trip during January 1 to April 30 each year; specify two commercial fishing seasons for red porgy of January 1 through April 30 (Season 1) and May 1 through December 31 (Season 2) within the fishing year; allocate 30 percent of the commercial quota to Season 1 and 70 percent to Season 2; and establish a commercial trip limit of 60 fish in Season 1. This proposed rule would also remove the in-season reduction of the commercial trip limit in Season 1 and Season 2 for vermilion snapper, establish a commercial minimum size limit of 20 inches (50.8 cm) FL for almaco jack, establish a commercial trip limit of 500 lb (227 kg) for the other jacks complex, remove the 12-inch (30.5-cm) TL commercial minimum size limit for queen snapper, silk snapper, and blackfin snapper, and reduce the commercial minimum size limit for gray triggerfish from 14 inches (35.6 cm) to 12 inches (30.5 cm) FL in the EEZ off the east coast of Florida. Therefore, this proposed rule is expected to directly regulate businesses that are active in the commercial snapper-grouper fishing industry.

As of August 17, 2018, the number of vessels with a valid or renewable Federal commercial permit for South Atlantic snapper-grouper was 644, composed of 536 transferable, unlimited snapper-grouper permits and 108 non-transferable, 225-lb (102 kg) trip-limited permits. With the exception of species-specific trip limits, there is no aggregate snapper-grouper harvest limit per trip for vessels with unlimited snapper-grouper permits, while vessels with trip-limited permits cannot harvest more than 225 lb (102 kg) of all snapper-grouper species per trip. On average, only 584 vessels used their commercial permits for harvesting purposes from 2012 through 2016. Some permit holders retain their permits for speculative or other non-harvesting purposes. The majority of vessels harvest multiple snapper-grouper species. The proposed rule will only directly regulate permit holders that actually use their permits for harvesting purposes. Therefore, it is expected that approximately 584 vessels will be directly regulated by this proposed rule.

Although NMFS started to collect ownership data for businesses that possess commercial snapper-grouper permits in 2017, this data is currently incomplete and historical data is not available. Therefore, it is not currently feasible to accurately determine affiliations between these particular businesses. As a result of the incomplete ownership data, for purposes of this analysis, it is assumed each of these vessels is independently owned by a single business, which is expected to result in an overestimate of the actual number of businesses directly regulated by this proposed rule. Therefore, this proposed rule is estimated to directly regulate 584 businesses in the commercial snapper-grouper fishing industry.

All monetary estimates in the following analysis are in 2016 dollars. For vessels that were active in the

snapper-grouper fishing industry from 2012 through 2016, average annual gross revenue was approximately $44,000 per vessel. Average annual net cash flow per vessel was approximately $8,300 while net revenue from operations was approximately $2,000 per vessel. Net revenue from operations is the best available estimate of economic profit.

The Small Business Administration has established size standards for all major industry sectors in the U.S. including commercial fishing businesses. On December 29, 2015, NMFS issued a final rule establishing a small business size standard of $11 million in annual gross receipts (revenue) for all businesses primarily engaged in the commercial fishing industry (NAICS code 11411) for RFA compliance purposes only (80 FR 81194, December 29, 2015). In addition to this gross revenue standard, a business primarily involved in commercial fishing is classified as a small business if it is independently owned and operated, and is not dominant in it field of operations (including its affiliates). The maximum average annual gross revenue from 2012 through 2016 for a single vessel in the commercial snapper-grouper fishing industry was about $1.6 million. Based on the information above, all businesses directly regulated by this proposed rule are determined to be small businesses for the purpose of this analysis.

This proposed rule, if implemented, would be expected to directly regulate the 584 active vessels with commercial permits in the South Atlantic snapper-grouper fishery of the 644 vessels that currently possess those permits. All directly regulated businesses have been determined, for the purpose of this analysis, to be small entities. Based on this information, the proposed rule is expected to affect a substantial number of small businesses.

The action to reduce the commercial trip limit for blueline tilefish from 300 lb (136 kg) to 100 lb (45 kg) from January 1 through April 30 is expected to directly regulate approximately 134 vessels. These vessels' average annual gross revenues were $82,411 per vessel from 2012 through 2016. Average annual net revenue from operations for these vessels was approximately 4 percent of their average annual gross revenue from 2014 through 2016. Thus, annual net revenue from operations (economic profit) for these vessels is estimated to be about $3,300 per vessel. Average annual gross revenue per vessel is expected to increase by about $13 per year, which would result in an increase in economic profit of about 0.4 percent for these vessels.

For snowy grouper, the action to establish two commercial fishing seasons of January 1 through June 30 (Season 1) and July 1 through December 31 (Season 2) rather than a single season within the fishing year, allocate 70 percent of the commercial quota to Season 1 and 30 percent to Season 2, and to add any remaining commercial quota from Season 1 to Season 2 only, is expected to directly regulate approximately 149 vessels. These vessels' average annual gross revenues were $85,475 per vessel from 2012 through 2016. Average annual net revenue from operations for these vessels was approximately 4 percent of their average annual gross revenue from 2014 through 2016. Therefore, annual net revenue from operations for these vessels is estimated to be about $3,400 per vessel. This action is not expected to affect landings, annual gross revenue, or harvesting costs, and thus economic profit for these vessels is not expected to change.

For greater amberjack, the action to establish two commercial fishing seasons of March 1 through August 31 (Season 1) and September 1 through the end of February (Season 2) within the fishing year, allocate 60 percent of the commercial quota to Season 1 and 40 percent to Season 2, add any remaining commercial quota from Season 1 to Season 2 only, and reduce the commercial trip limit from 1,200 lb (545 kg) in round or gutted weight to 1,000 lb (454 kg) in round or gutted weight for Season 2 is expected to directly regulate approximately 263 vessels. These vessels' average annual gross revenues were $62,578 per vessel from 2012 through 2016. Average annual net revenue from operations for these vessels was approximately 4 percent of their average annual gross revenue from 2014 through 2016. Thus, average annual net revenue from operations for these vessels is estimated to be about $2,500 per vessel. This action is expected to reduce average annual gross revenues to these vessels by about $34, which represents less than 0.1 percent of their average annual gross revenues, and about 11.4 percent of their average annual economic profit. Although a quantitative estimate cannot be provided due to lack of data, this action is also expected to cause a minor increase in these vessels' operating costs. In general, trip limits are expected to increase costs because commercial fishing vessels must take more trips to harvest and land the same amount of fish. The more restrictive the trip limit, the greater the expected increase in costs. The proposed reduction in the commercial trip limit for Season 2 is 200 lb (91 kg) in round or gutted weight per trip, or about 17 percent of the current trip limit. A 17 percent reduction is not a large reduction in general and the reduction only applies in Season 2. Thus, this action would be expected to slightly reduce these vessels' economic profits.

For red porgy, the actions to remove the sale and purchase prohibition and the possession limit of three fish per person per day or three fish per person per trip during January 1 to April 30 each year, establishing two commercial fishing seasons of January 1 through April 30 (Season 1) and May 1 through December 31 (Season 2) within the fishing year, allocate 30 percent of the commercial quota to Season 1 and 70 percent to Season 2, and establish a commercial trip limit of 60 fish in Season 1 is expected to directly regulate approximately 160 vessels. These vessels' average annual gross revenues were $73,366 per vessel from 2012 through 2016. Average annual net revenue from operations for commercial vessels in the snapper-grouper fishery was approximately 4.5 percent of their average annual gross revenue from 2014 through 2016. Thus, annual net revenue from operations for these vessels is estimated to be about $3,300 per vessel. The expected increase in annual gross revenue from this action is about $335 per vessel, representing an increase of about 0.5 percent of average annual gross revenues but a 9 percent increase in economic profit. The decision to harvest red porgy during the months when sales and purchase are currently prohibited could lead to additional harvesting costs, but these would be self-imposed and, assuming standard business practices by owners of commercial vessels, the additional gross revenues will exceed the additional costs (*i.e.,* economic profit is expected to increase). Moreover, the red porgy landings that would be expected during January through April are likely fish that were previously discarded due to the current prohibition. If these landings are fish that were previously discarded, then no additional costs would be incurred and the additional gross revenue would represent additional economic profit to these vessels as well.

The action to remove the in-season commercial trip limit reduction for vermilion snapper in both seasons is expected to directly regulate approximately 206 vessels. These vessels' average annual gross revenues were $66,330 per vessel from 2011 through 2016. Average annual net revenue from operations for these vessels was approximately negative 1

percent of their average annual gross revenue from 2014 through 2016 (*i.e.,* these vessels have been generating economic losses). Thus, annual net revenue from operations for these vessels is estimated to be about negative $6,600 per vessel. This action is expected to result in a reduction of $42 in average annual gross revenue per vessel, which is a minimal change relative to annual average gross revenues, but would increase economic losses by about 0.6 percent. However, the action is also expected to change the cost of harvesting vermilion snapper. In general, trip limits are expected to increase costs because commercial fishing vessels must take more trips to harvest and land the same amount of fish. The more restrictive the trip limit, the greater the expected increase in costs. Under the current regulations, the commercial trip limit for both seasons is reduced by 50 percent, from 1,000 lb (454 kg) gutted weight to 500 lb (227 kg) gutted weight, when 75 percent of the commercial quota in either season is harvested, which is significant. Further, changes in trip limits within a fishing year and particularly within a season can introduce inefficiencies in the production process as commercial fishing vessels must adjust their operations to account for such changes. While these inefficiencies are likely not as great when the trip limit changes are known well in advance, they become particularly acute when the owners of commercial fishing vessels do not know if or when the trip limit change is going to occur, which is the case under the current regulations. Further, because at least some owners of commercial fishing vessels would prefer to fish when the trip limit is greater, trip limit reductions can result in mini-fishing derbies (race-to-fish) within a season. Splitting the commercial quota between seasons only partially mitigates this effect. Although models are not available to quantitatively estimate the expected changes in costs, the elimination of the trip limit reduction is expected to significantly reduce these vessels' harvesting costs, likely more than offsetting the relatively minor reduction in gross revenue. Therefore, this action is expected to increase economic profit for these vessels.

The action to establish a commercial minimum size limit of 20 inches (50.8 cm) FL for almaco jack is expected to directly regulate approximately 165 vessels. These vessels' average annual gross revenues were $77,267 per vessel from 2012 through 2016. Average annual net revenue from operations for these vessels was approximately 4 percent of their average annual gross revenue from 2014 through 2016. Thus, average annual net revenue from operations for these vessels is estimated to be about $3,100 per vessel. Average annual gross revenue per vessel is expected to decrease by about $4 per vessel under the action, which is minimal (*i.e.,* about 0.1 percent of economic profit), and thus unlikely to affect these vessels' fishing behavior. However, establishing a minimum size limit will also lead to discarded fish. Thus, commercial fishing vessels would have to exert more effort per trip or take more trips to land the same amount of almaco jack, which would lead to higher costs. The more restrictive the minimum size limit, the greater the amount of discarded fish and thus the greater the expected increase in costs. The increase in costs per vessel could be considerably higher than the minimal increase in average annual gross revenue per vessel, depending on the amount of almaco jack that vessels are forced to discard and how much additional effort they exert to maintain their landings and revenue. However, the increase in cost may be partially offset through a higher price received for larger sized fish, but the extent to which this effect will occur is unknown due to lack of data on the variability of prices across almaco jack of different sizes. Based on this information, this action may reduce the economic profits of these 165 vessels.

The action to establish a commercial trip limit of 500 lb (227 kg) for the other jacks complex is expected to directly regulate approximately 210 vessels. These vessels' average annual gross revenues were $69,363 per vessel from 2012 through 2016. Average annual net revenue from operations for these vessels was approximately 4 percent of their average annual gross revenue from 2014 through 2016. Therefore, annual net revenue from operations for these vessels is estimated to be about $2,800 per vessel. Given the proposed commercial minimum size limit for almaco jack discussed in the previous action, establishing a commercial trip limit for the other jacks complex is expected to result in a reduction of $28 in average annual gross revenue per vessel, or about 1 percent of the average annual economic profit. However, establishing a minimum size limit is also expected to increase costs, which would decrease economic profit even further. The magnitude of the increase in costs depends on how much additional effort commercial vessels must exert to maintain their landings and revenues. Therefore, economic profit for these vessels is expected to be reduced.

The action to remove the 12-inch (30.5-cm) TL commercial minimum size limit for queen snapper, silk snapper, and blackfin snapper is expected to directly regulate approximately 94 vessels. These vessels' average annual gross revenues were $93,154 per vessel from 2012 through 2016. Average annual net revenue from operations for these vessels was approximately 4 percent of their average annual gross revenue from 2014 through 2016. Thus, annual net revenue from operations for these vessels is estimated to be about $3,700 per vessel. This action is expected to result in a minimal increase in landings of queen snapper, silk snapper, and blackfin snapper. However, commercial fishing vessels have only harvested about 43 percent of the commercial ACL for the deep-water complex since blueline tilefish was removed from that complex. Therefore, landings of queen snapper, silk snapper, and blackfin snapper could increase significantly without any concern of exceeding the commercial ACL for the deep-water complex. Further, with the elimination of the minimum size limit, vessels would be able to increase their landings per unit of effort for these species, thereby decreasing the cost per pound of fish landed. Therefore, this action would be expected to increase the economic profit of these vessels to some extent.

The action to reduce the commercial minimum size limit for gray triggerfish in the EEZ off the east coast of Florida from 14 inches (35.6 cm) to 12 inches (30.5 cm) FL is expected to directly regulate approximately 213 vessels. These vessels' average annual gross revenues were $65,661 per vessel from 2012 through 2016. Average annual net revenue from operations for these vessels was approximately 2 percent of their average annual gross revenue from 2014 through 2016. Thus, annual net revenue from operations for these vessels is estimated to be about $1,300 per vessel. This action is expected to result in an increase in annual gross revenue per vessel of approximately $10, which would represent an increase the average vessel's economic profit of about 0.8 percent per year. Reducing the minimum size limit for gray triggerfish will also allow commercial fishing vessels to harvest these species with less effort. As such, this action would also be expected to decrease the cost per pound of harvest, though by how much is unknown due to the lack of appropriate models. Thus, this action is expected to result in a modest increase in these vessels' economic profit.

Based on the information above, average annual gross revenues for the 584 active commercial snapper-grouper vessels is expected to increase by about $33,400, or approximately $57 per vessel, as a result of all the actions in this proposed rule. This increase represents only about 0.1 percent of these vessels' average annual gross revenues, but about 3 percent of their average annual economic profit. Harvesting costs are expected to significantly decrease for vessels harvesting vermilion snapper and slightly decrease for vessels harvesting gray triggerfish, while they are expected to increase for vessels harvesting greater amberjack, almaco jack, and species in the other jacks complex. Because of these countervailing effects on harvesting costs, harvesting costs for many commercial snapper-grouper vessels will likely change little if at all. Thus, economic profit for the average commercial snapper-grouper vessel is expected to increase slightly or remain relatively the same, though some vessels could experience a reduction in economic profit.

Five alternatives, including the *status quo,* were considered for the proposed action to reduce the commercial trip limit for blueline tilefish from 300 lb (136 kg) to 100 lb (45 kg) from January 1 through April 30. The *status quo* alternative and the other four alternatives were not selected because they are not expected to achieve the Council's goal of enabling more equitable access to the resource for fishermen from different areas of the South Atlantic. The *status quo* alternative is also not expected to increase economic profits for the affected small entities.

Two alternatives, including the *status quo,* were considered for the proposed action to establish, for snowy grouper, two commercial fishing seasons of January 1 through June 30 (Season 1) and July 1 through December 31 (Season 2) within the calendar fishing year, allocate 70 percent of the commercial ACL to Season 1 and 30 percent to Season 2, and transfer any remaining quota from Season 1 to Season 2. The *status quo* alternative and the other alternative were not selected because they are not expected to achieve the Council's goal of enabling more equitable access to the resource for fishermen from different areas of the South Atlantic.

Nine alternatives, including the *status quo,* were considered for the proposed action to establish, for greater amberjack, two commercial fishing seasons of March 1 through August 31 (Season 1) and September 1 through February 31 (Season 2) within the March through February fishing year, allocate 60 percent of the commercial ACL to Season 1 and 40 percent to Season 2, transfer any remaining quota from Season 1 to Season 2, and reduce the commercial trip limit from 1,200 lb (545 kg) in round or gutted weight to 1,000 lb (454 kg) in round or gutted weight for Season 2. The *status quo* alternative was not selected because it is not expected to achieve the Council's goal of enabling more equitable access to the resource for fishermen from different areas of the South Atlantic. Six of the other alternatives are expected to decrease economic profits for the affected small entities more than the proposed action and thus were not selected. The other two alternatives are expected to reduce economic profits less than the proposed action, but were not selected because they are not expected to achieve the Council's goal of enabling more equitable access to the resource for fishermen from different areas of the South Atlantic.

For red porgy, seven alternatives, including the *status quo,* were considered for the proposed action to remove the sale and purchase prohibition and the possession limit of three per person per day or three per person per trip during January 1 to April 30 each year, specify two commercial fishing seasons of January 1 through April 30 (Season 1) and May 1 through December 31 (Season 2) within the fishing year, allocate 30 percent of the commercial ACL to Season 1 and 70 percent to Season 2, and establish a commercial trip limit of 60 fish in Season 1. The *status quo* was not selected because it is not expected to achieve the Council's goal of enabling more equitable access to the resource for fishermen from different areas of the South Atlantic and is not expected to increase economic profits for the affected small entities.

Five alternatives, including the *status quo,* were considered for the proposed action to remove the trip limit reduction in both seasons for vermilion snapper. None of these alternatives were selected because they are expected to result in lower economic profits for the affected small entities, while three of these alternatives are also expected to result in significantly higher regulatory costs to the government.

Four alternatives, including the *status quo,* were considered for the proposed action to establish a commercial minimum size limit of 20 inches (50.8 cm) FL for almaco jack. The *status quo* was not selected because almaco jack less than 20 inches (50.8 cm) FL are not considered to be of a marketable size (*i.e.,* they are difficult if not impossible to sell at a price that would not lead to economic losses) and therefore would likely be discarded. Thus, the *status quo* alternative is not expected to achieve the Council's goals of improving the marketability of certain species and minimizing discards. The other three alternatives are expected to result in even higher discards, which is contrary to the Council's goal of minimizing discards, and are also expected to reduce economic profits for the affected small entities more than the proposed action.

Three alternatives, including the *status quo,* were considered for the proposed action to establish a commercial trip limit of 500 lb (227 kg) for the other jacks complex. The *status quo* alternative was not selected as it is not expected to achieve the Council's goal of enabling more equitable access to the resource for fishermen from different areas of the South Atlantic. The other two alternatives are expected to reduce economic profits more than the proposed action and therefore were not selected.

One alternative, the *status quo,* was considered for the proposed action to remove the 12-inch (30.5-cm) TL commercial minimum size limit for queen snapper, silk snapper, and blackfin snapper. The *status quo* alternative was not selected because it is expected to result in higher discards, which is contrary to the Council's goal of minimizing discards, and is also expected to result in lower economic profits for the affected small entities.

One alternative, the *status quo,* was considered for the proposed action to reduce the commercial minimum size limit for gray triggerfish in the EEZ off the east coast of Florida from 14 inches (35.6 cm) to 12 inches (30.5 cm) FL. The *status quo* alternative was not selected because it is expected to result in higher discards, which is contrary to the Council's goal of minimizing discards, and is also expected to result lower economic profits for the affected small entities.

No new reporting, record-keeping, or other compliance requirements are introduced by this proposed rule. Accordingly, this proposed rule does not implicate the Paperwork Reduction Act.

List of Subjects in 50 CFR Part 622

Fisheries, Fishing, Grouper, Snapper, South Atlantic.

Dated: October 7, 2019.

Samuel D. Rauch III,

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

For the reasons set out in the preamble, 50 CFR part 622 is proposed to be amended 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.*

§ 622.184 [Amended]

■ 2. In § 622.184, remove paragraph (c).

■ 3. In § 622.185, revise paragraphs (a)(3) and (c)(2), and add paragraph (c)(6) to read as follows:

§ 622.185 Size limits.

* * * * *

(a) * * *

(3) *Cubera, gray, and yellowtail snappers*—12 inches (30.5 cm), TL.

* * * * *

(c) * * *

(2) *Gray triggerfish.* (i) For a fish taken by a person not subject to the bag limit specified in § 622.187(b)(8)—12 inches (30.5 cm), FL.

(ii) For a fish taken by a person that is subject to the bag limit specified in § 622.187(b)(8)—(A) In the South Atlantic EEZ off Florida—14 inches (35.6 cm), FL.

(B) In the South Atlantic EEZ off North Carolina, South Carolina, and Georgia—12 inches (30.5 cm), FL.

* * * * *

(6) *Almaco jack.* For a fish taken by a person not subject to the bag limit specified in § 622.187(b)(8)—20 inches (50.8 cm), FL.

■ 4. In § 622.190, revise paragraphs (a)(1), (3), and (6) to read as follows:

§ 622.190 Quotas.

* * * * *

(a) * * *

(1) *Snowy grouper*—(i) For the period January 1 through June 30 each year—107,754 lb (48,876 kg).

(ii) For the period July 1 through December 31 each year—46,181 lb (20,947 kg).

(iii) Any unused portion of the quota specified in paragraph (a)(1)(i) of this section will be added to the quota specified in paragraph (a)(1)(ii) of this section. Any unused portion of the quota specified in paragraph (a)(1)(ii) of this section, including any addition of quota specified in paragraph (a)(1)(i) of this section that was unused, will become void and will not be added to any subsequent quota.

* * * * *

(3) *Greater amberjack*—(i) For the period March 1 through August 31 each year—461,633 lb (209,393 kg).

(ii) For the period September 1 through the end of February each year—307,755 lb (139,595 kg).

(iii) Any unused portion of the quota specified in paragraph (a)(3)(i) of this section will be added to the quota specified in paragraph (a)(3)(ii) of this section. Any unused portion of the quota specified in paragraph (a)(3)(ii) of this section, including any addition of quota specified in paragraph (a)(3)(i) of this section that was unused, will become void and will not be added to any subsequent quota.

* * * * *

(6) *Red porgy*—(i) For the period January 1 through April 30 each year—47,308 lb (21,458 kg), gutted weight; 49,200 lb (22,317 kg), round weight.

(ii) For the period May 1 through December 31 each year—110,384 lb (50,069 kg), gutted weight; 114,800 lb (52,072 kg), round weight.

(iii) Any unused portion of the quota specified in paragraph (a)(6)(i) of this section will be added to the quota specified in paragraph (a)(6)(ii) of this section. Any unused portion of the quota specified in paragraph (a)(6)(ii) of this section, including any addition of quota specified in paragraph (a)(6)(i) of this section that was unused, will become void and will not be added to any subsequent quota.

* * * * *

■ 5. In § 622.191, revise paragraphs (a)(4) through (6), (10), and add paragraph (a)(14) to read as follows:

§ 622.191 Commercial trip limits.

* * * * *

(a) * * *

(4) *Red porgy.* The following commercial trip limits apply until the applicable commercial quota specified in § 622.190(a)(6) is reached. See § 622.190(c)(1) for the limitations regarding red porgy after the applicable commercial quota is reached.

(i) From January 1 through April 30—60 fish.

(ii) From May 1 through December 31—120 fish.

(5) *Greater amberjack.* The following commercial trip limits apply until the applicable commercial quota specified in § 622.190(a)(3) is reached. See § 622.190(c)(1) for the limitations regarding greater amberjack after the applicable commercial quota is reached.

(i) From March 1 through August 31—1,200 lb (544 kg).

(ii) From September 1 through the end of February—1,000 lb (454 kg).

(6) *Vermilion snapper.* Until the applicable commercial quota specified in § 622.190(a)(4) is reached—1,000 lb (454 kg), gutted weight. See § 622.190(c)(1) for the limitations regarding vermilion snapper after the applicable commercial quota is reached.

* * * * *

(10) *Blueline tilefish.* The following commercial trip limits apply until the commercial ACL specified in § 622.193(z)(1)(i) is reached. See § 622.193(z)(1)(i) for the limitations regarding blueline tilefish after the commercial ACL is reached.

(i) From January 1 through April 30—100 lb (45 kg), gutted weight; 106 lb (48 kg), round weight.

(ii) From May 1 through December 31—300 lb (136 kg), gutted weight; 318 lb (144 kg), round weight.

* * * * *

(14) *Other jacks complex (lesser amberjack, almaco jack, and banded rudderfish).* Until the commercial ACL specified in § 622.193(l)(1)(i) is reached—500 lb (227 kg), gutted weight; 520 lb (236 kg), round weight. See § 622.193(l)(1)(i) for the limitations regarding the other jacks complex after the commercial ACL is reached.

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[FR Doc. 2019–22197 Filed 10–16–19; 8:45 am]

BILLING CODE 3510–22–P

Notices

Federal Register
Vol. 84, No. 201
Thursday, October 17, 2019

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.

JUDICIAL CONFERENCE OF THE UNITED STATES

Advisory Committee on the Federal Rules of Bankruptcy Procedure

AGENCY: Advisory Committee on the Federal Rules of Bankruptcy Procedure, Judicial Conference of the United States.

ACTION: Notice of proposed amendments.

SUMMARY: The Advisory Committee on Bankruptcy Rules have proposed amendments to the following rules and forms:

Interim Bankruptcy Rules: 1007(b), 1007(h), 1020, 2009, 2012(a), 2015, 3010(b), 3011, and 3016; and Bankruptcy Forms: 101, 201, 309E, 309E2, 309F, 309F2, 314, 315, and 425A.

DATES: All written comments and suggestions with respect to the proposed amendments may be submitted on or after the opening of the period for public comment on October 16, 2019, but no later than November 13, 2019.

ADDRESSES: The text of the proposed rules and the accompanying committee notes, along with the related forms, are posted on the Judiciary's website at: *http://www.uscourts.gov/rules-policies/proposed-amendments-published-public-comment.* Written comments must be submitted electronically, following the instructions provided on the website. All comments submitted will be posted on the website and available to the public.

FOR FURTHER INFORMATION CONTACT: Rebecca A. Womeldorf, Secretary, Committee on Rules of Practice and Procedure of the Judicial Conference of the United States, Thurgood Marshall Federal Judiciary Building, One Columbus Circle NE, Suite 7–300, Washington, DC 20544, Telephone (202) 502–1820.

Dated: October 11, 2019.

Rebecca A. Womeldorf,

Secretary, Committee on Rules of Practice and Procedure, Judicial Conference of the United States.

[FR Doc. 2019–22621 Filed 10–16–19; 8:45 am]

BILLING CODE 2210–55–P

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

[Doc. No. AMS–NOP–19–0090; NOP–19–04]

National Organic Program: Request for an Extension of a Currently Approved Information Collection

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the Agricultural Marketing Service's (AMS) intention to request approval from the Office of Management and Budget, for an extension of the currently approved information collection National Organic Program (NOP) Reporting and Recordkeeping Requirements.

DATES: Comments received by December 16, 2019 will be considered.

ADDRESSES: Interested persons are invited to submit written comments concerning this notice. Comments must be sent to Valerie Frances, Agricultural Marketing Specialist, National Organic Program, AMS/USDA, 1400 Independence Ave. SW, Room 2642–S., Ag Stop 0268, Washington, DC 20250–0268 or by internet: *http://www.regulations.gov.* Written comments responding to this notice should be identified with the document number AMS–NOP–19–0090; NOP–19–04. It is USDA's intention to have all comments concerning this notice, including names and addresses when provided, regardless of submission procedure used, available for viewing on the *Regulations.gov* (*http://www.regulations.gov*) internet site. Comments submitted in response to this notice will also be available for viewing in person at USDA–AMS, National Organic Program, Room 2624-South Building, 1400 Independence Ave. SW, Washington, DC, from 9 a.m. to 12 noon and from 1:00 p.m. to 4 p.m., Monday through Friday (except official Federal holidays). Persons wanting to visit the USDA South Building to view comments received in response to this notice are requested to make an appointment in advance by calling (202) 720–3252.

FOR FURTHER INFORMATION CONTACT: Paul I. Lewis, Ph.D., Director, Standards Division, National Organic Program, USDA–AMS, 1400 Independence Ave. SW, Room 2642-So., Ag Stop 0268, Washington, DC 20250, Telephone: (202) 720–3252, Fax: (202) 205–7808.

SUPPLEMENTARY INFORMATION:

Title: National Organic Program.

OMB Number: 0581–0191.

Expiration Date of Approval: January 31, 2020.

Type of Request: Extension of a currently approved information collection.

Abstract: The Organic Foods Production Act of 1990 (OFPA) as amended (7 U.S.C. 6501–6522) mandates that the Secretary develop the NOP to accredit eligible State program's governing State officials or private persons as certifying agents who would certify producers or handlers of agricultural products that have been produced using organic methods as provided for in OFPA. The USDA organic regulation (7 CFR part 205): (1) Established national standards governing the marketing of certain agricultural products as organically produced products; (2) assures consumers that organically produced products meet a consistent standard; and (3) facilitates interstate commerce in fresh and processed food that is organically produced.

Reporting and recordkeeping are essential to the integrity of the organic certification system. A paper trail is a critical element in carrying out the mandate of OFPA and NOP. Reporting and recordkeeping serve the AMS mission, program objectives, and management needs by providing information on the efficiency and effectiveness of the program. The information affects decisions because it is the basis for evaluating compliance with OFPA and NOP, for administering the program, for management decisions and planning, and for establishing the cost of the program. It supports administrative and regulatory actions in response to noncompliance with OFPA and NOP.

In general, the information collected is used by USDA, State program governing State officials, and certifying agents. It is created and submitted by State and foreign program officials, peer review auditors, accredited certifying agents, organic inspectors, certified organic producers and handlers, those seeking accreditation or certification, and parties interested in changing the National List of Allowed and Prohibited Substances at sections 205.600 through 205.607. Additionally, it causes most of these entities to have procedures and space for recordkeeping.

USDA. USDA is the accrediting authority. USDA accredits domestic and foreign certifying agents who certify domestic and foreign organic producers and handlers, using information from the agents documenting their business operations and program expertise. USDA also permits States to establish their own state organic programs after the programs are approved by the Secretary, using information from the States documenting their ability to operate such programs and showing that such programs meet the requirements of OFPA and NOP.

States. States may operate their own organic programs. State officials obtain the Secretary's approval of their programs by submitting information to USDA documenting their ability to operate such programs and showing that such programs meet the requirements of OFPA and NOP. The Secretary, or delegated representative, will review a State organic program not less than once during each 5-year period following the date of the initial program approval. To date, one State organic program is approved by USDA.

Certifying agents. Certifying agents are State, private, or foreign entities who are accredited by USDA to certify domestic and foreign producers and handlers as organic in accordance with OFPA and NOP. Each entity wanting to be an agent seeks accreditation from USDA, submitting information documenting its business operations and program expertise. Accredited certifying agents determine if a producer or handler meets organic requirements, using detailed information from the operation documenting its specific practices and on-site inspection reports from organic inspectors. As of August 7, 2019, there are 78 certifying agents accredited under NOP.

Administrative costs for reporting, disclosure of information, and recordkeeping vary among certifying agents. Factors affecting costs include the number and size of clients, the categories of certification provided, and the type of systems maintained.

When an entity applies for accreditation as a certifying agent, it must provide a copy of its procedures for complying with recordkeeping requirements (§ 205.504(b)(3)). Once accredited, agents must make their records available for inspection and copying by authorized representatives of the Secretary (§ 205.501(a)(9)). USDA charges certifying agents for the time required to do these document reviews. Audits require less time when the documents are well organized and centrally located.

Recordkeeping requirements for certifying agents are divided into three categories of records with varying retention periods: (1) Records created by certifying agents regarding applicants for certification and certified operations, maintain 10-years, consistent with OFPA's requirement for maintaining all records concerning activities of certifying agents; (2) records obtained from applicants for certification and certified operations, maintain 5-years, the same as OFPA's requirement for the retention of records by certified operations; and (3) records created or received by certifying agents regarding accreditation, maintain 5-years, consistent with OFPA's requirement for renewal of agent's accreditation (§ 205.510(b)).

Organic inspectors. Inspectors, on behalf of certifying agents, conduct on-site inspections of certified operations and operations applying for certification. They report the findings from their inspection to the certifying agent. Inspectors are the agents themselves, employees of the agents, or individual contractors. We estimate that about half are certifying agents or their employees and half are individual contractors. Individuals who apply for positions as inspectors submit to the agents information documenting their qualifications to conduct such inspections. According to International Organic Inspectors Association (IOIA), there are at least 250 inspectors currently providing services.[1]

Producers and handlers. Producers and handlers, domestic and foreign, apply to certifying agents for organic certification, submit detailed information documenting their specific practices, provide annual updates to continue their certification, and report changes in their practices. Producers include farmers, livestock and poultry producers, and wild crop harvesters. Handlers include those who transport or transform food and include millers, bulk distributors, food manufacturers, processors, or packers. Some handlers are part of a retail operation that processes organic products in a location other than the premises of the retail outlet. Based upon AMS NOP's Organic Integrity Database (INTEGRITY) on August 7, 2019, there are approximately 42,309 certified operations globally.[2] Based on past growth of the industry, AMS estimates the addition of 2,496 new certified organic operations a year. In addition, AMS estimates that there are 4,866 producers exempt from certification, but who must still maintain records pursuant to section 205.101(c).

Administrative costs for reporting and recordkeeping vary among certified operators. Factors affecting costs include the type and size of operation, and the type of systems maintained.

AMS believes that operations using product labels containing the term ''organic'' handle an average of 20 labels annually. Based on INTEGRITY on August 7, 2019, there are over 18,584 certified organic handlers. For each certified handler, AMS estimates that the average annual burden to develop product labels with organic claims is two hour per product label times 20 product labels per handler. The annual burden will be lower for smaller operations and livestock feed handlers, and higher for large operations that produce a significant volume of organic processed product.

Interested parties. Any interested party may petition the National Organic Standards Board (NOSB) for the purpose of having a substance evaluated for recommendation to the Secretary for inclusion on or deletion from the National List. Based on the number of petitions received in the past, AMS estimates 25 parties petitioning the NOSB to amend the National List in a given year. The annual burden for each interested party to prepare a complete petition is an average of 30 hours.

Estimate of Burden: Public reporting burden for this collection of information is estimated to average 4.99 hours per response.

Respondents: Producers, handlers, certifying agents, inspectors and State, Local or Tribal governments and interested parties.

Estimated Number of Respondents: 50,025.

Estimated Number of Responses: 1,138,229.

Estimated Number of Responses per Respondent: 22.75.

Estimated Total Annual Burden on Respondents: 5,667,494.

[1] Not all inspectors are members of IOIA.

[2] Organic Integrity Databse: *https://organic.ams.usda.gov/integrity/*

Comments are invited on: (1) 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) 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) 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 those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

All responses to this notice will be summarized and included in the request for OMB approval. All comments will become a matter of public record.

Authority: 7 U.S.C. 6501–6522.

Dated: October 10, 2019.

Bruce Summers,

Administrator, Agricultural Marketing Service.

[FR Doc. 2019–22564 Filed 10–16–19; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF AGRICULTURE

Submission for OMB Review; Comment Request

October 11, 2019.

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 November 18, 2019 will be considered. Written comments should be addressed to: Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), New Executive Office Building, 725–17th Street NW, Washington, DC 20502. Commenters are encouraged to submit their comments to OMB via email to: *OIRA_Submission@OMB.EOP.GOV* or fax (202) 395–5806 and to Departmental Clearance Office, USDA, OCIO, Mail Stop 7602, Washington, DC 20250–7602. Copies of the submission(s) may be obtained by calling (202) 720–8958.

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.

Rural Housing Service

Title: 7 CFR 3570 Community Facilities Technical Assistance and Training Grant Program.

OMB Control Number: 0575–0198.

Summary of Collection: The Community Facilities Technical Assistance and Training (TAT) is a competitive grant program which the Rural Housing Service (RHS) administers. Section 306 of the Consolidated Farm and Rural Development Act (CONACT), 7 U.S.C. 1926, was amended by Section 6006 of the Agriculture Act of 2014 (P.L. 113–79) to establish the Community Facilities Technical Assistance and Training Grant. Section 6006 authorized grants be made to public bodies and private nonprofit corporations (including Indian Tribes) that will serve rural areas for the purpose of enabling the grantees to provide to associations technical assistance and training with respect to essential community facilities authorized under Section 306(a)(1) of the Consolidated Farm and Rural Development Act (7 U.S.C. 1926(a)). Grants can be made for 100 percent of the cost of assistance.

Need and Use of the Information: Eligible entities receive TAT grants to help small rural communities or areas identify and solve problems relating to essential community facilities. The grant recipients may provide technical assistance to public bodies and private nonprofit corporations. Applicants applying for TAT grants must submit an application, which includes an application form, narrative proposal, various other forms, certifications, and supplemental information. The Rural Development State Offices and the RHS National Office staff will use the information collected to determine applicant eligibility, project feasibility, and the applicant's ability to meet the grant and regulatory requirements. Failure to collect proper information could result in improper determinations of eligibility or improper use of funds.

Description of Respondents: Not-for-Profit Institutions.

Number of Respondents: 51.

Frequency of Responses: Reporting: Annually.

Total Burden Hours: 1,397.

Title: 7CFR 1956–C, Debt Settlement—Community and Business Programs.

OMB Control Number: 0575–0124.

Summary of Collection: The Community and Direct Business Programs loans and grants are authorized by the Consolidated Farm and Rural Development Act. Rural Housing Service (RHS) is a credit agency for agricultural and rural development for the United States Department of Agriculture and offers supervised credit to develop, improve and operate family farms, modest housing, essential community facilities, and business and industry across rural America. 7 CFR 1956–C, Debt Settlement—Community and Business Programs provides policies and procedures as well as a mechanism for debt settlement in connection with Community Facilities loans and grants, direct Business and Industry loans, Indian Tribal Land Acquisition loans and Irrigation and Drainage. The debt settlement program provides the delinquent client with an equitable tool for the compromise, adjustment, cancellation, or charge-off of a debt owed to the Agency.

Need and Use of the Information: The field offices will collect information from applicants, borrowers, consultants, lenders, and attorneys to determine eligibility, financial capacity and derive an equitable resolution. This information collected is similar to that required by a commercial lender in similar circumstances. Failure to collect the information could result in improper servicing of these loans.

Description of Respondents: Not for profit institutions; Business or other for-profit; State, Local or Tribal Government.

Number of Respondents: 116.

Frequency of Responses: Reporting: On occasion.

Total Burden Hours: 1,005.

Kimble Brown,

Departmental Information Collection Clearance Officer.

[FR Doc. 2019–22694 Filed 10–16–19; 8:45 am]

BILLING CODE 3410–XV–P

DEPARTMENT OF AGRICULTURE

Submission for OMB Review; Comment Request

October 11, 2019.

The Department of Agriculture has submitted the following information collection requirement(s) to Office of Management and Budget (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; 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 November 18, 2019 will be considered. Written comments should be addressed to: Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), New Executive Office Building, 725—17th Street NW, Washington, DC 20502. Commenters are encouraged to submit their comments to OMB via email to: *OIRA_Submission@OMB.EOP.GOV* or fax (202) 395–5806 and to Departmental Clearance Office, USDA, OCIO, Mail Stop 7602, Washington, DC 20250–7602. Copies of the submission(s) may be obtained by calling (202) 720–8958.

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Rural Utilities Service

Title: New Equipment Contract (Form 395) for Telecommunications and Broadband Borrowers.

OMB Control Number: 0572–0149.

Summary of Collection: The Rural Electrification Act of 1936, 7 U.S.C. 901 *et seq.,* as amended (RE Act), in Title I, sec. 2, The Administrator is authorized and empowered to make loans in the States and Territories of the United States for rural electrification and the furnishing of electric energy to persons in rural areas who are not receiving central station service, and for the purpose of furnishing and improving telephone service in rural areas, as hereinafter provided; to make or cause to be made, studies, investigations, and reports concerning the condition and progress of the electrification of and the furnishing of adequate telephone service in rural areas in the several States and Territories; and to publish and disseminate information with respect thereto.

Need and Use of the Information: In an effort to improve customer service provided to RUS rural borrowers, the Agency has proposed to revise, consolidate, and/or streamline its current contracts and contracting procedures. In this activity RUS has and will continue to work with industry groups to obtain their input as to what types of changes they and borrowers may want to see made to the contracts.

Description of Respondents: Business or other for-profit.

Number of Respondents: 51.

Frequency of Responses: Reporting: On occasion.

Total Burden Hours: 161.

Kimble Brown,

Departmental Information Collection Clearance Officer.

[FR Doc. 2019–22689 Filed 10–16–19; 8:45 am]

BILLING CODE 3410–15–P

DEPARTMENT OF AGRICULTURE

Submission for OMB Review; Comment Request

October 10, 2019.

The Department of Agriculture has submitted the following information collection requirement(s) to Office of Management and Budget (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; 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 November 18, 2019 will be considered. Written comments should be addressed to: Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), New Executive Office Building, 725—17th Street NW, Washington, DC 20502. Commenters are encouraged to submit their comments to OMB via email to: *OIRA_Submission@OMB.EOP.GOV* or fax (202) 395–5806 and to Departmental Clearance Office, USDA, OCIO, Mail Stop 7602, Washington, DC 20250–7602. Copies of the submission(s) may be obtained by calling (202) 720–8958.

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.

Rural Utilities Service

Title: Special Evaluation Assistance for Rural Communities and Households Program (SEARCH).

OMB Control Number: 0572–0146.

Summary of Collection: The Food, Conservation and Energy Act of 2008, Public Law 110–234 (Farm Bill) amended Section 306(a)(2) of the Consolidated Farm and Rural Development Act (CONACT) (7 U.S.C. 1926(a)(2)). The amendment created a grant program to make Special Evaluation Assistance for Rural Communities and Households (SEARCH) Program grants.

Under the SEARCH program, the Secretary may make predevelopment and planning grants to public or quasi-public agencies, organizations operated on a not-for-profit basis or Indian tribes on Federal and State reservations and other federally recognized Indian tribes. The grant recipients use the grant funds for feasibility studies, design assistance, and technical assistance for direct loans, grants and guaranteed loans, to financially distress communities in rural areas with populations of 2,500 or fewer inhabitants for water and waste disposal projects as authorized in Sections 306(a)(1), 306(a)(2) and 306(a)(24) of the CONACT.

Need and Use of the Information: Applicants applying for SEARCH grants

must submit an application which includes an application form, various other forms, certifications, and supplemental information. Rural Utility Service will use the information collected from applicants, borrowers, and consultants to determine applicant eligibility, project feasibility, and the applicant's ability to meet the grant and regulatory requirements.

Failure to collect proper information could result in improper determinations of eligibility, improper use of funds, or hindrances in making grants authorized by the SEARCH program.

Description of Respondents: Not-for-profit Institutions and State, Local or Tribal Government.

Number of Respondents: 111.

Frequency of Responses: Reporting: On occasion.

Total Burden Hours: 3,380.

Kimble Brown,

Departmental Information Collection Clearance Officer.

[FR Doc. 2019–22560 Filed 10–16–19; 8:45 am]

BILLING CODE 3410–15–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS–2018–0073]

Decision To Authorize the Importation of Fresh Guava From Taiwan Into the Continental United States

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: We are advising the public of our decision to authorize the importation of fresh guava fruit from Taiwan into the continental United States. Based on the findings of the pest risk analysis, which we made available to the public to review and comment through a previous notice, we have concluded that the application of one or more designated phytosanitary measures will be sufficient to mitigate the risks of introducing or disseminating plant pests or noxious weeds via the importation of fresh guava fruit from Taiwan.

DATES: The articles covered by this notification may be authorized for importation after October 17, 2019.

FOR FURTHER INFORMATION CONTACT: Mr. Tony Román, Senior Regulatory Policy Specialist, Regulatory Coordination and Compliance, PPQ, APHIS, 4700 River Road Unit 133, Riverdale, MD 20737–1231; (301) 851–2242.

SUPPLEMENTARY INFORMATION: Under the regulations in ''Subpart L—Fruits and Vegetables'' (7 CFR 319.56–1 through 319.56–12, referred to below as the regulations), the Animal and Plant Health Inspection Service (APHIS) prohibits or restricts the importation of fruits and vegetables into the United States from certain parts of the world to prevent plant pests from being introduced into and spread within the United States.

Section 319.56–4 of the regulations contains a notice-based process based on established performance standards for authorizing the importation of fruits and vegetables. The performance standards, known as designated phytosanitary measures, are listed in paragraph (b) of that section. Under the process, APHIS proposes to authorize the importation of a fruit or vegetable into the United States if, based on the findings of a pest risk analysis, we determine that the measures can mitigate the plant pest risk associated with the importation of that fruit or vegetable. APHIS then publishes a notice in the **Federal Register** announcing the availability of the pest risk analysis that evaluates the risks associated with the importation of that fruit or vegetable.

In accordance with that process, we published a notice [1] in the **Federal Register** on December 14, 2018 (83 FR 64314–64315, Docket No. APHIS–2018–0073), in which we announced the availability, for review and comment, of a pest risk assessment (PRA) that evaluated the risks associated with the importation into the continental United States of fresh guava fruit from Taiwan and a risk management document (RMD) prepared to identify phytosanitary measures that could be applied to the commodity to mitigate the pest risk.

We solicited comments on the PRA and RMD for 60 days ending on February 12, 2019. We received five comments by that date. They were from private citizens, the California Department of Food and Agriculture (CDFA), and the Florida Department of Agriculture and Consumer Services (FDACS).

One of the commenters expressed general support for the importation of guava from Taiwan into the United States, while another expressed general opposition to the importation of fruits and vegetables into the United States. The other three commenters provided comments regarding the notice and its supporting documentation. Below, we discuss these comments, by topic.

Comments on the Pest Risk Assessment

The PRA contained a pest list of pests associated with guava and known to occur in Taiwan. The PRA identified 23 [2] pests as being of quarantine significance and likely to follow the pathway on guava from Taiwan, and therefore possible candidates for risk mitigation.

CDFA stated that, in addition to the 23 pests identified as being of quarantine significance, there were another 12 pests listed on the pest list that were rated as either an ''A'' pest or ''B'' pest according to CDFA's pest rating system: *Aleurodicus dispersus, Ceroplastes floridensis, Coccus viridis, Ferrisia virgata, Kilifia acuminata, Milviscutulus mangiferae, Paracoccus marginatus, Planococcus minor, Pseudococcus jackbeardsleyi, Pulvinaria psidii, Rusellapsis pustulanus,* and *Selenothrips rubrocinctus.* Under CDFA's rating system, a pest given an ''A'' rating is a plant pest of known economic importance subject to a State of California-enforced action that involves eradication, quarantine regulation, containment, rejection, or other holding action. A pest given a ''B'' rating is a pest of known economic importance subject to eradication, containment, control, or other holding action at the discretion of the individual county agricultural commissioner within the State of California.[3] The commenter stated that mitigations should be developed for these pests as well.

In § 319.56–4 of the regulations, paragraph (c) provides that if a fruit or vegetable is not authorized importation into the United States, APHIS will not authorize its importation until we examine the pest risk associated with its importation and determine that the risk posed by each quarantine pest associated with the importation of the commodity can reasonably be mitigated by the application of one or more mitigation measures. Additionally, consistent with international standards to which the United States is a signatory,[4] the regulations define a *quarantine pest* as: ''A pest of potential

[1] To view the notice, PRA, RMD, supporting documents, and the comments that we received, go to *http://www.regulations.gov/#!docketDetail;D=APHIS-2018-0073.*

[2] Due to a typographical error, the PRA erroneously stated that 24 pests had been identified, although only 23 were listed; the RMD correctly stated that only 23 had been identified. This notice will use the latter number.

[3] For further information, see *https://ucanr.edu/sites/plantpest/Regualtory_Information/Pest_Ratings/.*

[4] See *https://www.ippc.int/largefiles/adopted_ISPMs_previousversions/en/ISPM_05_2007_En_2007-07-26.pdf.*

economic importance to the area endangered thereby and not yet present there, or present but not widely distributed there and being officially controlled.'' For purposes of an APHIS risk assessment, the ''endangered area'' is the geographical area of the United States into which a foreign country has requested that APHIS authorize importation of the commodity; in the case of the guava from Taiwan, this is the continental United States.

With regard to 11 of the 12 pests cited by CDFA (*Aleurodicus dispersus, Ceroplastes floridensis, Coccus viridis, Ferrisia virgata, Kilifia acuminata, Milviscutulus mangiferae, Planococcus minor, Pseudococcus jackbeardsleyi, Pulvinaria psidii, Rusellapsis pustulanus,* and *Selenothrips rubrocinctus*), while these pests were listed in the pest list of our PRA, they are all present in the United States and not under Federal official control, and therefore do not meet our definition of a *quarantine pest.* Therefore, we do not consider it necessary to develop mitigations for these pests, irrespective of their rating within CDFA's system.

However, APHIS has developed a program, the Federally Recognized State Managed Phytosanitary Program (FRSMP), to afford protections to States when commodities are determined at a port of entry to harbor a plant pest that is not a quarantine pest but is of concern to a particular State. Information regarding the petition process for FRSMP is found here: *https://www.aphis.usda.gov/plant_health/plant_pest_info/frsmp/downloads/petition_guidelines.pdf.*

With regard to the twelfth pest mentioned by CDFA (*Paracoccus marginatus*), this pest was, in fact, not included in the pest list in our PRA. We agree that *P. marginatus* is associated with guava and known to occur on fruit, but could find no evidence suggesting it is present in Taiwan; this is why it was not included in the pest list. CDFA did not provide a reference regarding the pest's presence in Taiwan; therefore, we cannot evaluate their assertion. We also note that *P. marginatus* is present in the United States and not under official control, and thus not a quarantine pest.

Finally, CDFA stated that *Phyllostica psidiicola,* a fungal pathogen, is present in Taiwan, not present in the continental United States, and known to cause severe black rot in guavas. CDFA requested that it be included in the PRA.

We agree that *Phyllostica psidiicola* is present in Taiwan and not present in the continental United States, and have determined that it is a quarantine pest and could follow the pathway on importation of guavas from Taiwan into the continental United States. Therefore, we have prepared an addendum to the PRA that evaluates *P. psidiicola,* assigns it a Medium risk rating, and determines that it is a possible candidate for risk mitigation. We also have revised our RMD to include *P. psidiicola* as a quarantine pest that could follow the pathway on the importation of guavas from Taiwan into the United States. The addendum to the PRA and the revised RMD are available on *Regulations.gov*, or by contacting the individual listed in this notice under **FOR FURTHER INFORMATION CONTACT**.

The inclusion of *P. psidiicola* in the RMD does not alter the mitigations of the RMD from those we initially proposed. *P. psidiicola* causes corky lesions on the surface on infected fruit that are easily detected during visual inspections, and we proposed both pre-export inspection by the national plant protection organization of Taiwan and port-of-entry inspections as components of our systems approach for the importation of guava from Taiwan.

That being said, the revised RMD does include one additional mitigation measure not included in the initial RMD. We discuss this mitigation measure and the basis for its inclusion later in this document.

Comments on the Risk Management Document

We proposed that a portion of a biometric sample of all consignments of guavas from Taiwan intended for export to the United States would have to be cut open by the NPPO of Taiwan and inspected for internally feeding quarantine pests.

FDACS questioned whether the fruit cutting would be effective. They requested data from the NPPO regarding the efficacy of fruit cutting to detect quarantine pests that feed internally.

The efficacy of fruit cutting as a means of detecting quarantine pests is long established,[5] and the inspectors who will conduct the cutting in Taiwan have been trained by the NPPO in proper fruit cutting to sample for pests. While we acknowledge FDACS' legitimate interest in ensuring that infested guava are not imported from Taiwan into the State of Florida, we would only request fruit-cutting data from an NPPO and consider sharing it with external parties when there is reason to believe that the NPPO is not conducting fruit cutting or is doing so in an ineffective manner. This is not the case with Taiwan.

We also note that all guava imported into the United States will be subject to additional cutting by Customs and Border Protection in accordance with 7 CFR part 305 at ports of entry into the United States.

We proposed that the guava would have to be treated with cold treatment for *Bactrocera* spp. fruit flies, or alternatively, irradiated.

FDACS expressed concern that the cold treatment would not be effectively applied. They stated that misapplication of cold treatment is a recurring issue, and cited two examples that they considered evidence of failure of in-transit cold treatment and indicative of the liabilities of cold treatment as a mitigation measure: The discovery of live fruit flies on cold-treated clementines from Spain, later, clementines from Morocco. Because of the possibility of cold treatment failure and the high likelihood that fruit flies may become established in Florida, if introduced, FDACS requested that we prohibit the importation of guava from Taiwan into the State of Florida.

The detection of fruit flies on clementines from Spain occurred in 2001 and was determined to be the result of an inadequate cold treatment schedule, rather than misapplication of an effective treatment schedule.[6] It resulted in a holistic review and revision of the manner in which APHIS evaluates and approves phytosanitary treatments, and should not be considered indicative of current practices.

Based on a site visit that APHIS conducted, the detection of fruit flies on clementines from Morocco was determined to be the result of failure to pre-cool the fruit adequately prior to applying cold treatment. We also determined that this pre-cooling failure was, in turn, due to uniquely inhospitable climatic conditions in the area of Morocco surrounding the pre-cooling facility, a desert where daytime temperatures during the summer months routinely exceed 90 °F. We addressed this failure by revising the operational workplan that Morocco had entered into with APHIS to specify additional pre-cooling and temperature

[5] For example, see: Cavey, J.F. 2003. *Mitigating introduction of invasive plant pests in the United States.* Pages 350—361(Chapter 13). In *Invasive Species: Vectors and Management Strategies,* G.M. Ruiz and J.T. Carlton, editors. Island Press, Washington DC. See also: Gould, W.P. 1995. *Probability of Detecting Caribbean Fruit Fly (Diptera: Tephritidae) Infestations by Fruit Dissection.* Florida Entomologist 78(3): 502–507.

[6] These findings are discussed at length in a 2002 interim rule (67 FR 63529–63539, Docket No. 02–071–1) that revised our phytosanitary treatment regulations based on the detection.

reading procedures at pre-cooling facilities.[7]

Given Taiwan's more temperate climate, we do not consider a similar pre-cooling failure likely to occur in Taiwan.

Additionally, we note that cold treatment is not the only mitigation measure that we proposed in order to address *Bactrocera* spp. fruit flies. We proposed that places of production would have to have a fruit fly trapping system in place, as certified by the NPPO of Taiwan; that fallen fruit would have to be removed from places of production to eliminate possible fruit fly host material; that packinghouses where the guava was processed for consignment to the United States would have to be registered with the NPPO of Taiwan and determined to be pest exclusionary; and that a portion of a biometric sample of each consignment of guava intended for export to the United States would have to cut open by the NPPO of Taiwan and inspected for fruit fly larvae and other quarantine pests.

For the above reasons, we do not consider it necessary to prohibit the importation of guava from Taiwan into the State of Florida.

A commenter suggested that the guava could be irradiated as a treatment for fruit flies.

We agree, and included this treatment option in the RMD.

Finally, following the close of the comment period, the NPPO of Taiwan informed us that, as a standard industry practice, all guava intended for export from Taiwan for commercial sale are bagged. Accordingly, the NPPO indicated that they would be amenable to including bagging as an additional, voluntarily imposed mitigation measure to address the pest risk associated with the importation of guava into the continental United States, with the specific logistics of this bagging included in the operational workplan that they will enter into with APHIS. This additional bagging requirement is included in the revised RMD.

Therefore, in accordance with § 319.56–4(c)(3)(iii), we are announcing our decision to authorize the importation of fresh guava fruit from Taiwan into the continental United States subject to the following phytosanitary measures:

- Importation in commercial consignments only;
- Development of an operational workplan that the NPPO of Taiwan must enter into with APHIS;
- Registration of places of production and packinghouses with the NPPO of Taiwan;
- Regular inspections of places of production by the NPPO;
- Grove sanitation and trapping for fruit flies in places of production;
- Safeguarding and identification of the lot throughout the growing, packing and export process;
- Bagging of fruit intended for export;
- Phytosanitary treatment (cold treatment or irradiation);
- Pre-export inspection by the NPPO, including fruit cutting of a portion of a biometric sample, and issuance of a phytosanitary certificate with an additional declaration that states that the fruit have been produced in accordance with the requirements of the systems approach, inspected, and found free of *P. psidii* and *P. psidiicola*; and
- Port of entry inspections.

These conditions will be listed in the Fruits and Vegetables Import Requirements database (available at *https://epermits.aphis.usda.gov/manual*). In addition to these specific measures, fresh guava fruit from Taiwan will be subject to the general requirements listed in § 319.56–3 that are applicable to the importation of all fruits and vegetables.

Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the reporting and recordkeeping requirements included in this notice are covered under the Office of Management and Budget (OMB) control number 0579–0049. The estimated annual burden on respondents is 1,632 hours, which will be added to 0579–0049 in the next quarterly update.

E-Government Act Compliance

The Animal and Plant Health Inspection Service is committed to compliance with the EGovernment Act to promote 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. For information pertinent to E-Government Act compliance related to this notice, please contact Mr. Joseph Moxey, APHIS' Information Collection Coordinator, at (301) 851–2483.

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 action as not a major rule, as defined by 5 U.S.C. 804(2).

Authority: 7 U.S.C. 1633, 7701–7772, and 7781–7786; 21 U.S.C. 136 and 136a; 7 CFR 2.22, 2.80, and 371.3.

Done in Washington, DC, this 10th day of October 2019.

Kevin Shea,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2019–22648 Filed 10–16–19; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS–2018–0030]

Notice of a Determination Regarding the Fever Tick Status of the State of Baja California, Mexico

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: We are advising the public that we have determined that the State of Baja California, Mexico is free from *Rhipicephalus* (formerly *Boophilus*) *spp.* ticks, known as fever ticks. The evaluation determined that this region is free from fever ticks and that ruminants imported from the area pose a low risk of exposing ruminants within the United States.

DATES: This change in fever tick status will be recognized on November 18, 2019.

FOR FURTHER INFORMATION CONTACT: Dr. Betzaida Lopez, Senior Staff Veterinarian, Strategy and Policy, VS, APHIS, 4700 River Road Unit 39, Riverdale, MD 20737; (301) 851–3300.

SUPPLEMENTARY INFORMATION: The regulations in 9 CFR part 93 prohibit or restrict the importation of certain animals, birds, and poultry into the United States to prevent the introduction of communicable diseases of livestock and poultry. Subpart D of part 93 (§§ 93.400 through 93.436, referred to below as the regulations) governs the importation of ruminants; within the regulations, §§ 93.424 through 93.429 specifically address the importation of ruminants from Mexico into the United States.

The regulations in paragraph (b)(1) of § 93.427 contain conditions for the importation of ruminants from regions of Mexico that we consider free from *Rhipicephalus* (formerly *Boophilus*) *spp.* ticks, known as fever ticks. Regions of Mexico that we consider free from fever ticks are listed at *https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/animal-and-animal-*

[7] See *https://www.aphis.usda.gov/import_export/plants/plant_imports/federal_order/downloads/2018/DA-2018-01.pdf.*

product-import-information/animal-health-status-of-regions/animal-health-status-of-regions.

The regulations in 9 CFR 92.2 contain requirements for requesting the recognition of the animal health status of a region or for the approval of the export of a particular type of animal or animal product to the United States from a foreign region. If, after review and evaluation of the information submitted in support of the request, the Animal and Plant Health Inspection Service (APHIS) believes the request can be safely granted, APHIS will make its evaluation available for public comment through a notice published in the **Federal Register**. Following the close of the comment period, APHIS will review all comments received and will make a final determination regarding the request that will be detailed in another notice published in the **Federal Register**.

In accordance with that process, Mexico asked APHIS to recognize the State of Baja California, Mexico as a region free from fever ticks. In response to this request, we prepared an evaluation of the fever tick status of this region. The evaluation concluded that the State of Baja California, Mexico is free from fever ticks, and that ruminants imported from the region pose a low risk of exposing ruminants within the United States to fever ticks.

On March 19, 2019, we published in the **Federal Register** (84 FR 10023–10024, Docket No. APHIS–2018–0030) a notice [1] in which we announced the availability for review and comment of our evaluation of the fever tick status of the State of Baja California, Mexico. We solicited comments on the notice for 60 days ending on May 20, 2019. We received no comments on our evaluation.

Therefore, based on the findings of our evaluation and the absence of comments that would lead us to reconsider those findings, we are announcing our determination to add the State of Baja California, Mexico to the list of regions of Mexico declared free from fever ticks. This list is available on the APHIS website at *https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/animal-and-animal-product-import-information/animal-health-status-of-regions/animal-health-status-of-regions.*

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 action as not a major rule, as defined by 5 U.S.C. 804(2).

Authority: 7 U.S.C. 1622 and 8301–8317; 21 U.S.C. 136 and 136a; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.4.

Done in Washington, DC, this 10th day of October 2019.

Kevin Shea,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2019–22645 Filed 10–16–19; 8:45 am]

BILLING CODE 3410–34–P

[1] To view the notice and the evaluation, go to *http://www.regulations.gov/#!docketDetail;D=APHIS-2018-0030.*

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS–2018–0043]

Notice of Determination of the Foot-and-Mouth Disease Status of Singapore

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: We are advising the public of our determination to recognize Singapore as being free of foot-and-mouth disease (FMD). Based on our evaluation of the FMD status of Singapore, which we made available to the public for review and comment through a previous notice, the Administrator has determined that Singapore is free of FMD.

DATES: This change in Singapore's FMD status will be recognized on November 18, 2019.

FOR FURTHER INFORMATION CONTACT: Dr. Roberta A. Morales, Senior Staff Veterinarian, Regionalization Evaluation Services, Strategy and Policy, VS, APHIS, 920 Main Campus Drive, Raleigh, NC 27606; (919) 855–7735; *Roberta.A.Morales@usda.gov*.

SUPPLEMENTARY INFORMATION: The regulations in 9 CFR part 94 (referred to below as the regulations) govern the importation of certain animals and animal products into the United States to prevent the introduction of various animal diseases, including foot-and-mouth disease (FMD). The regulations prohibit or otherwise restrict the importation of live ruminants and swine, and products from these animals, from regions where the Animal and Plant Health Inspection Service (APHIS) considers FMD to exist.

Within part 94, § 94.1 contains requirements governing the importation of ruminants and swine from regions where FMD exists and the importation of the meat of any ruminants or swine from regions where FMD exists to prevent the introduction of this disease into the United States. We consider FMD to exist in all regions except those listed in accordance with paragraph (a) of that section as free of FMD.

Section 94.11 of the regulations contains requirements governing the importation of meat of any ruminants or swine from regions that have been determined to be free of FMD, but that are subject to certain restrictions because of their proximity to or trading relationships with FMD-affected regions. Such regions are listed in accordance with paragraph (a) of that section.

The regulations in 9 CFR part 92, § 92.2, contain requirements for requesting the recognition of the animal health status of a region. If, after review and evaluation of the information submitted in support of the request, APHIS believes the request can be safely granted, APHIS will indicate its intent and make its evaluation available for public comment through a document published in the **Federal Register**. Following the close of the comment period, APHIS will review all comments received and will make a final determination regarding the request that will be detailed in another document published in the **Federal Register**.

In accordance with that process, Singapore requested that APHIS evaluate the FMD status of that country. In response to this request, APHIS conducted a qualitative risk assessment to evaluate the FMD status of Singapore. Based on the results of this evaluation, we have determined that Singapore is free of FMD. APHIS also determined that the surveillance, prevention, and control measures implemented by Singapore are sufficient to minimize the likelihood of introducing FMD into the United States via imports of species susceptible to this disease or products of those species.

Accordingly, we published a notice [1] in the **Federal Register** on March 19, 2019 (84 FR 10024–10025, Docket No. APHIS–2018–0043), in which we announced the availability, for review and comment, of a risk assessment that evaluated the risk of introduction of FMD into the United States through the importation of animals and animal products from Singapore.

We solicited comments on the notice for 60 days ending May 20, 2019. We did not receive any comments. Therefore, in accordance with the regulations, we are announcing our

[1] To view the notice and supporting documents, go to *https://www.regulations.gov/docket?D=APHIS-2018-0043.*

decision to recognize Singapore as free of FMD. The list of regions recognized as free of FMD can be found on the APHIS website at *https://www.aphis.usda.gov/animalhealth/disease-status-of-regions*. Copies of the lists are also available via postal mail, fax, or email upon request to Regionalization Evaluation Services, Strategy and Policy, Veterinary Services, Animal and Plant Health Inspection Service, 4700 River Road Unit 39, Riverdale, MD 20737.

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 action as not a major rule, as defined by 5 U.S.C. 804(2).

Authority: 7 U.S.C. 1633, 7701–7772, 7781–7786, and 8301–8317; 21 U.S.C. 136 and 136a; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.4.

Done in Washington, DC, this 10th day of October 2019.

Kevin Shea,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2019–22646 Filed 10–16–19; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Natural Resources Conservation Service

[Docket ID NRCS–2019–0015]

Adoption of Another Agency's Final Environmental Impact Statement To Implement the Feral Swine Eradication and Control Pilot Program

AGENCY: Natural Resources Conservation Service (NRCS), U.S. Department of Agriculture (USDA).

ACTION: Notice of Availability for the Record of Decision (ROD).

SUMMARY: NRCS announces the availability of the agency's Record of Decision (ROD) to adopt the Final Environmental Impact Statement (FEIS), ''Feral Swine Damage Management: A National Approach EIS'', prepared by the U.S. Department of Agriculture's Animal and Plant Health Inspection Service (APHIS), under the Environmental Impact Statement (EIS) adoption provisions of the Council on Environmental Quality (CEQ).

FOR FURTHER INFORMATION CONTACT: Martin Lowenfish, Branch Chief for Areawide Planning, Natural Resources Conservation Service, at *Martin.Lowenfish@usda.gov* or (202) 690–4979. Persons with disabilities who require alternative means for communication should contact the USDA Target Center at (202) 720–2600 (voice).

SUPPLEMENTARY INFORMATION: NRCS will adopt the FEIS titled, ''Feral Swine Damage Management; A National Approach EIS'', prepared by APHIS under the EIS adoption provisions of CEQ) regulations (40 CFR 1506.3). NRCS is taking this action to address the mandates in section 2408 of the Agriculture Improvement Act of 2018 (2018 Farm Bill, Pub. L. 115–334) to provide financial assistance for a Feral Swine Eradication and Control Pilot Program in collaboration with APHIS. The purpose of the pilot program, as stated in the Act, is to respond to the threat feral swine pose to agriculture, native ecosystems, and human and animal health. NRCS's actions under section 2408 of the 2018 Farm Bill are narrower than the scope of the larger APHIS effort defined in the FEIS and are limited to providing financial assistance specifically for outreach, training, equipment, and operations for feral swine trapping, consistent with APHIS technical standards. Subsequent actions, including disposal, are the responsibility of those carrying out the trapping activities, and must occur consistent with all associated Federal, State, and local laws. The details on the FEIS were provided in the published Notice of Intent to adopt FEIS dated on July 17, 2019 (84 FR 34118) and associated Notice of Availability published by the U.S. Environmental Protection Agency (84 FR 32168). Two comments were received in response to these notices. The first, submitted by the State Department of Land and Natural Resources, in support of the actions and methods defined in the FEIS and is appended to this NOA. The second, submitted by a private citizen indicating they disagreed with this use of Federal funding. The Agriculture Improvement Act of 2018 left no discretion to the agency concerning this matter.

The ROD is available by requesting a copy at the above address. Documentation developed during the agency's review of the FEIS is on file and may be reviewed by contacting Martin Lowenfish at the above number.

No administrative action on implementation of the proposal will be taken until 30 days after the date of this publication in the **Federal Register**.

Kevin Norton,

Associate Chief, Natural Resources Conservation Service.

[FR Doc. 2019–22652 Filed 10–16–19; 8:45 am]

BILLING CODE 3410–16–P

DEPARTMENT OF AGRICULTURE

Rural Business-Cooperative Service

Notice of Request for Reinstatement of Discontinued Collection

AGENCY: Rural Business-Cooperative Service, USDA.

ACTION: Proposed collection; comments requested.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the Rural Business-Cooperative Service's (RBCS) intention to request an extension for a currently approved information collection in support of the program for 7 CFR part 4290, subpart A, Rural Business Investment Companies Program.

DATES: Comments on this notice must be received by December 16, 2019.

FOR FURTHER INFORMATION CONTACT: Thomas P. Dickson, Rural Development Innovation Center—Regulatory Team 2, USDA, 1400 Independence Avenue SW, STOP 1522, Room 5164, South Building, Washington, DC 20250–1522. Telephone: (202) 690–4492. Email: *Thomas.dickson@usda.gov.*

SUPPLEMENTARY INFORMATION:

Title: Rural Business Investment Companies Program.

OMB Number: 0570–0051.

Type of Request: Reinstatement of a discontinued collection.

Abstract: RBCS administers the Rural Business Investment Program (RBIP). The primary objective of this program is to promote economic development and the creation of wealth and job opportunities in rural areas and to establish a developmental capital program, with the mission of addressing unmet equity investment needs of small enterprises located in rural areas. RBCS collects information from applicants to confirm eligibility for the program and to evaluate the quality of the applications.

Estimate of Burden: Public reporting burden for this collection is estimated to average 300 hours per response.

Estimated Number of Respondents: 2 per year.

Estimated Number of Responses per Respondent: 1.

Estimated Number of Responses: 241.

Estimated Total Annual Burden on Respondents: 904 hours.

Copies of this information collection can be obtained from Diane M. Berger, Rural Development Innovation Center—Regulatory Team, (715) 619–3124.

Comments

Comments are invited on: (a) Whether the proposed collection of information

is necessary for the proper performance of the functions of the RBCS, including whether the information will have practical utility; (b) the accuracy of RBCS's estimate of the burden to collect the required information, including the validity of the strategy 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 through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology. Comments on the paperwork burden may be sent to: Thomas P. Dickson, Rural Development Innovation Center—Regulatory Team 2, USDA, 1400 Independence Avenue SW, STOP 1522, Room 5164, South Building, Washington, DC 20250–1522. Telephone: (202) 690–4492. Email: *Thomas.dickson@usda.gov.* All responses to this notice will be summarized and included in the request for OMB approval. All comments will become a matter of public record.

Bette Brand,

Administrator, Rural Business-Cooperative Service.

[FR Doc. 2019–22622 Filed 10–16–19; 8:45 am]

BILLING CODE P

DEPARTMENT OF COMMERCE

Economic Development Administration

Notice of Petitions by Firms for Determination of Eligibility To Apply for Trade Adjustment Assistance

AGENCY: Economic Development Administration, U.S. Department of Commerce.

ACTION: Notice and opportunity for public comment.

SUMMARY: The Economic Development Administration (EDA) has received petitions for certification of eligibility to apply for Trade Adjustment Assistance from the firms listed below. Accordingly, EDA has initiated investigations to determine whether increased imports into the United States of articles like or directly competitive with those produced by each of the firms contributed importantly to the total or partial separation of the firms' workers, or threat thereof, and to a decrease in sales or production of each petitioning firm.

SUPPLEMENTARY INFORMATION:

LIST OF PETITIONS RECEIVED BY EDA FOR CERTIFICATION OF ELIGIBILITY TO APPLY FOR TRADE ADJUSTMENT ASSISTANCE

[10/1/2019 through 10/8/2019]

Firm name	Firm address	Date accepted for investigation	Product(s)
Novel Iron Works, Inc	250 Ocean Road, Greenland, NH 03840.	10/3/2019	The firm manufactures structural steel components.
Jerpbak-Bayless Company	34150 Solon Road, Solon, OH 44139.	10/4/2019	The firm manufactures metal parts, primarily of steel.
Cider Riot, LLC	807 NE Couch Street, Portland, OR 97232.	10/8/2019	The firm manufactures hard cider.

Any party having a substantial interest in these proceedings may request a public hearing on the matter. A written request for a hearing must be submitted to the Trade Adjustment Assistance Division, Room 71030, Economic Development Administration, U.S. Department of Commerce, Washington, DC 20230, no later than ten (10) calendar days following publication of this notice. These petitions are received pursuant to section 251 of the Trade Act of 1974, as amended.

Please follow the requirements set forth in EDA's regulations at 13 CFR 315.9 for procedures to request a public hearing. The Catalog of Federal Domestic Assistance official number and title for the program under which these petitions are submitted is 11.313, Trade Adjustment Assistance for Firms.

Irette Patterson,

Program Analyst.

[FR Doc. 2019–22605 Filed 10–16–19; 8:45 am]

BILLING CODE 3510–WH–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B–63–2019]

Foreign-Trade Zone 8—Toledo, Ohio; Application for Production Authority; Arbor Foods Inc. (Blended Syrup); Toledo, Ohio

An application has been submitted to the Foreign-Trade Zones (FTZ) Board by the Toledo-Lucas County Port Authority, grantee of FTZ 8, requesting production authority on behalf of Arbor Foods Inc. (Arbor), located in Toledo, Ohio. The application conforming to the requirements of the regulations of the FTZ Board (15 CFR 400.23) was docketed on October 10, 2019.

The Arbor facility (over 40 employees, with two full-time employees for sugar blends) is located within Site 1 of FTZ 8. The facility is used for production of blended sugar. Arbor currently has FTZ authority to produce dry-blended sugar for the U.S. market, with a ''grandfathered'' quantitative limit of 37.9 million pounds of imported ''ex-quota'' sugar. Arbor also has authority to produce blended syrup (aka wet-blended sugar) for export only—with no quantitative limit on use of ex-quota sugar for that export activity. Arbor's pending application seeks authorization to produce blended syrup for the U.S. market using up to the 37.9 million pounds of ex-quota sugar annually which, as noted above, is currently limited to production of dry-blended sugar.

On its domestic sales, production of blended syrup under FTZ procedures would allow Arbor to choose the duty rate during customs entry procedures that applies to blended syrup (duty rate: 6.0%) for the foreign-status input (granular sucrose, either cane or beet, duty rate: 35.74 20B5; per kg). Arbor estimates that 54% of the blended syrup is comprised of the foreign-status component. Arbor would be able to avoid duty on the foreign-status component which becomes scrap/waste.

Customs duties also could possibly be deferred or reduced on foreign-status production equipment. The request indicates that the savings from FTZ procedures would help expand the plant's sugar blend operations and allow Arbor to ''reactivate'' its commercial activity.

In accordance with the FTZ Board's regulations, Juanita Chen and Elizabeth Whiteman of the FTZ Staff are designated examiners to evaluate and analyze the facts and information presented in the application and case record and to report findings and recommendations to the FTZ Board.

Public comment is invited from interested parties. Submissions shall be addressed to the FTZ Board's Executive Secretary and sent to *ftz@trade.gov.* The closing period for their receipt is December 16, 2019. Rebuttal comments in response to material submitted during the foregoing period may be submitted during the subsequent 15-day period to December 31, 2019.

A copy of the application will be available for public inspection in the ''Reading Room'' section of the FTZ Board's website, which is accessible via *www.trade.gov/ftz.*

For further information, contact Juanita Chen at *juanita.chen@trade.gov* or 202–482–1378, or Elizabeth Whiteman at *elizabeth.whiteman@trade.gov* or 202–482–0473.

Dated: October 10, 2019.

Andrew McGilvray,

Executive Secretary.

[FR Doc. 2019–22659 Filed 10–16–19; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B–64–2019]

Foreign-Trade Zone (FTZ) 33—Pittsburgh, Pennsylvania; Notification of Proposed Production Activity; Steelite International USA, Inc. (Hospitality Industry Serveware); New Castle, Pennsylvania

Steelite International USA, Inc. (Steelite) submitted a notification of proposed production activity to the FTZ Board for its facility in New Castle, Pennsylvania. The notification conforming to the requirements of the regulations of the FTZ Board (15 CFR 400.22) was received on October 3, 2019.

The Steelite facility is located within FTZ 33. The facility will be used for production of tableware and serveware for the hotel and restaurant industries. Pursuant to 15 CFR 400.14(b), FTZ activity would be limited to the specific foreign-status materials and components and specific finished products described in the submitted notification (as described below) and subsequently authorized by the FTZ Board.

Production under FTZ procedures could exempt Steelite from customs duty payments on the foreign-status components used in export production. On its domestic sales, for the foreign-status materials/components noted below, Steelite would be able to choose the duty rates during customs entry procedures that apply to: brass faucet body for juice dispenser combined with shank; buffet transport cart; buffet display cart; buffet display with melamine trays; carving board set with heat lamp; chafer for use with a grill (butane, electric, or Sterno®); chrome-plated chafer knob; coffee urn (electric heat); glass shelving for buffet display with stainless steel stand; granite carving board with stainless steel frame; ice box with plastic inserts; complete induction food warming table; complete induction heating stand; polycarbonate carving board with stainless steel frame; buffet set including wooden risers, steel stand with glass shelves, and induction warmers with their parts; cast iron chafer (for use with any heat source); various steel products (heat lamp; induction chafer; chafer with electric heat; soup heater (electric heat)); various stainless steel products (insulated coffee urn; body for insulated coffee urn with faucet, clamp, and faucet seal washer; chafer and frame (used with electric heat and Sterno®); insulated coffee urn cover; juice dispenser cover with knob; ice box with plastic inserts; ice cream box; insulated milk container; pastry stand with trays; circular seafood display (elevated platter); bucket; plastic coated buffet riser; carving station frame; beverage tub); various polycarbonate juice dispensers (with stainless steel frame and stand; with stainless steel faucet and without cover; with silver-plated stainless steel cover and stand; with stainless steel cover and stand; with stainless steel cover and wood stand; with stainless steel frame); various polycarbonate juicers (with stainless steel cover and stand; with stainless steel frame; with stainless steel frame and wood stand); various iron or steel products (portable grill; grill cooker for use with solid fuel; Sterno® chafer; Sterno® grill riser box; Sterno® chafer frame; stand for portable grill with aluminum plate and iron or steel frame); various silver-plated stainless steel products (faucet insert set for chafer; insulated urn; circular seafood display (elevated platter); stand for polycarbonate juice dispenser; round grill chafer cover; coffee pot); and, various wood products (juice dispenser stand; buffet display set (primarily wooden with minority stainless steel risers and glass shelves); carving board) (duty rate ranges from duty-free to 7.2%). Steelite would be able to avoid duty on foreign-status components which become scrap/waste. Customs duties also could possibly be deferred or reduced on foreign-status production equipment.

The components and materials sourced from abroad include: various aluminum components (disk for chafers and/or soup heaters to regulate heat; pastry stand with shelves; plate for butane cooker and carving board frame; plate for induction warmer set; tray); base for stainless steel pastry stand; buffet display cart and/or transport cart components (bungee strap (elastic); foam liner); burner holder for induction chafer; ceramic tile; chrome-plated faucet body set for juice dispenser; double-sided Velcro®; electric heat plate for induction warmer; electric heater and/or heater plate for use with chafers; electric toggle switch for heat lamp; electric wire; faucet nut and juicer shank for juice dispenser; glass shelving for buffet display; granite carving board; insulated wire nut; nut for insulated coffee urn; iron rod base for buffet display; melamine tray; on and off plate for toggle switch for heat lamp; porcelain pan for chafer; power cord and plug; PVC rod; raw steel buffet stand; ring terminal; silicone adhesive; silicone seat cup; stem for stainless steel chrome-plated faucet; strain relief fitting for heat lamp; thread lock adhesive; frame for multi-use chafer stainless steel with silver plating; heat lamp light bulb; cast iron chafer; various steel components (base of heat lamp; handle for carving board set; buffet display cart and/or transport cart and its parts (divider; frame; glass trunk; shelf; ID tag; bumper rail); electric heating food warmer; heat lamp shade; heat plate for induction warmer; induction chafer without stand; induction warmer; induction warmer adapter; induction warmer stand and frame; induction warming plate; lamp socket; grill grate for induction warmer set; bridge for buffet table; magnetic socket holder for buffet table; adapter to convert Sterno® holder to electric heater holder; ring for juice dispenser faucet nuts; plastic-coated buffet riser; warming plate for induction chafer; induction heater; induction heater adapter; heat lamp post; induction heater carving station); various brass components (chafer knob;

juice dispenser parts (faucet adapter; faucet body without shank; faucet bonnet; faucet handle; faucet; handle; knob); foot cover-up for chafer legs; handle (for carving board set; for ice cream box; for insulated urn); chafer cover knob; chafer leg; chafer side handle); various rubber components (buffet display cart and/or transport cart parts (bumper; edge; wheel (with steel connector)); bumper; edge; buffet cart wheel); various plastic components (buffet display cart and/or transport cart parts (curtain divider; divider clip; lamp clip); ice box parts (cover; ice mold; insert; pan); faucet seal washer; post for glass shelves; resin shelf for buffet display; attaching strip for buffet cart curtain; washer; buffet cart wheels); various iron or steel components (flange stud; Sterno® chafer frame; helical spring clamp; insert adapter for top of chafer (Sterno®); non-flange stud; pan head screw; adapter plate to convert between quart capacity for soup heater; Sterno® chafer cover; grill grate for use with solid fuel; locknut; lockwasher; holder for electric heater holder for chafer; Sterno® chafer holder; Sterno® chafer stand; washer; water pan (for use with Sterno® chafers); Sterno® grill riser box; thumb screw; circular heat lamp base; spring; screw; thumb nut for Sterno® chafer; nut; frame for butane grill; hex head bolt; insert pan for soup heater (Sterno®); portable grill stand (for use with fuel)); various stainless steel components (insulated coffee urn and its parts (leg stand; body; cover and knob; side handle; internal shank; stand); internal bracket and faucet; juice dispenser knob (brass-plated); knob for stainless steel cover; wire rack; chafer stand (for use with electric heat and Sterno®); carving station frame; adapter for soup heater to convert between quart capacity (electric heat or Sterno®); bar spacing; bar for ice box cover; wine bucket knob; beverage tub; beverage tub (plated in another metal); buffet riser; carving board frame; chafer (used with electric heat and Sterno®); chafing dish for use with grills; coffee pot; coffee urn body; chafer cover (use with electric heat and Sterno®); chafer cover (Sterno® heat); faucet adapter for juice dispenser; faucet ring; food pan; frame for chafer used with electric heat and/or Sterno®; frame for soup heater used with electric heat and/or Sterno®; grill chafer (used with electric heat and Sterno®); grill chafer (used with electric heat and Sterno®) with glass cover; ice box; ice cream box and its parts (insert; cover; knob); insulated milk container; juice dispenser feet; pastry stand; pastry tray; post and spacers for pastry stand; round grill chafer cover with silver plating; serving fork; stand for chafers and/or coffee towers; Sterno® chafer; tile for use with food cooling unit; top nest for juice dispenser; top ring for juice dispenser; water pan; water pan (with silver plating); juice dispenser cover; plastic-coated buffet riser; juice dispenser stand; chrome-plated parts (faucet handle for juice dispenser; faucet set for juice dispenser; flex arms for heat lamp top; faucet body set for juice dispenser without shank; faucet ring for juice dispenser); bent pin for faucet handle for juice dispenser; insert pan for soup heater; ice bucket; spring for faucet; chafer (multi-use); faucet handle for juice dispenser; chafer knob; juice dispenser knob; soup heater cover (electric heat or Sterno®)); various polycarbonate components (body for juice dispenser with stainless steel shank and ice ring; body with shank and ice sleeve for juice dispenser; body with stainless steel frame for juice dispenser; body with stainless steel shank and ice sleeve for juice dispenser; body with stainless steel shank for juice dispenser; carving board); various silver-plated components (juice dispenser knob; ring for juice dispenser faucet nuts; juice dispenser stand); various silver-plated stainless steel components (juice dispenser cover; carving station frame; knob for polycarbonate juice dispenser; stand for polycarbonate juice dispenser; handle for carving display); and, various wood components (juice dispenser stand; buffet riser; carving board) (duty rate ranges from duty-free to 25%). The request indicates that certain materials/components are subject to special duties under Section 301 of the Trade Act of 1974 (Section 301), depending on the country of origin. The applicable Section 301 decisions require subject merchandise to be admitted to FTZs in privileged foreign status (19 CFR 146.41).

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 November 26, 2019.

A copy of the notification will be available for public inspection in the ''Reading Room'' section of the Board's website, which is accessible via *www.trade.gov/ftz.*

For further information, contact Juanita Chen at *juanita.chen@trade.gov* or 202–482–1378.

Dated: October 10, 2019.

Andrew McGilvray,

Executive Secretary.

[FR Doc. 2019–22658 Filed 10–16–19; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–475–835]

Finished Carbon Steel Flanges From Italy: Preliminary Results of Antidumping Duty Administrative Review; 2017–2018

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) preliminarily determines that finished carbon steel flanges from Italy are being sold in the United States at less than normal value during the period of review (POR). The POR is February 8, 2017 through July 31, 2018. Interested parties are invited to comment on these preliminary results.

DATES: Applicable October 17, 2019.

FOR FURTHER INFORMATION CONTACT: Edythe Artman or Brian C. Davis, AD/CVD Operations, Office VI, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–3931 or (202) 482–7924, respectively.

SUPPLEMENTARY INFORMATION:

Background

These preliminary results of review are issued in accordance with section 751(a) of the Tariff Act of 1930, as amended (the Act). On October 4, 2018, in accordance with section 751(a) of the Act and 19 CFR 351.221(c)(1)(i), Commerce published the notice of initiation for the administrative review.[1] In the *Initiation Notice,* Commerce stated that, where appropriate, it intended to select respondents based on U.S. Customs and Border Protection (CBP) data for U.S. imports during the POR.[2] After receiving no comments on the CBP data from parties with an administrative protective order, Commerce selected ASFO S.p.A. (ASFO) and Forgital Italy S.p.A. (Forgital) from 27 possible respondents for individual examination in this review.[3]

Commerce exercised its discretion to toll all deadlines affected by the partial federal government closure from December 22, 2018 through the

[1] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 83 FR 50077 (October 4, 2018) (*Initiation Notice*).

[2] *Id.*

[3] *See* Memorandum, ''Antidumping Duty Administrative Review of Finished Carbon Steel Flanges from Italy: Respondent Selection,'' dated November 16, 2018, 1–5.

resumption of operations on January 29, 2019, moving the deadline for the preliminary results of this review to June 12, 2019.[4] On June 6, 2019, we extended the time limit for completion of the preliminary results of the review to no later than October 10, 2019.[5] For a complete description of the events that followed the initiation of the review, *see* the Preliminary Decision Memorandum.[6]

A list of topics included in the Preliminary Decision Memorandum is included in the Appendix 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* and to all parties in the Central Records Unit, located in room B8094 of the main Commerce building. In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly at *http://enforcement.trade.gov/frn/.* The signed and the electronic versions of the Preliminary Decision Memorandum are identical in content.

Scope of the Order

The products covered by the scope of the order are finished carbon steel flanges from Italy. For a complete description of the scope, *see* the Preliminary Decision Memorandum.

Methodology

Commerce is conducting this review in accordance with section 751(a)(1)(B) of the Act. For a full description of the methodology underlying the preliminary results, *see* the Preliminary Decision Memorandum.

Facts Available

Pursuant to section 776(a) of the Act, Commerce is preliminarily relying upon facts otherwise available to assign estimated weighted-average dumping margins to the respondents selected for individual examination in this review, because both ASFO and Forgital withheld necessary information that was requested by Commerce, thereby significantly impeding the conduct of the review. Further, Commerce preliminarily determines that both ASFO and Forgital failed to cooperate by not acting to the best of their abilities to comply with requests for information and, thus, Commerce is applying an adverse inference in selecting among the facts available, in accordance with section 776(b) of the Act. For a full description of the methodology underlying our conclusions regarding the application of adverse facts available (AFA), *see* the Preliminary Decision Memorandum.

Rate for Non-Selected Companies

In accordance with the U.S. Court of Appeals for the Federal Circuit's decision in *Albemarle Corp.* v. *United States,*[7] we are applying to the non-selected companies a rate based on the simple average of the individual rates preliminarily applied to ASFO and Forgital in this administrative review, or 204.53 percent. For a detailed discussion, *see* the Preliminary Decision Memorandum.

Preliminary Results of Review

We preliminarily determine that, for the period February 8, 2017 through July 31, 2018, the following dumping margins exist:

Producer/exporter	Weighted-average dumping margin (percent)
ASFO S.p.A	204.53
Forgital Italy S.p.A	204.53
ASFO S.p.A.—FOMAS Group	204.53
Assotherm srl	204.53
Bifrangi S.p.A	204.53
CAT Carpenteria Metallica srl	204.53
Costruzione Ricambi Macchine Industriali	204.53
Filmag Italia S.r.l	204.53
FOC Ciscato S.p.Ar	204.53
FOMAS	204.53
Forgia Di Bollate S.p.A	204.53
Forgiatura A. Vienna diAntonio Vienna	204.53
Franchini Acciai S.p.A	204.53
Galperti Forged Products	204.53
Inox Laghi S.r.l	204.53
KIASMA SRL	204.53
Iml Industria Meccanica Ligure	204.53
Martin Valmore srl	204.53
M.E.G.A. S.p.A	204.53
Metalfar Prodotti Industriali, S.p.A	204.53
Officine Ambrogio Melesi & C. S.R.L	204.53
Officine di Cortabbio s.r.l	204.53
OFFICINE MECCANICHE CIOCCA S.p.A	204.53
Office SANTAFEDE	204.53
Siderforgerossi Group S.p.A	204.53
UNIGEN Steel Engineering	204.53
VALVITALIA S.p.A	204.53

Disclosure and Public Comment

Normally, Commerce discloses the calculations performed in connection with preliminary results to interested parties within five days after the date of publication of this notice.[8] Because Commerce preliminarily applied total AFA to each of the mandatory respondents in this review, in accordance with section 776 of the Act, there are no calculations to disclose.

Interested parties may submit case briefs no later than 30 days after the date of publication of this notice.[9] Rebuttal briefs, the content of which is limited to the issues raised in the case briefs, must be filed within five days from the deadline date for the submission of case briefs.[10] Parties who submit case or rebuttal briefs in this proceeding are requested to submit with each argument: (1) A statement of the issue; (2) a brief summary of the argument; and (3) a table of authorities.[11] Case and rebuttal briefs should be filed using ACCESS.[12]

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing must submit a written request to the Assistant Secretary for Enforcement and Compliance, filed electronically via ACCESS. An electronically filed document must be received successfully in its entirety by the Department's electronic records system, ACCESS, by 5:00 p.m. Eastern Time within 30 days after the date of publication of this notice.[13] Requests should contain: (1) The party's name, address and telephone number; (2) the number of participants; and (3) a list of issues parties intend to discuss. Issues raised in the hearing will be limited to those raised in the respective case and rebuttal briefs. If a request for a hearing is made, Commerce intends to hold the

[4] *See* Memorandum to the Record from Gary Taverman, Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance, ''Deadlines Affected by the Partial Shutdown of the Federal Government,'' dated January 28, 2019. All deadlines in this segment of the proceeding have been extended by 40 days.

[5] *See* Memorandum, ''Finished Carbon Steel Flanges from Italy: Extension of Deadline for Preliminary Results of Antidumping Duty Administrative Review; 2017–2018,'' dated June 6, 2019.

[6] *See* Memorandum, ''Decision Memorandum for Preliminary Results of Antidumping Duty Administrative Review: Finished Carbon Steel Flanges from Italy; 2017–2018,'' dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

[7] *See Albemarle Corp.* v. *United States,* 821 F.3d 1345 (Fed. Cir. 2016).

[8] *See* 19 CFR 351.224(b).

[9] *See* 19 CFR 351.309(c)(1)(ii).

[10] *See* 19 CFR 351.309(d)(1) and (2).

[11] *See* 19 CFR 351.309(c)(2) and (d)(2).

[12] *See generally* 19 CFR 351.303.

[13] *See* 19 CFR 351.310(c).

hearing at the U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230, at a date and time to be determined.[14] Parties should confirm the date, time, and location of the hearing two days before the scheduled date.

Unless extended, Commerce intends to issue the final results of this administrative review, which will include the results of our analysis of all 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.

Assessment Rates

Upon completion of the administrative review, Commerce shall determine, and CBP shall assess, antidumping duties on all appropriate entries covered by this review.[15] If the preliminary results are unchanged for the final results, we will instruct CBP to apply an *ad valorem* assessment rate of 204.53 percent to all entries of subject merchandise during the POR which were produced and/or exported by ASFO, Forgital and the aforementioned companies which were not selected for individual examination. We intend to issue liquidation instructions to CBP 15 days after publication of the final results of this review.

Cash Deposit Requirements

The following cash deposit requirements will be effective upon publication of the final results of this administrative review for all shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date of the final results of this administrative review, as provided by section 751(a)(2)(C) of the Act: (1) The cash deposit rate for ASFO, Forgital and the other companies listed above will be equal to the dumping margin established in the final results of this administrative review; (2) for previously reviewed or investigated companies not listed above, the cash deposit rate will continue to be the company-specific rate published for the most recently completed segment of this proceeding in which they were reviewed; (3) if the exporter is not a firm covered in this review, a prior review, or in the investigation, but the producer is, the cash deposit rate will be the rate established for the most recently completed segment of this proceeding for the producer of the merchandise; and (4) the cash deposit rate for all other producers or exporters will continue to be the all-others rate of 79.17 percent, the rate established in the investigation of this proceeding.[16] These cash deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice also serves as a 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 this notice in accordance with sections 751(a)(1) and 777(i)(1) of the Act and sections 19 CFR 351.213(h)(1) and 351.221(b)(4).

Dated: October 9, 2019.

Jeffrey I. Kessler,

Assistant Secretary for Enforcement and Compliance.

Appendix

List of Topics Discussed in the Preliminary Decision Memorandum

[FR Doc. 2019–22668 Filed 10–16–19; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–912]

Certain New Pneumatic Off-The-Road Tires from the People's Republic of China; 2012–2013: Notice of Court Decision Not in Harmony With Final Results of Administrative Review and Notice of Amended Final Results of Antidumping Duty Administrative Review

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: On September 3, 2019, the United States Court of International Trade (the Court) issued a final judgment in *China Manufacturers Alliance, LLC. and Double Coin Holdings Ltd., et al.* v. *United States,* Consol. Court No. 15–00124; Slip Op. 19–115 (CIT September 3, 2019) (*China Mfr. Alliance III*), sustaining the Department of Commerce's (Commerce) remand results for the fifth administrative review of the antidumping duty (AD) order on certain new pneumatic off-the-road tires (OTR tires) from the People's Republic of China (China) covering the period of review (POR) September 1, 2012 through August 31, 2013. Commerce is notifying the public that the Court has made a final judgment that is not in harmony with Commerce's final results of the administrative review, and that Commerce is amending the final results with respect to certain exporters identified herein.

DATES: Applicable September 13, 2019.

FOR FURTHER INFORMATION CONTACT: Keith Haynes, 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) 482–5139.

SUPPLEMENTARY INFORMATION:

Background

On April 15, 2015, Commerce issued its *Final Results* [1] in the fifth administrative review of the AD order on OTR tires from China. The plaintiffs in this litigation, mandatory respondent Double Coin Holdings Ltd and its affiliated U.S. importer China Manufacturers Alliance, LLC, and mandatory respondent Guizhou Tyre Co., Ltd. and Guizhou Tyre Import and Export Co., Ltd. (collectively, GTC), timely filed complaints with the Court challenging certain aspects of Commerce's *Final Results*.[2] Domestic interested parties Titan Tire Corporation and United Steel, Paper and Forestry, Rubber, Manufacturing, Energy, Allied Industrial and Service Workers International Union, AFL–CIO–CLC intervened as defendant-intervenors, but withdrew from these cases on September 29, 2017.[3]

On February 6, 2017, the Court remanded Commerce's *Final Results*.[4] In

[14] *See* 19 CFR 351.310(d).

[15] *See* 19 CFR 351.212(b).

[16] *See Finished Carbon Steel Flanges from India and Italy: Antidumping Duty Orders,* 82 FR 40136, 40138 (August 24, 2017).

[1] *See Certain New Pneumatic Off-the-Road Tires from the People's Republic of China: Final Results of Antidumping Duty Administrative Review; 2012–2013,* 80 FR 20197 (April 15, 2015) (*Final Results*) and accompanying Issues and Decision Memorandum (IDM).

[2] *See China Mfr. Alliance III,* at 2.

[3] *Id.*

[4] *See China Manufacturers Alliance, LLC et al.* v. *United States,* Consol. Court No. 15–00124, Slip Op

Continued

its First Remand Redetermination, Commerce: (1) Continued to reduce GTC's U.S. sales prices to account for irrecoverable value-added tax (VAT); (2) determined that ''Shanghai Port Surcharges,'' but not other brokerage and handling or ocean freight charges, were double counted and removed the charges from the international freight surrogate value calculation; (3) made an inflation adjustment to domestic warehousing costs to match the surrogate value to the POR; and (4) assigned Double Coin a *de minimis* 0.14 percent margin instead of assigning it a 105.31 percent margin as part of the China-wide entity, under respectful protest.[5] After issuing its First Remand Redetermination, Commerce moved for a partial voluntary remand on the issue of Double Coin's margin in light of the Court of Appeals for the Federal Circuit's (CAFC) decision in *Diamond Sawblades 2017*.[6]

On January 16, 2019, the Court sustained, in part, and remanded, in part, Commerce's First Remand Redetermination and denied Commerce's motion for partial voluntary remand.[7] The Court sustained Commerce's determinations to make an inflation adjustment to domestic warehousing costs and that Shanghai Port Charges were double counted for GTC.[8] In denying Commerce's motion for partial voluntary remand, the Court found that the only rate supported by the record evidence that Commerce could apply to Double Coin is the 0.14 percent margin applied in the First Remand Redetermination.[9] The Court remanded Commerce's determinations: (1) That the brokerage and handling and ocean freight charges other than the Shanghai Port Charges were not double counted for GTC; [10] and (2) to continue reducing GTC's U.S. sales prices to account for irrecoverable VAT.[11]

In its Second Remand Redetermination, Commerce recalculated GTC's U.S. sale prices without making deductions for irrecoverable VAT, under respectful protest, and adjusted GTC's brokerage and handling and ocean freight costs for certain double-counted expenses.[12]

In light of these determinations, Commerce has made changes to GTC's margin calculation and the margin assigned to Double Coin.[13] After accounting for all such changes and issues addressed in the remand redeterminations, the resulting weighted-average dumping margin for GTC is 4.59 percent, and the margin assigned to Double Coin is 0.14 percent. On September 3, 2019, the Court sustained the Second Remand Redetermination.[14]

Consistent with the decision of the CAFC in *Timken Co.* v. *United States,* 893 F.2d 337 (Fed. Cir. 1990) (*Timken*), as clarified by *Diamond Sawblades Mfrs. Coalition* v. *United States,* 626 F.3d 1374 (Fed. Cir. 2010) (*Diamond Sawblades*), Commerce is notifying the public that the final judgment in this case is not in harmony with Commerce's *Final Results.* Thus, Commerce is amending the *Final Results* with respect to the weighted-average dumping margins for the mandatory respondents, as listed above.

Timken Notice

In its decision in *Timken,* 893 F.2d at 341, as clarified by *Diamond Sawblades,* the CAFC held that, pursuant to section 516A(e) of the Tariff Act of 1930, as amended (the Act), Commerce must publish a notice of a court decision that is not ''in harmony'' with a Commerce determination and must suspend liquidation of entries pending a ''conclusive'' court decision. The Court's September 3, 2019 judgment sustaining the Second Remand Redetermination constitutes a final decision of the Court that is not in harmony with Commerce's *Final Results.* As such, Commerce has published this notice in fulfillment of the publication requirement of *Timken.*

Amended Final Results

Because there is now a final court decision, Commerce is amending the *Final Results* with respect to the mandatory respondents. The revised weighted-average dumping margins for these exporters during the period September 1, 2012 through August 31, 2013 are as follows:

Exporter	Weighted-average dumping margin (percent)
Double Coin Holdings Ltd	0.14
Guizhou Tyre Co., Ltd./Guizhou Tyre Export and Import Co., Ltd	4.59

Accordingly, Commerce will continue the suspension of liquidation of the subject merchandise pending the end of the period of appeal or, if appealed, pending a final and conclusive court decision. In the event the Court's ruling is not appealed or, if appealed, and upheld by the CAFC, Commerce will instruct U.S. Customs and Border Protection (CBP) to assess antidumping duties on unliquidated entries of subject merchandise exported by the companies identified above using the assessment rates calculated by Commerce in the remand redeterminations, as listed in the above table.

Cash Deposit Requirements

Because the AD order on OTR tires from China was revoked,[15] Commerce will not issue cash deposit instructions as a result of this Court decision.

Notification to Interested Parties

Commerce has issued and published this notice in accordance with sections 516A(e), 751(a)(1), and 777(i)(1) of the Act.

Dated: October 9, 2019.

Jeffrey I. Kessler,

Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2019–22666 Filed 10–16–19; 8:45 am]

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17–12 (CIT February 6, 2017) (*China Mfr. Alliance I*).

[5] *See Final Results of Redetermination Pursuant to Remand,* Court No. 15–00124, Slip Op. 17–12 (CIT 2017) (First Remand Redetermination); *see also Viraj Group, Ltd.* v. *United States,* 343 F.3d 1371, 1376 (Fed. Cir. 2003).

[6] *See Diamond Sawblades Mfrs. Coal.* v. *United States,* 866 F.3d 1304 (CAFC 2017) (*Diamond Sawblades 2017*).

[7] *See China Manufacturers Alliance, LLC et al.* v. *United States,* Consol. Court No. 15–00124, Slip Op 19–7 (CIT January 16, 2019) at 42–43 (*China Mfr. Alliance II*).

[8] *Id.* at 8–9.

[9] *Id.* at 41–42.

[10] *Id.* at 25.

[11] *Id.* at 18–19.

[12] *See Final Results of Redetermination Pursuant to Court Remand,* Court No. 15–00124, Slip Op. 19–7 (CIT 2019) (Second Remand Redetermination).

[13] *See* Memorandum, ''Draft Results of Redetermination Pursuant to Second Court Remand in the 2012–2013 Antidumping Duty Administrative of Certain New Pneumatic Off-the-Road Tires from the People's Republic of China: Margin Calculation and Surrogate Value Memorandum for Guizhou Tyre Co., Ltd. and Guizhou Tyre Import and Export Co., Ltd.,'' dated March 21, 2019; *see also* First Remand Redetermination at 21; and Memorandum, ''Draft Results of Redetermination Pursuant to Second Court Remand in the 2012–2013 Antidumping Duty Administrative Review of Certain New Pneumatic Off-the-Road Tires from the People's Republic of China: Margin Calculation and Surrogate Value Memorandum for Guizhou Tyre Co., Ltd. and Guizhou Tyre Import and Export Co., Ltd.,'' dated March 21, 2019.

[14] *See China Mfr. Alliance III.*

[15] *See Certain New Pneumatic Off-the-Road Tires from the People's Republic of China: Final Results of Sunset Reviews and Revocation of Antidumping Duty and Countervailing Duty Orders,* 84 FR 20616 (May 10, 2019).

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–893]

Frozen Warmwater Shrimp From the People's Republic of China: Partial Rescission of Antidumping Duty Administrative Review; 2018–2019

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) is partially rescinding its administrative review of the antidumping duty order on frozen warmwater shrimp (shrimp) from the People's Republic of China (China) for the period of review February 1, 2018, through January 31, 2019.

DATES: Applicable October 17, 2019.

FOR FURTHER INFORMATION CONTACT: Jasun Moy or Kabir Archuletta, AD/CVD Operations, Office V, Enforcement and Compliance, International Trade Administration, Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–8194, or (202) 482–2593, respectively.

SUPPLEMENTARY INFORMATION:

Background

On February 8, 2019, Commerce published in the **Federal Register** a notice of ''Opportunity to Request Administrative Review'' of the antidumping duty order on shrimp from China for the period of review February 1, 2018, through January 31, 2019.[1] Pursuant to requests from interested parties, on May 2, 2019, in accordance with section 751(a) of the Tariff Act of 1930, as amended (the Act), and 19 CFR 351.221(c)(1)(i), Commerce initiated an administrative review of the antidumping duty order on shrimp from China with respect to 102 companies.[2] On June 10, 2019, Ad Hoc Shrimp Trade Action Committee (the petitioner) timely withdrew its requests for an administrative review of all of the companies for which it had requested a review.[3]

[1] *See Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity to Request Administrative Review,* 84 FR 2816 (February 8, 2019).

[2] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 84 FR 18777 (May 2, 2019).

[3] *See* Petitioner's Letter, ''Certain Frozen Warmwater Shrimp from the People's Republic of China: Domestic Producers' Withdrawal of Review Requests,'' dated June 10, 2019.

Partial Rescission of the Administrative Review

Pursuant to 19 CFR 351.213(d)(1), Commerce will rescind an administrative review, in whole or in part, if the party that requested the review withdraws its request within 90 days of the publication date of the notice of initiation of the requested review. The petitioner timely withdrew all of its review requests. Because Commerce received no other requests for review for 14 of the companies for which a review was initiated, we are rescinding this review of shrimp from China for the period February 1, 2018, through January 31, 2019, in part, with respect to these 14 entities, in accordance with 19 CFR 351.213(d)(1). These 14 entities are: (1) Dalian Hengtai Foods Co., Ltd.; (2) Dalian Philica Supply Chain Management Co., Ltd.; (3) Dalian Sunrise Foodstuffs Co., Ltd.; (4) Dongwei Aquatic Products (Zhangzhou) Co., Ltd.; (5) Fujian Dongwei Food Co., Ltd.; (6) Fujian Hongao Trade Development Co.; (7) Fujian R & J Group Ltd.; (8) Gallant Ocean Group; (9) Guangdong Rainbow Aquatic Development; (10) Penglai Yuming Foodstuff Co., Ltd.; (11) Rizhao Meijia Keyuan Foods Co. Ltd.; (12) Suizhong Tieshan Food Co., Ltd.; (13) Yangjiang Guolian Seafood Co., Ltd.; and (14) Zhangzhou Xinhui Foods Co., Ltd. The instant review will continue with respect to the remaining companies for which a review was initiated.

Assessment

Commerce will instruct U.S. Customs and Border Protection (CBP) to assess antidumping duties on all appropriate entries. For the companies for which this review is rescinded, antidumping duties shall be assessed at rates equal to the cash deposit rate 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). Commerce intends to issue appropriate assessment instructions to CBP 15 days after publication of this notice in the **Federal Register**.

Notification to Importers

This notice serves as the only reminder to importers whose entries will be liquidated as a result of this rescission notice, 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 the presumption that reimbursement of the antidumping duties occurred and the subsequent assessment of double antidumping duties.

Notification Regarding Administrative Protective Order

This notice also 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 and 777(i)(1) of the Act and 19 CFR 351.213(d)(4).

Dated: October 10, 2019.

James Maeder,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2019–22665 Filed 10–16–19; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[A–201–836]

Light-Walled Rectangular Pipe and Tube from Mexico: Preliminary Results of Antidumping Duty Administrative Review and Preliminary Determination of No Shipments; 2017–2018

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) preliminarily determines that producers and/or exporters subject to this administrative review made sales of subject merchandise at less than normal value (NV) during the August 1, 2017 through July 31, 2018 period of review (POR). Interested parties are invited to comment on these preliminary results of review.

DATES: Applicable October 17, 2019.

FOR FURTHER INFORMATION CONTACT: Samuel Brummitt or John Conniff, 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) 482–7851 or (202) 482–1009, respectively.

SUPPLEMENTARY INFORMATION:

Background

On October 4, 2018, Commerce published in the **Federal Register** a notice of the initiation of the administrative review of the antidumping duty (AD) order [1] on light-walled rectangular pipe and tube from Mexico for 19 companies.[2]

On November 5, 2018, we received a timely filed certification of no shipments of subject merchandise from Fabricaciones y Servicios de Mexico (FASEMEX).[3] Commerce exercised its discretion to toll all deadlines affected by the partial federal government closure from December 22, 2018 through the resumption of operations on January 28, 2019.[4] On April 10, 2019, we further extended the time limit for completion of the preliminary results of the review to no later than October 10, 2019.[5]

For a complete description of the events that followed the initiation of the review, *see* the Preliminary Decision Memorandum.[6] 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* and to all parties in the Central Records Unit, located in room B8094 of the main Commerce building. In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly at *http://enforcement.trade.gov/frn/.* The signed and the electronic versions of the Preliminary Decision Memorandum are identical in content. A list of topics included in the Preliminary Decision Memorandum is included in the Appendix to this notice.

Scope of the Order

The scope of this order covers certain welded carbon-quality light-walled steel pipe and tube, of rectangular (including square) cross section, having a wall thickness of less than 4 mm. The term carbon-quality steel includes both carbon steel and alloy steel which contains only small amounts of alloying elements. Specifically, the term carbon-quality includes products in which none of the elements listed below exceeds the quantity by weight respectively indicated; 1.80 percent of manganese, or 2.25 percent of silicon, or 1.00 percent of copper, or 0.50 percent of aluminum, or 1.25 percent of chromium, or 0.30 percent of cobalt, or 0.40 percent of lead, or 1.25 percent of nickel, or 0.30 percent of tungsten, or 0.10 percent of molybdenum, or 0.10 percent of niobium, or 0.15 percent of vanadium, or 0.15 percent of zirconium.

The description of carbon-quality is intended to identify carbon-quality products within the scope. The welded-carbon quality rectangular pipe and tube subject to the order is currently classified under the Harmonized Tariff Schedule of the United States (HTSUS) subheadings 7306.61.50.00 and 7306.61.70.60. This tariff classification is provided for convenience and Customs purposes; however, the written description of the scope of the order is dispositive.

Methodology

Commerce is conducting this review in accordance with sections 751(a)(2) of the Tariff Act of 1930, as amended (the Act). Export price was calculated in accordance with section 772 of the Act. Normal value was calculated in accordance with section 773 of the Act. For a full description of the methodology underlying our conclusions, *see* the Preliminary Decision Memorandum.

Preliminary Determination of No Shipments

Prior to the issuance of the questionnaire, FASEMEX reported that it made no sales of subject merchandise during the POR.[7] On November 9, 2018, we placed the U.S. Customs and Border Protection (CBP) inquiry instructions on the record that we sent to CBP regarding FASEMEX's statement of no shipments.[8] We received no information from CBP contrary to the statements of no shipments from FASEMEX. Consistent with our practice,[9] we are not preliminarily rescinding the review with respect to FASEMEX. Rather, we will complete the review for FASEMEX and issue appropriate instructions to CBP based on the final results of this review.

Preliminary Results of Review

We preliminarily determine that, for the period August 1, 2017 through July 31, 2018, the following weighted-average dumping margins exist:

Producer/exporter	Weighted-average margin (percent)
Aceros Cuatro Caminos S.A. de C.V	3.29
Arco Metal S.A. de C.V	3.29
Galvak, S.A. de C.V	3.29
Grupo Estructuras y Perfiles	3.29
Hylsa S.A. de C.V	3.29
Industrias Monterrey S.A. de C.V	3.29
International de Aceros, S.A. de C.V	3.29
Maquilacero S.A. de C.V	2.48
Nacional de Acero S.A. de C.V	3.29
PEASA-Productos Especializados de Acero	3.29
Perfiles LM, S.A. de C.V.[10]	3.29
Productos Laminados de Monterrey S.A. de C.V	3.29
Regiomontana de Perfiles y Tubos S.A. de C.V	3.80
Talleres Acero Rey S.A. de C.V	3.29
Ternium Mexico S.A. de C.V	3.29
Tuberia Laguna, S.A. de C.V	3.29
Tuberias Aspe	3.29
Tuberias y Derivados S.A de C.V	3.29

Disclosure and Public Comment

We will disclose to parties to the proceeding any calculations performed

[1] *See Light-Walled Rectangular Pipe and Tube from Mexico, the People's Republic of China, and the Republic of Korea: Antidumping Duty Orders; Light-Walled Rectangular Pipe and Tube from the Republic of Korea: Notice of Amended Final Determination of Sales at Less Than Fair Value,* 73 FR 45403 (August 5, 2008) (*Order*).

[2] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 83 FR 50077 (October 4, 2018) (*Initiation Notice*).

[3] *See* FASEMEX's Letter, ''Case No.: A–201–836—Light-Walled Rectangular Pipe and Tube,'' dated November 5, 2018 (FASEMEX No Shipments Letter).

[4] *See* Memorandum to the Record from Gary Taverman, Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance, ''Deadlines Affected by the Partial Shutdown of the Federal Government,'' dated January 28, 2019. All deadlines in this segment of the proceeding have been extended by 40 days.

[5] *See* Memorandum, ''Light-Walled Rectangular Pipe and Tube from Mexico: Extension of Time Limit for Preliminary Results of Antidumping Duty Administrative Review; 2017–2018,'' dated April 10, 2019.

[6] *See* Memorandum, ''Decision Memorandum for the Preliminary Results of Antidumping Duty Administrative Review: Light-Walled Rectangular Pipe and Tube from Mexico; 2017–2018,'' dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

[7] *See* FASEMEX No Shipments Letter.

[8] *See* Memorandum, ''Light-walled rectangular pipe and tube from Mexico (A–201–836),'' dated November 9, 2018.

[9] *See, e.g., Certain Frozen Warmwater Shrimp from Thailand; Preliminary Results of Antidumping Duty Administrative Review, Partial Rescission of Review, Preliminary Determination of No Shipments; 2012–2013,* 79 FR 15951, 15952 (March 24, 2014), unchanged in *Certain Frozen Warmwater Shrimp from Thailand: Final Results of Antidumping Duty Administrative Review, Final Determination of No Shipments, and Partial Rescission of Review; 2012–2013,* 79 FR 51306 (August 28, 2014).

[10] *See Light-Walled Rectangular Pipe and Tube from Mexico: Initiation and Expedited Preliminary Results of Changed Circumstances Review,* 82 FR 54322 (November 17, 2017) and accompanying Preliminary Decision Memorandum, unchanged in *Light-Walled Rectangular Pipe and Tube from Mexico: Final Results of Changed Circumstances Review,* 83 FR 13475 (March 29, 2018) (Commerce

in connection with these preliminary results of review within five days after the date of publication of this notice.[11] Interested parties may submit case briefs not later than 30 days after the date of publication of this notice in the **Federal Register**.[12] Rebuttal briefs, limited to issues raised in the case briefs, may be filed not later than five days after the date for filing case briefs.[13] Parties who submit case or rebuttal briefs in this proceeding 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.[14] Case and rebuttal briefs should be filed using ACCESS.[15]

Interested parties who wish to request a hearing must submit a written request to the Assistant Secretary for Enforcement and Compliance within 30 days of the date of publication of this notice.[16] Requests should contain: (1) The party's name, address and telephone number; (2) the number of participants; and (3) a list of issues parties intend to discuss. Issues raised in the hearing will be limited to those raised in the respective case and rebuttal briefs. If a request for a hearing is made, we intend to hold the hearing at the U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230, at a date and time to be determined.[17] Parties should confirm by telephone the date, time, and location of the hearing two days before the scheduled date.

Unless extended, we intend to issue the final results of this administrative review, which will include the results of our analysis of all 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.

Assessment Rates

For any individually examined respondents whose weighted-average dumping margin is above *de minimis* (*i.e.,* 0.50 percent), we will calculate importer-specific *ad valorem* duty assessment rates based on the ratio of the total amount of dumping calculated for the importer's examined sales to the total entered value of those same sales in accordance with 19 CFR 351.212(b)(1).[18] We will instruct CBP to assess antidumping duties on all appropriate entries covered by this review when the importer-specific assessment rate calculated in the final results of this review is not zero or *de minimis.* If a respondent's weighted-average dumping margin is zero or *de minimis* within the meaning of 19 CFR 351.106(c)(1), or an importer-specific rate is zero or *de minimis,* we will instruct CBP to liquidate the appropriate entries without regard to antidumping duties. The final results of this review shall be the basis for the assessment of antidumping duties on entries of merchandise covered by this review where applicable.

Regarding entries of subject merchandise during the period of review that were produced by Maquilacero and Regiopytsa and for which they did not know that the merchandise was destined for the United States, we will instruct CBP to liquidate un-reviewed entries at the all-others rate of 3.76 percent, as established in the less-than-fair-value investigation, if there is no rate for the intermediate company(ies) involved in the transaction.[19] For a full discussion of this matter, *see Assessment Policy Notice.*[20]

In accordance with 19 CFR 356.8, we intend to issue liquidation instructions to CBP on or after 41 days after publication of the final results of this review.

Cash Deposit Requirements

The following cash deposit requirements will be effective upon publication of the final results of this administrative review for all shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date of the final results of this administrative review, as provided by section 751(a)(2)(C) of the Act: (1) The cash deposit rate for each specific company listed above will be equal to the weighted-average dumping margin established in the final results of this administrative review; (2) for previously reviewed or investigated companies not listed above, the cash deposit rate will continue to be the company-specific rate published for the most recently completed segment of this proceeding in which they were reviewed; (3) if the exporter is not a firm covered in this review, a prior review, or in the investigation but the producer is, the cash deposit rate will be the rate established for the most recently completed segment of this proceeding for the producer of the merchandise; and (4) the cash deposit rate for all other producers or exporters will continue to be the all-others rate of 3.76 percent. These cash deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice also serves as a 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 the Department'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 this notice in accordance with sections 751(a)(1) and 777(i)(1) of the Act and 19 CFR 351.221(b)(4).

Dated: October 10, 2019.

Jeffrey I. Kessler,

Assistant Secretary for Enforcement and Compliance.

Appendix—List of Topics Discussed in the Preliminary Decision Memorandum

[FR Doc. 2019–22667 Filed 10–16–19; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[C–570–955]

Certain Magnesia Carbon Bricks From the People's Republic of China: Rescission of Countervailing Duty Administrative Review; 2017

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

determined that Perfiles LM, S.A. de C.V. is the successor-in-interest to Perfiles y Herrajes).

[11] *See* 19 CFR 351.224(b).

[12] *See* 19 CFR 351.309(c)(1)(ii).

[13] *See* 19 CFR 351.309(d)(1).

[14] *See* 19 CFR 351.309(c)(2) and (d)(2).

[15] *See* 19 CFR 351.303.

[16] *See* 19 CFR 351.310(c).

[17] *See* 19 CFR 351.310(d).

[18] In these preliminary results, Commerce applied the assessment rate calculation methodology 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).

[19] *See Order,* 73 FR at 45405.

[20] *See Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties,* 68 FR 23954 (May 6, 2003) (*Assessment Policy Notice*).

SUMMARY: The Department of Commerce (Commerce) is rescinding the administrative review of the countervailing duty (CVD) order on certain magnesia carbon bricks (magnesia carbon bricks) from the People's Republic of China (China) for the period of review January 1, 2017, through December 31, 2017 (POR).

DATES: Applicable October 17, 2019.

FOR FURTHER INFORMATION CONTACT: Gene H. Calvert, 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) 482–3586.

SUPPLEMENTARY INFORMATION:

Background

On September 11, 2018, Commerce published in the **Federal Register** a notice of opportunity to request an administrative of the CVD order on magnesia carbon bricks from China for the POR.[1] On October 1, 2018, the Magnesia Carbon Bricks Fair Trade Committee (MC Bricks Committee) timely submitted a request to review the Companies Subject to Review, in accordance with 19 CFR 351.213(b).[2] No other party submitted a request for an administrative review of magnesia carbon bricks from China for the POR. On November 15, 2018, Commerce published in the **Federal Register** a notice of initiation of this administrative review.[3] In the *Initiation Notice,* we stated that in the event we limited the number of respondents for individual examination, we intended to select respondents based on U.S. Customs and Border Protection (CBP) data for U.S. imports of magnesia carbon bricks from China during the POR.[4] On December 4, 2018, we notified interested parties that CBP's database, which is comprised of actual U.S. entries of subject merchandise, indicated that there were no entries of magnesia carbon bricks from China that are subject to CVD duties with respect to the Companies Subject to Review during the POR.[5] Commerce solicited comments from interested parties on the CBP Entry Data.[6] On December 11, 2018 the MC Bricks Committee filed timely comments on the CBP Entry Data stating that Commerce should obtain CBP entry information for ''Type-1'' entries that were imported or exported by Fedmet and place that information on the record as Commerce did in the most-recently completed administrative review of magnesia carbon bricks from China.[7] On December 13, 2018, Fedmet and the Fengchi Companies each submitted timely certifications of no shipments, and they both requested that Commerce rescind the administrative review of the respective entities.[8] In its certification of no shipments, Fedmet stated that it is a U.S. importer and distributor of non-subject merchandise from China and an importer of various types of refractory bricks from non-subject sources.[9] Fedmet also requested that Commerce terminate this administrative review with respect to Fedmet, arguing that the MC Bricks Committee had no grounds to request an administrative review of Fedmet, and that Commerce has no lawful basis to conduct this review with respect to Fedmet.[10]

On June 28, 2019, Commerce requested that CBP confirm whether any shipments of magnesia carbon bricks from China entered the United States during the POR with respect to the Companies Subject to Review.[11] On this same day, CBP responded to Commerce's inquiry and confirmed that there were no shipments of magnesia carbon bricks from China during the POR with respect to the Companies Subject to Review.[12] On September 12, 2019, Commerce issued a memorandum stating that it intended to rescind this administrative review based on the lack of suspended entries with respect to the Companies Subject to Review, and invited comments from interested parties.[13] No interested party commented on Commerce's intent to rescind this administrative review.

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.[14] Normally, upon completion of an administrative review, the suspended entries are liquidated at the assessment rate calculated for the review period.[15] Therefore, for an administrative review to be conducted, there must be a reviewable, suspended entry for which Commerce can instruct CBP to liquidate at the newly calculated assessment rate.[16] Based on our examination of the record, we continue to find that there is no evidence of reviewable entries, shipments, or U.S. sales of subject merchandise during the POR.[17] Accordingly, in the absence of suspended entries of subject merchandise during the POR for this administrative review, Commerce is rescinding this administrative review of the CVD order on magnesia carbon bricks from China, pursuant to 19 CFR 351.213(d)(3). Commerce intends to issue appropriate assessment instructions to CBP 15 days after the

[1] *See Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity to Request Administrative Review,* 83 FR 45888 (September 11, 2018).

[2] *See* Letter from the MC Bricks Committee, ''Certain Magnesia Carbon Bricks from the People's Republic of China: Request for Administrative Review,'' dated October 1, 2018. The MC Bricks Committee is an ad hoc association comprised of three U.S. producers of magnesia carbon bricks: Resco Products, Inc.; Magnesita Refractories Company; and HarbisonWalker International, Inc. The Companies Subject to Review are: Fedmet Resources Corporation (Fedmet); Fengchi Imp. and Exp. Co., Ltd., Fengchi Imp. and Exp. Co., Ltd. of Haicheng City, Fengchi Mining Co., Ltd. of Haicheng City, and Fengchi Refractories Co., of Haicheng City (collectively, the Fengchi Companies); Liaoning Zhongmei High Temperature Material Co., Ltd.; Liaoning Zhongmei Holding Co., Ltd.; RHI Refractories Liaoning Co., Ltd.; Shenglong Refractories Co., Ltd.; Yingkou Heping Samwha Minerals, Co., Ltd.; and Yingkou Heping Sanhua Materials Co., Ltd.

[3] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 83 FR 57411 (November 15, 2018) (*Initiation Notice*).

[4] *Id.* at the section, ''Respondent Selection.''

[5] *See* Memorandum, ''Administrative Review of the Countervailing Duty Order on Certain Magnesia Carbon Bricks from the People's Republic of China; 2017: Release of U.S. Customs and Border Protection (CBP) Data for Respondent Selection,'' dated December 4, 2018 (CBP Entry Data).

[6] *Id.*

[7] *See* Letter from the MC Bricks Committee, ''Certain Magnesia Carbon Bricks from the People's Republic of China: Comments on CBP Data Query,'' dated December 11, 2018.

[8] *See* Letter from Fedmet, ''Magnesia Carbon Bricks from the People's Republic of China, Case No. C–570–955: No Shipments Certification,'' dated December 13, 2018 (Fedmet's Certification of No Shipments); *see also* Letter from the Fengchi Companies, ''Magnesia Carbon Bricks from the People's Republic of China, Case No. C–570–955: No Shipments Certification,'' dated December 13, 2018.

[9] *See* Fedmet's Certification of No Shipments.

[10] *Id.*

[11] *See* CBP message no. 9179316, dated June 28, 2019.

[12] *See* Memorandum, ''Certain magnesia carbon bricks from the People's Republic of China (China) (C–570–955),'' dated July 2, 2019.

[13] *See* Memorandum, ''Administrative Review of the Countervailing Duty Order on Certain Magnesia Carbon Bricks from the People's Republic of China: Intent to Rescind the 2017 Administrative Review,'' dated September 12, 2019 (Intent to Rescind Memorandum).

[14] *See, e.g., Circular Welded Carbon Quality Steel Pipe from the People's Republic of China: Rescission of Countervailing Duty Administrative Review; 2017,* 84 FR 14650 (April 11, 2019); *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); and *Lightweight Thermal Paper from the People's Republic of China: Notice of Rescission of Countervailing Duty Administrative Review,* 81 FR 50683 (August 2, 2016).

[15] *See* 19 CFR 351.212(b)(2).

[16] *See, e.g., Certain Magnesia Carbon Bricks from the People's Republic of China: Rescission of Countervailing Duty Administrative Review; 2016,* 84 FR 22437 (May 17, 2019).

[17] *See* Intent to Rescind Memorandum.

date of publication of this notice in the **Federal Register**.

Administrative Protective Order

This notice serves as a 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 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.

We are issuing and publishing this notice in accordance with sections 751(a)(1) and 777(1) of the Act, and 19 CFR 351.213(d)(4).

Dated: October 8, 2019.

James Maeder,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2019–22672 Filed 10–16–19; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–580–867]

Large Power Transformers From the Republic of Korea: Preliminary Results of Antidumping Duty Administrative Review; 2017–2018

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) preliminarily determines that both Hyosung Heavy Industries Corporation (Hyosung) and Hyundai Electric & Energy Systems Co. (Hyundai) made sales of subject merchandise at less than normal value during the period of review (POR) August 1, 2017 through July 31, 2018. Interested parties are invited to comment on these preliminary results.

DATES: Applicable October 17, 2019.

FOR FURTHER INFORMATION CONTACT: Joshua DeMoss or John Drury, AD/CVD Operations, Office VI, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–3362 or (202) 482–0195, respectively.

SUPPLEMENTARY INFORMATION:

Background

Commerce initiated this review on October 4, 2018.[1] We selected two mandatory respondents in this review, Hyosung and Hyundai. On January 29, 2019, Commerce exercised its discretion to toll all deadlines affected by the partial closure of the Federal Government from December 22, 2018, through January 25, 2019.[2] On September 19, 2019, we extended the deadline for issuing the preliminary results of the review to October 9, 2019. For a more detailed description of the events that followed the initiation of this review, *see* the Preliminary Decision Memorandum, dated concurrently with these results and hereby adopted by this notice.[3]

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 to ACCESS is available to registered users at *http://access.trade.gov* and is available to all parties in the Central Records Unit, Room B8024 of the main Commerce building. In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly at *http://enforcement.trade.gov/frn/index.html.* A list of topics discussed in the Preliminary Decision Memorandum is attached as an Appendix to this notice. The signed Preliminary Decision Memorandum and the electronic versions of the Preliminary Decision Memorandum are identical in content.

Scope of the Order

The scope of this order covers large liquid dielectric power transformers having a top power handling capacity greater than or equal to 60,000 kilovolt amperes (60 megavolt amperes), whether assembled or unassembled, complete or incomplete.

The merchandise subject to the order is currently classified in the Harmonized Tariff Schedule of the United States at subheadings 8504.23.0040, 8504.23.0080 and 8504.90.9540. This tariff classification is provided for convenience and Customs purposes; however, the written description of the scope of the order is dispositive. For a complete description of the scope of the order, *see* the Preliminary Decision Memorandum.

Methodology

Commerce is conducting this review in accordance with section 751(a)(2) of the Tariff Act of 1930, as amended (the Act). For a full description of the methodology underlying our conclusions, *see* the Preliminary Decision Memorandum.

Facts Available

Pursuant to section 776(a) of the Act, Commerce is preliminarily relying upon facts otherwise available to assign an estimated weighted-average dumping margin to Hyundai in this review. Preliminarily, Commerce finds that Hyundai withheld necessary information that was requested by Commerce, significantly impeded the review, and provided information that could not be verified. Further, Commerce preliminarily determines that Hyundai failed to cooperate by not acting to the best of its ability to comply with requests for information and, thus, Commerce is applying adverse facts available (AFA) to Hyundai, in accordance with section 776(b) of the Act. For a full description of the methodology underlying our conclusions regarding the application of AFA, *see* the Preliminary Decision Memorandum.

Rate for Non-Selected Companies

In accordance with the U.S. Court of Appeals for the Federal Circuit's decision in *Albemarle Corp.* v. *United States,*[4] we are applying to the non-selected companies the rate preliminarily applied to Hyosung in this administrative review.[5] This is the only rate determined in this review for individual respondents, and thus we are preliminarily applying it to the four non-selected companies. For a detailed

[1] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 83 FR 50077 (October 4, 2018) (*Initiation Notice*).

[2] *See* Memorandum to the Record from Gary Taverman, Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance, ''Deadlines Affected by the Partial Shutdown of the Federal Government,'' dated January 28, 2019. All deadlines in this segment of the proceeding have been extended by 40 days.

[3] *See* Memorandum, ''Decision Memorandum for Preliminary Results of Antidumping Duty Administrative Review: Large Power Transformers from the Republic of Korea; 2017–2018'' (Preliminary Decision Memorandum), dated concurrently with this notice.

[4] *See Albemarle Corp.* v. *United States,* 821 F.3d 1345 (Fed. Cir. 2016).

[5] *See, e.g., Certain Small Diameter Carbon and Alloy Seamless Standard, Line, and Pressure Pipe (Under 4½ Inches) from Japan: Preliminary Results of Antidumping Duty Administrative Review and Preliminary Determination of No Shipments; 2014–2015,* 81 FR 45124, 45124 (July 12, 2016), unchanged in *Certain Small Diameter Carbon and Alloy Seamless Standard, Line, and Pressure Pipe (Under 4½ Inches) from Japan: Final Results of Antidumping Duty Administrative Review and Final Determination of No Shipments; 2014–2015,* 81 FR 80640, 80641 (November 16, 2016).

discussion, *see* the Preliminary Decision Memorandum.

Preliminary Results of Review

We preliminarily determine that, for the period August 1, 2017 through July 31, 2018, the following weighted-average dumping margins exist:[6]

Producer/exporter	Weighted-average dumping margin (percent)
Hyosung Corporation	40.73
Hyosung Heavy Industries Corporation	40.73
Hyundai Heavy Industries Co., Ltd.[7]	60.81
Hyundai Electric & Energy Systems Co., Ltd	60.81
Iljin Electric Co., Ltd	40.73
Iljin	40.73
LSIS Co., Ltd	40.73

Disclosure and Public Comment

Commerce will disclose to parties to the proceeding any calculations performed in connection with these preliminary results of review within five days after the date of publication of this notice.[8] Commerce will announce the briefing schedule to interested parties at a later date. Interested parties may submit case briefs on the deadline that Commerce will announce.[9] Rebuttal briefs, the content of which is limited to the issues raised in the case briefs, must be filed within five days from the deadline date for the submission of case briefs.[10]

Parties who submit case or rebuttal briefs in this proceeding are requested to submit with each argument: (1) A statement of the issue; (2) a brief summary of the argument; and (3) a table of authorities.[11] Case and rebuttal briefs should be filed using ACCESS.[12] Case and rebuttal briefs must be served on interested parties.[13] Executive summaries should be limited to five pages total, including footnotes.

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing must submit a written request to the Assistant Secretary for Enforcement and Compliance within 30 days of the date of publication of this notice. Requests should contain: (1) The party's name, address and telephone number; (2) the number of participants; and (3) a list of issues parties intend to discuss. Issues raised in the hearing will be limited to those raised in the respective case and rebuttal briefs. If a request for a hearing is made, Commerce intends to hold the hearing at the U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230, at a date and time to be determined.[14] Parties should confirm the date, time, and location of the hearing two days before the scheduled date.

Commerce intends to publish the final results of this administrative review, including the results of its analysis of issues raised in any case or rebuttal brief, no later than 120 days after publication of these preliminary results, unless extended.[15]

Assessment Rates

Upon completion of this administrative review, Commerce shall determine, and U.S. Customs and Border Protection (CBP) shall assess, antidumping duties on all appropriate entries. If a respondent's weighted-average dumping margin is not zero or *de minimis* in the final results of this review and the respondent reported reliable entered values, we will calculate importer-specific *ad valorem* assessment rates for the merchandise based on the ratio of the total amount of dumping calculated for the examined sales made during the period of review to each importer to the total entered value of those same sales in accordance with 19 CFR 351.212(b)(1). If the respondent has not reported reliable entered values, we will calculate a per-unit assessment rate for each importer by dividing the total amount of dumping for the examined sales made during the period of review to that importer by the total sales quantity associated with those transactions. Where an importer-specific *ad valorem* assessment rate is zero or *de minimis,* we will instruct CBP to liquidate the appropriate entries without regard to antidumping duties in accordance with 19 CFR 351.106(c)(2). If the respondent's weighted-average dumping margin is zero or *de minimis* in the final results of review, we will instruct CBP not to assess duties on any of its entries in accordance with the *Final Modification for Reviews, i.e.,* ''{w}here the weighted-average margin of dumping for the exporter is determined to be zero or *de minimis,* no antidumping duties will be assessed.'' [16]

If the preliminary results are unchanged for the final results, we will instruct CBP to apply an *ad valorem* assessment rate of 60.81 percent to all entries of subject merchandise during the period of review which were produced and/or exported by Hyundai.

Regarding entries of subject merchandise during the period of review that were produced by Hyosung and Hyundai and for which they did not know that the merchandise was destined for the United States, we will instruct CBP to liquidate un-reviewed entries at the all-others rate of 22.00 percent, as established in the less-than-fair-value investigation of the order, if there is no rate for the intermediate company(ies) involved in the transaction.[17] For a full discussion of this matter, *see Assessment Policy Notice.*[18]

We intend to issue liquidation instructions to CBP 15 days after publication of the final results of this review.

Cash Deposit Requirements

The following cash deposit requirements will be effective upon publication of the final results of this administrative review for all shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date of the final results of this administrative review, as provided by section 751(a)(2)(C) of the Act: (1) The cash deposit rate for Hyosung and Hyundai and other companies listed above will be equal to the weighted-average dumping margin established in the final results of this administrative review; (2) for previously reviewed or investigated companies not listed above, the cash deposit rate will continue to be the company-specific rate published for

[6] As AFA, we preliminarily assign Hyundai a dumping margin of 60.81 percent, an AFA rate used in the previous review. *See Large Power Transformers from the Republic of Korea: Final Results of Antidumping Duty Administrative Review; 2016–2017,* 84 FR 16461 (April 19, 2019). This rate achieves the purpose of applying an adverse inference, *i.e.,* it is sufficiently adverse to ensure that the uncooperative party does not obtain a more favorable result by failing to cooperate than if it had fully cooperated. According to 776(c)(2) of the Act, this rate does not require corroboration.

[7] *See Large Power Transformers from the Republic of Korea: Notice of Final Results of Antidumping Duty Changed Circumstances Review,* 83 FR 45094 (September 5, 2018), and accompanying Issues and Decision Memorandum.

[8] *See* 19 CFR 351.224(b).

[9] *See* 19 CFR 351.309(c)(1)(ii) and (d)(1).

[10] *See* 19 CFR 351.309(d)(1) and (d)(2).

[11] *See* 19 CFR 351.309(c)(2).

[12] *See generally* 19 CFR 351.303.

[13] *See* 19 CFR 351.303(f).

[14] *See* 19 CFR 351.310(d).

[15] *See* section 751(a)(3)(A) of the Act; 19 CFR 351.213(h).

[16] *See Antidumping Proceedings: Calculation of the Weighted-Average Dumping Margin and Assessment Rate in Certain Antidumping Proceedings: Final Modification,* 77 FR 8101, 8102 (February 14, 2012) (*Final Modification for Reviews*).

[17] *See Large Power Transformers from the Republic of Korea: Antidumping Duty Order,* 77 FR 53177 (August 31, 2012).

[18] *See Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties,* 68 FR 23954 (May 6, 2003) (*Assessment Policy Notice*).

the most recently completed segment of this proceeding in which they were reviewed; (3) if the exporter is not a firm covered in this review, a prior review, or in the investigation but the producer is, the cash deposit rate will be the rate established for the most recently completed segment of this proceeding for the producer of the merchandise; and (4) the cash deposit rate for all other producers or exporters will continue to be the all-others rate of 22.00 percent, the rate established in the investigation of this proceeding.[19] These cash deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice also serves as a 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 this notice in accordance with sections 751(a)(1) and 777(i)(1) of the Act.

Dated: October 9, 2019.

Jeffrey I. Kessler,

Assistant Secretary for Enforcement and Compliance.

Appendix

List of Topics Discussed in the Preliminary Decision Memorandum

[FR Doc. 2019–22669 Filed 10–16–19; 8:45 am]

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[19] *See Large Power Transformers from the Republic of Korea: Antidumping Duty Order,* 77 FR 53177 (August 31, 2012).

DEPARTMENT OF COMMERCE

International Trade Administration

Subsidy Programs Provided by Countries Exporting Softwood Lumber and Softwood Lumber Products to the United States; Request for Comment

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) seeks public comment on any subsidies, including stumpage subsidies, provided by certain countries exporting softwood lumber or softwood lumber products to the United States during the period January 1, 2019, through June 30, 2019.

DATES: Comments must be submitted within 30 days after publication of this notice.

FOR FURTHER INFORMATION CONTACT: Kristen Johnson, AD/CVD Operations, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW. Washington, DC 20230; telephone: (202) 482–4793.

SUPPLEMENTARY INFORMATION:

Background

Pursuant to section 805 of Title VIII of the Tariff Act of 1930 (the Softwood Lumber Act of 2008), the Secretary of Commerce is mandated to submit to the appropriate Congressional committees a report every 180 days on any subsidy provided by countries exporting softwood lumber or softwood lumber products to the United States, including stumpage subsidies. Commerce submitted its last subsidy report on July 1, 2019. As part of its newest report, Commerce intends to include a list of subsidy programs identified with sufficient clarity by the public in response to this notice.

Request for Comments

Given the large number of countries that export softwood lumber and softwood lumber products to the United States, we are soliciting public comment only on subsidies provided by countries which had exports accounting for at least one percent of total U.S. imports of softwood lumber by quantity, as classified under Harmonized Tariff Schedule of the United States (HTSUS) codes 4407.1001, 4407.1100, 4407.1200, 4407.1905, 4407.1906, 4407.1910, during the period January 1, 2019, through June 30, 2019. Official U.S. import data published by the United States International Trade Commission's DataWeb indicate that four countries (Brazil, Canada, Germany, and Sweden) exported softwood lumber to the United States during that time period in amounts sufficient to account for at least one percent of U.S. imports of softwood lumber products. We intend to rely on similar previous six-month periods to identify the countries subject to future reports on softwood lumber subsidies. For example, we will rely on U.S. imports of softwood lumber and softwood lumber products during the period July 1, 2019, through December 31, 2019, to select the countries subject to the next report.

Under U.S. trade law, a subsidy exists where an authority: (i) Provides a financial contribution; (ii) provides any form of income or price support within the meaning of Article XVI of the GATT 1994; or (iii) makes a payment to a funding mechanism to provide a financial contribution to a person, or entrusts or directs a private entity to make a financial contribution, if providing the contribution would normally be vested in the government and the practice does not differ in substance from practices normally followed by governments, and a benefit is thereby conferred.[1]

Parties should include in their comments: (1) The country which provided the subsidy; (2) the name of the subsidy program; (3) a brief description (no more than 3–4 sentences) of the subsidy program; and (4) the government body or authority that provided the subsidy.

Submission of Comments

As specified above, to be assured of consideration, comments must be received no later than 30 days after the publication of this notice in the **Federal Register**. All comments must be submitted through the Federal eRulemaking Portal at *http://www.regulations.gov,* Docket No. ITA–2019–0007, unless the commenter does not have access to the internet. The materials in the docket will not be edited to remove identifying or contact information, and Commerce cautions against including any information in an electronic submission that the submitter does not want publicly disclosed. Attachments to electronic comments will be accepted in Microsoft Word, Excel, or Adobe PDF formats only.

Commenters who do not have access to the internet may submit the original and one electronic copy of each set of comments by mail or hand delivery/courier.

All comments should be addressed to James Maeder, Deputy Assistant

[1] *See* section 771(5)(B) of the Tariff Act of 1930, as amended.

Secretary for Antidumping and Countervailing Duties, at U.S. Department of Commerce, Room 18022, 1401 Constitution Avenue NW, Washington, DC 20230.

Dated: October 9, 2019.

James Maeder,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2019–22692 Filed 10–16–19; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

National Institute of Standards and Technology

Submission for OMB Review; Comment Request

The Department of Commerce will submit to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

Agency: National Institute of Standards and Technology (NIST).

Title: Baldrige Performance Excellent Program (BPEP) Team Leader Consensus and Team Leader Site Visit Information Collections.

OMB Control Number: 0693–0079.

Form Number(s): None.

Type of Request: Extension and revision of a current information collection.

Number of Respondents: Examiner Performance Assessment—40 per year; Team Leader Performance Assessment—300 per year.

Average Hours per Response: Examiner Performance Assessment—20 minutes; Team Leader Performance Assessment—5 minutes.

Burden Hours: Examiner Performance Assessment—13.5 hours; Team Leader Performance Assessment—25 hours.

Needs and Uses: The purpose of the information is to help staff collect data on the skills of the examiners, including alumni examiners, in order to best manage training and selection. Because the examiner selection is so competitive, examiners need to demonstrate competencies such as understanding the Baldrige Criteria, team skills, and writing skills. The program also needs to collect peer-based information to understand an examiner's skill level in order to make decisions on whether the examiner should be elevated to ''senior examiner'' and therefore team leader. The blinded data will be shared with the team leader for improvement purposes, and for future assignments.

Affected Public: Individual or Households.

Frequency: Annually.

Respondent's Obligation: Voluntary.

This information collection request may be viewed at *reginfo.gov.* Follow the instructions to view Department of Commerce collections currently under review by OMB.

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *OIRA_Submission@omb.eop.gov* or fax to (202) 395–5806.

Sheleen Dumas,

Departmental Lead PRA Officer, Office of the Chief Information Officer, Commerce Department.

[FR Doc. 2019–22620 Filed 10–16–19; 8:45 am]

BILLING CODE 3510–13–P

DEPARTMENT OF COMMERCE

National Institute of Standards and Technology

Deprecation of the United States (U.S.) Survey Foot

AGENCY: The National Institute of Standards and Technology and the National Geodetic Survey (NGS), National Ocean Service (NOS), National Oceanic and Atmospheric Administration (NOAA), Department of Commerce (DOC).

ACTION: Notice; request for comment.

SUMMARY: The National Institute of Standards and Technology (NIST) and the National Geodetic Survey (NGS), National Ocean Service (NOS), National Oceanic and Atmospheric Administration (NOAA), are taking collaborative action to provide national uniformity in the measurement of length. This notice announces a decision to deprecate the use of the ''U.S. survey foot'' on December 31, 2022. After that date, the ''U.S. survey foot'' will be superseded by the ''foot'' (formerly known as the ''international foot''), which is already in use throughout the U.S. This notice describes the plan, resources, training, and other activities of NIST and NOAA that will assist those affected by this transition, and invites comments and other information from land surveyors, engineers, Federal, State and local government officials, businesses, and any other member of the public engaged in or affected by surveying and mapping operations.

DATES: Comments and other information must be received by December 2, 2019.

ADDRESSES: NIST and NOAA are using the *https://www.regulations.gov* system for the submission and posting of public comments in this proceeding. All comments in response to this notice are therefore to be submitted electronically through *https://www.regulations.gov,* via the web form accessed by following the ''Submit a Formal Comment'' link near the top right of the **Federal Register** web page for this notice.

FOR FURTHER INFORMATION CONTACT:

U.S. survey foot deprecation resources: https://www.nist.gov/pml/us-surveyfoot.

Information on standards development and maintenance: Elizabeth Gentry, 301–975–3690, *Elizabeth.Gentry@nist.gov.*

Technical and historical information on usage of the foot: Michael Dennis, 240–533–9611, *Michael.Dennis@noaa.gov.*

SUPPLEMENTARY INFORMATION:

Background

This action is designed to establish national uniformity in length measurements based on the foot. For more than sixty years, two nearly identical definitions of the foot have been in use in the U.S. for geodetic and land surveys. A **Federal Register** notice published on July 1, 1959 (24 FR 5348) by the National Bureau of Standards (renamed the National Institute of Standards and Technology in 1988) and the U.S. Coast and Geodetic Survey (reorganized as the National Geodetic Survey under the National Oceanic and Atmospheric Administration in 1970) refined the definition of the yard in terms of the International System of Units (SI), commonly known as the metric system. The 1959 notice was issued after an international agreement among six nations resolved a long-standing difference in the relationship of the U.S. yard to the British yard. The notice reported that there was a slight difference (2 parts per million) between the 1959 definition (*i.e.,* one yard = 0.914 4 meter, exactly) and an 1893 definition (*i.e.,* 1 yard = 3600/3937 meter, or approximately 0.914 401 83 meter).

The 1959 **Federal Register** notice then adopted a revised value for the foot for use throughout the U.S., and identified it as the ''international foot'' to show that it corresponded with the foot in use by the United Kingdom and other countries. The notice defined this international foot as 0.304 8 meter (*e.g.,* equal to 0.999 999 8 of the value for the foot officially adopted in 1893). Additionally, to avoid disrupting the surveying practices at the time, the

notice established an interim approach that permitted the limited use of the historic 1893 value of the foot exclusively in the field of geodetic surveys. It was identified as the ''U.S. survey foot'' with the defined value of 0.304 800 61 meter (approximately). The 1959 notice specifically stated that the ''U.S. survey foot'' should be used ''until such a time as it becomes desirable and expedient to readjust the basic geodetic survey networks in the United States, after which the ratio of a yard, equal to 0.914 4 meter, shall apply.''

As announced in a **Federal Register** notice published on March 24, 1977 (42 FR 15943), NOAA officially adopted the meter as the unit for length in the National Spatial Reference System (NSRS). However, U.S. surveying and mapping practitioners continued to use the ''U.S. survey foot,'' including when they employed the NGS-defined State Plane Coordinates System of 1927 and 1983 (SPCS 27 and SPCS 83, respectively). Because the ''international foot'' is the basis for all other length measurements and calibrations in the U.S., it is no longer necessary to continue to maintain two unit values for the foot.

Consequences for Surveying, Mapping, and Engineering in the United States

Although the use of the ''U.S. survey foot'' was intended to be an interim measure, its use continues to be prevalent in land surveying and mapping in much of the U.S. Of the 50 U.S. jurisdictions that have legislated SPCS 83 (48 States plus Puerto Rico and Guam), the ''U.S. survey foot'' has been specified for SPCS 83 in 40 States, either through statute (28 States) or **Federal Register** notices (12 States). Six States have adopted the ''international foot'' for SPCS 83, while two States (plus Puerto Rico and Guam) have not formally designated the type of foot to be used. It is important to note that State legislation and **Federal Register** notices regarding the ''U.S. survey foot'' are specifically associated with SPCS 83, and therefore are not applicable to the NSRS Modernization in 2022.

It is also important to note that while the difference between the two definitions is 2 parts per million, this small discrepancy accumulates over large distances and can result in significant errors in surveying and civil engineering projects, regardless of the size of the project. For example, when a one-mile distance is surveyed, the difference is approximately 0.01 ft or 0.12 in. However, the impact becomes substantial when longer distance measurements or conversions are made, such as those involving rectangular plane coordinates of SPCS 83. In these cases, the difference between the two definitions can also result in large direction and position location errors, in many cases reaching tens of feet for SPCS 83 coordinates.

Because of this situation, there has been a long history of misunderstandings and confusion over which definition of the foot was used to carry out a specific land survey or civil engineering project. There have been many instances where software or electronic surveying devices default to one or the other foot definitions, but users incorrectly assume the actual unit of measure in use. This ongoing ambiguity has resulted in professional liability by the inadvertent violation of State law, the introduction of systematic errors in surveying and engineering projects, misreported position and location, land sale and project delays, boundary disputes, additional costs associated with correcting unit mistakes, and other unintended consequences. Because State jurisdictions with different legal definitions of the foot share borders, mapping projects in these geographic zones may experience elevated error risks as a surveyor transitions between a State that uses the ''U.S. survey foot'' and a State that uses the ''international foot.'' This risk is exacerbated when professional surveyors and engineers are licensed to practice in multiple States that use different versions of the foot, and for large projects when the team participants come from different States and even different countries. In addition to the cost due to errors, there is the cost of inefficiency, since it is necessary to keep track of the foot version, which increases with the size, duration, and complexity of projects.

Opportunity To Eliminate Confusion

Since the publication of the 1959 **Federal Register** notice, experience has overwhelmingly revealed that national uniformity cannot be ensured in this critical industry field when users are routinely confronted with two definitions of the foot. The best opportunity for eliminating the redundancy in values for the foot will occur with the NOAA program to modernize the NSRS in 2022.

The only practical solution is to deprecate the ''U.S. survey foot'' and to require that its use in surveying, mapping, and engineering be discontinued. Allowing the continued use of two definitions of the foot undercuts the value and benefit of national uniformity, and allows for additional opportunities for confusion and unnecessary costs to the users, the States, and professionals in the surveying, mapping, and engineering fields. No compelling justification to maintain two definitions for the foot exists.

Notice From the Director of the National Institute of Standards and Technology Regarding the Deprecation of the ''U.S. Survey Foot'' on December 31, 2022

Under Article 1, Section 8 of the United States Constitution, Congress retains the power to ''fix the Standard of Weights and Measures.'' Throughout that section, the words ''uniform throughout the United States'' are used in conjunction with many of the other duties and responsibilities that are listed. The ''fixing'' or defining the standards of weights and measures is intrinsic to ensure uniform measurement across the U.S., as well as with the rest of the world. In 1866, Congress acted to make the metric system of measurement (now known as the International System of Units (SI)) legal for use in the United States (15 U.S.C. 204). On May 20, 1875 the U.S. signed the Meter Convention (known as the ''International Treaty of the Meter''), which established the International Bureau of Weights and Measures, an intergovernmental organization under the General Conference on Weights and Measures that oversees the International Committee for Weights and Measures, which is the organization that maintains the SI to meet the measurement needs of the world. On April 5, 1893, the ''Mendenhall Order,'' issued by the U.S. Coast and Geodetic Survey with the approval of the U.S. Secretary of the Treasury, determined that the U.S. Customary units of the yard and pound would be defined in terms of the SI units of the meter and kilogram. The practice of defining the U.S. Customary units of measurement in terms of the SI continues today.

In 1988, Congress declared that the metric system was the preferred system of measurement for trade and commerce in the United States (15 U.S.C. 205b). The Director of the National Institute of Standards and Technology is authorized by statute ''to develop, maintain, and retain custody of the national standards of measurement, and provide the means and methods for making measurements consistent with those standards'' (15 U.S.C. 272(b)(2)), ''to assure the compatibility of United States national measurement standards with those of other nations'' (15 U.S.C. 272(b)(9)), and to ''cooperate with the States in securing uniformity in weights and measures laws'' (15 U.S.C. 272(c)(4)). Under this

authority, the SI is interpreted or modified by the Director of NIST for use in the United States. The SI is used exclusively to define, establish, and maintain the U.S. national standards of measurement and in securing uniformity of their use in the laws of the States.

''Deprecation'' is a term widely used in the field of legal metrology and other measurement science fields of study. It describes a decision to discontinue the use of a specific measurement unit or method of sale. A unit of measurement (*e.g.,* the foot or gallon) though legal, may be prohibited from being used in a specific commercial application if, for example, it has been identified as being redundant or a source of confusion, or if it could frustrate the ability of users to make quantity and value comparisons. For example, gasoline and other engine fuels are permitted to be sold from a retail service station by the gallon but may not be sold by the fluid pint or fluid ounce. As the situation with multiple definitions for the foot illustrates, measurement unit uniformity is only possible when a single measurement unit definition is used for a specific application (*e.g.,* land surveying).

The deprecation process begins with a notice to users that a unit of measure is to be deprecated and that use of the unit is to be avoided after a specific date. The notice also prescribes the new unit of measurement that will be accepted for use. The notice period allows users time to make the necessary changes to their measuring practices, processes, procedures, and devices. The notice period also provides an opportunity for education and training for all of those involved in the changeover and the identification of unforeseen issues so that appropriate preventive actions, exceptions, or additional requirements can be developed and implemented. After the notice period ends, the deprecated measurement unit is deemed obsolete, its use is to be avoided, and it is retained for historical purposes and legacy applications only.

Deprecation of the Survey Foot, Survey Mile, and Other Measures Derived From the Survey Foot

On December 31, 2022, the 1893 ''U.S. survey foot,'' as defined in a 1959 **Federal Register** notice (24 FR 5348, June 30, 1959), will be deprecated as a U.S. national standard of measurement and its use is to be avoided. The 1893 definition of the ''U.S. survey foot'' will be retained for historic reference but will be deemed obsolete. This notice also applies to the ''U.S. survey mile'' (equal to approximately 1609.347 meters), which is based on the ''U.S. survey foot,'' the use of which should also be avoided after December 31, 2022 and which will be retained for historical purposes but will be deemed obsolete. After December 31, 2022, any data derived from or published as a result of surveying, mapping, or any other activity within the U.S. that is expressed in terms of feet shall only be based on the ''foot'' equal to 0.304 8 meter (exactly), formerly known as the ''international foot'' in the 1959 **Federal Register** notice.

Likewise, other measures previously based only on the ''U.S. survey foot'' will be defined using the foot equal to 0.304 8 meter (exactly) after December 31, 2022. These measures are the ''chain,'' ''link,'' ''rod'' (also ''pole'' or ''perch''), ''furlong,'' and ''fathom'' for length, and the ''acre'' for area. Decimal SI equivalents for these measures are given in Table 1 for both the ''U.S. survey foot'' (approximate) and the ''foot'' (exact). For these measures, the difference between the two types of feet is usually of no practical consequence. For example, the greatest precision typically used for the chain in modern land surveying practice is three decimal places (or 0.1 link), and at that level of significance both versions of the foot give the same value. Similarly, the difference in area for 1 acre is only 0.000 004 acre (0.17 ft^2) for the two foot versions.

TABLE 1—APPROXIMATE DECIMAL SI EQUIVALENTS FOR MEASURES COMMONLY GIVEN IN ''U.S. SURVEY FEET'' AND EXACT EQUIVALENTS FOR THE ''FOOT'' THAT WILL BE ADOPTED AFTER DECEMBER 31, 2022 IN NIST SP 811, THE NIST GUIDE FOR THE USE OF THE INTERNATIONAL SYSTEM OF UNITS

Unit of measure based on feet	Type of quantity	''U.S. survey foot'' (approximate)	''foot'' (exact)
foot (ft)	length	0.304 800 6 . . . m	0.304 8 m
mile (mi)	length	1609.347 . . . m	1609.344 m
chain (ch)	length	20.116 84 . . . m	20.116 8 m
link (li)	length	0.201 168 4 . . . m	0.201 168 m
rod (rd), pole, perch	length	5.029 21 . . . m	5.029 2 m
furlong (fur)	length	201.168 4 . . . m	201.168 m
fathom	length	1.828 804 . . . m	1.828 8 m
acre (ac)	area	4046.872 609 9 . . . m^2	4046.856 422 4 m^2

In keeping with the terms of this notice, the ''U.S. survey foot'' will no longer be supported by NOAA in the modernized NSRS after 2022, including the State Plane Coordinate System of 2022 (SPCS2022), elevations, and all other components of the system. However, the ''U.S. survey foot'' will be permanently maintained in NOAA products and services for legacy applications, for example the computation of SPCS coordinates in States where it was specified for SPCS 83, and for all zones of SPCS 27.

Comments and Future Action

The Director of NIST and the Director of the National Geodetic Survey (NGS) solicit comments and suggestions from land surveyors, engineers, Federal, State and local officials, equipment manufacturers, and the public at large who are engaged in or affected by surveying and mapping operations for ways that the two agencies can help facilitate an orderly transition to a single definition for the foot. Throughout the notice period, NGS and the NIST Office of Weights and Measures will work together to provide opportunities for education and training for all of those involved in the changeover. After the public comments are evaluated, any unforeseen issues identified, and appropriate solutions developed, a second **Federal Register** notice addressing those issues will be published and publicly announced in other media as appropriate before June 30, 2020.

This action is being taken in conjunction with the NGS program to improve the National Spatial Reference System (NSRS), as described at *https://geodesy.noaa.gov/datums/newdatums/*

index.shtml. In 2022, NGS will replace the North American Datum of 1983 (NAD 83) and the North American Vertical Datum of 1988 (NAVD 88) with new geometric reference frames and a geopotential datum. The new reference frames and datum will rely primarily on Global Navigation Satellite Systems (GNSS), such as the Global Positioning System (GPS), as well as on a gravimetric geoid model resulting from the NGS Gravity for the Redefinition of the American Vertical Datum (GRAV–D) Project. These new reference frames and datum will be easier to access and maintain than NAD 83 and NAVD 88, which rely on physical survey marks that deteriorate over time.

On April 18, 2018, NGS issued a draft **Federal Register** notice (83 FR 17149) for public comment on draft policy and procedures for the State Plane Coordinate System of 2022 (SPCS2022), which will be referenced to the 2022 reference frames. In those draft documents, it was specified that SPCS2022 parameters will be exclusively defined using metric (SI) values. However, in addition to metric values, the documents stated that output coordinates could also optionally be provided in either ''international'' or ''U.S. survey feet,'' and that by default the type of foot would be the same as currently used for SPCS 83. The official version of SPCS2022 Policy, effective April 23, 2019 (*https://geodesy.noaa.gov/INFO/Policy/files/SPCS2022_Policy_NGS_2019-1214-01.pdf*), states that NGS has not yet determined whether or what type of foot will be supported for output coordinates (Section II.E.1). The policy will be updated after NIST and NOAA co-issue a **Federal Register** notice by June 30, 2020, announcing adoption of the ''foot'' equal to 0.304 8 meter (exactly) as the official definition for all applications in the U.S. after December 31, 2022.

Kevin A. Kimball,

Chief of Staff.

[FR Doc. 2019–22414 Filed 10–16–19; 8:45 am]

BILLING CODE 3510–13–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Notice Requesting Nominations for the Advisory Committee on Commercial Remote Sensing (ACCRES)

ACTION: Request for membership nominations.

SUMMARY: The Department of Commerce is seeking highly qualified individuals who are knowledgeable about the commercial space-based remote sensing industry and uses of space-based remote sensing data to serve on the Advisory Committee on Commercial Remote Sensing (ACCRES). The Committee is comprised of leaders in the commercial space-based remote sensing industry, space-based remote sensing data users, government, and academia. The **SUPPLEMENTARY INFORMATION** section of this notice provides committee and membership criteria.

SUPPLEMENTARY INFORMATION: ACCRES was established by the Secretary of Commerce on May 21, 2002, to advise the Secretary, through the Under Secretary of Commerce for Oceans and Atmosphere, on matters relating to the U.S. commercial remote sensing industry and NOAA's activities to carry out responsibilities of the Department of Commerce as set forth in the National and Commercial Space Programs Act of 2010 (the Act), Title 51 U.S.C. 60101 *et seq* (formerly the Land Remote Sensing Policy Act of 1992, 15 U.S.C. Secs. 5621–5625).

Committee members serve in a representative capacity for a term of two years and may serve additional terms, if reappointed. No more than 20 individuals at a time may serve on the Committee. ACCRES will have a fairly balanced membership consisting of approximately 9 to 20 members. Nominations are encouraged from all interested U.S. persons and organizations representing interests affected by the regulation of remote sensing. Nominees must represent stakeholders in remote sensing, space commerce, space policy, or a related field and be able to attend committee meetings that are held usually two times per year. Membership is voluntary, and service is without pay. Each nomination that is submitted should include the proposed committee member's name and organizational affiliation, a brief description of the nominee's qualifications and interest in serving on the Committee, a curriculum vitae or resume of the nominee, and no more than three supporting letters describing the nominee's qualifications and interest in serving on the Committee. Self-nominations are acceptable. The following contact information should accompany each submission: The nominee's name, address, phone number, and email address.

Nominations should be sent to Tahara Dawkins, Director, Commercial Remote Sensing Regulatory Affairs Office, 1335 East West Highway, G–101, Silver Spring, Maryland 20910 or email *tahara.dawkins@noaa.gov.* Nominations must be postmarked or emailed no later than 30 days from the publication date of this notice. The full text of the Committee Charter and its current membership can be viewed at the Agency's web page at: *http://www.nesdis.noaa.gov/CRSRA/accresHome.html.*

FOR FURTHER INFORMATION CONTACT: Tashaun Pierre, Commercial Remote Sensing Regulatory Affairs Office, NOAA Satellite and Information Services, 1335 East West Highway, Room G101, Silver Spring, Maryland 20910; telephone (301) 713–7077, email *Tashaun.pierre@noaa.gov.*

Stephen M. Volz,

Assistant Administrator for Satellite and Information Services.

[FR Doc. 2019–22660 Filed 10–16–19; 8:45 am]

BILLING CODE 3510–HR–P

DEPARTMENT OF DEFENSE

Office of the Secretary

Defense Health Board; Notice of Federal Advisory Committee Meeting

AGENCY: Under Secretary of Defense for Personnel and Readiness, 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 Health Board will take place.

DATES: Open to the public Monday, November 4, 2019 from 7:30 a.m. to 3:00 p.m.

ADDRESSES: The address of the open meeting is Madigan Army Medical Center, 9040 Jackson Ave., Cahill Conference Room 2–68–4, Tacoma, WA 98431. Registration is required. (Pre-meeting screening for base access and registration required. See guidance in **SUPPLEMENTARY INFORMATION**, ''meeting Accessibility.'')

FOR FURTHER INFORMATION CONTACT: Captain Gregory Gorman, Medical Corps, U.S. Navy, (703) 275–6060 (Voice), (703) 275–6064 (Facsimile), *gregory.h.gorman.mil@mail.mil* (Email). Mailing address is 7700 Arlington Boulevard, Suite 5101, Falls Church, Virginia 22042. Website: *http://www.health.mil/dhb.* 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 the Federal Advisory

Committee Act (FACA) (5 U.S.C., Appendix), the Government in the Sunshine Act (5 U.S.C. 552b), and 41 CFR 102–3.140 and 102–3.150.

Availability of Materials for the Meeting: Additional information, including the agenda, will be available at the DHB website, *http://www.health.mil/dhb.* A copy of the agenda or any updates to the agenda for the November 4, 2019, meeting will be available on the DHB website. Any other materials presented in the meeting may be obtained at the meeting.

Purpose of the Meeting: The DHB provides independent advice and recommendations to maximize the safety and quality of, as well as access to, health care for DoD health care beneficiaries. The purpose of the meeting is to provide progress updates on specific tasks before the DHB. In addition, the DHB will receive information briefings on current issues related to military medicine.

Agenda: The DHB anticipates receiving progress updates from the Neurological/Behavioral Health Subcommittee on the Examination of Mental Health Accession Screening: Predictive Value of Current Measures and Processes review and from the Health Care Delivery Subcommittee on the Active Duty Women's Health Care Services review. The DHB also expects to receive overview briefings from Madigan Army Medical Center, the Regional Health Command—Pacific, the 62nd Medical Squadron, and the Naval Hospital Bremerton information as well as information briefings on Joint Base Lewis-McChord (JBLM) Behavioral Health Resources and JBLM Women's Resources. Any changes to the agenda can be found at the link provided in this **SUPPLEMENTARY INFORMATION** section.

Meeting Accessibility: Pursuant to 5 U.S.C. 552b and 41 CFR 102–3.140 through 102–3.165 and subject to availability of space, this meeting is open to the public. Seating is limited and is on a first-come basis. All members of the public who wish to attend the public meeting must register by emailing their full name, rank/title, and organization/company to *dha.ncr.dhb.mbx.defense-health-board@mail.mil* or by contacting Ms. Theresa Fassig Normil at (703) 275–6012 no later than 12:00 p.m. on Friday, October 25, 2019. Members of the public who do not have base access will be required to provide additional information before access to JBLM can be arranged by the DHB staff and, when required, this information must be provided to the DHB Designated Federal Officer (DFO), Captain Gorman at *gregory.h.gorman.mil@mail.mil* or (703) 275–6060 (voice).

Special Accommodations: Individuals requiring special accommodations to access the public meeting should contact Ms. Theresa Fassig Normil at least five (5) business days prior to the meeting so that appropriate arrangements can be made.

Written Statements: Any member of the public wishing to provide comments to the DHB related to its current taskings or mission may do so at any time in accordance with section 10(a)(3) of the Federal Advisory Committee Act, 41 CFR 102–3.105(j) and 102–3.140, and the procedures described in this notice. Written statements may be submitted to the DHB DFO, Captain Gorman, at *gregory.h.gorman.mil@mail.mil.* Supporting documentation may also be included, to establish the appropriate historical context and to provide any necessary background information. If the written statement is not received at least five (5) business days prior to the meeting, the DFO may choose to postpone consideration of the statement until the next open meeting. The DFO will review all timely submissions with the DHB President and ensure they are provided to members of the DHB before the meeting that is subject to this notice. After reviewing the written comments, the President and the DFO may choose to invite the submitter to orally present their issue during an open portion of this meeting or at a future meeting. The DFO, in consultation with the DHB President, may allot time for members of the public to present their issues for review and discussion by the DHB.

Dated: October 10, 2019.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2019–22607 Filed 10–16–19; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

Membership of the Performance Review Board

AGENCY: Office of the Secretary of Defense (OSD), DoD.

ACTION: Notice of board membership.

SUMMARY: This notice announces the appointment of the Department of Defense, Fourth Estate, Performance Review Board (PRB) members, to include the Office of the Secretary of Defense, Joint Staff, Defense Field Activities, U.S Court of Appeals for the Armed Forces, and the following Defense Agencies: Defense Advanced Research Projects Agency, Defense Commissary Agency, Defense Contract Audit Agency, Defense Contract Management Agency, Defense Finance and Accounting Service, Defense Health Agency, Defense Information Systems Agency, Defense Legal Services Agency, Defense Logistics Agency, Defense Prisoners of War/Missing in Action Accounting Agency, Defense Security Cooperation Agency, Defense Threat Reduction Agency, Missile Defense Agency, and Pentagon Force Protection Agency. The PRB shall provide fair and impartial review of Senior Executive Service and Senior Professional performance appraisals and make recommendations regarding performance ratings and performance awards to the Deputy Secretary of Defense.

DATES: The board membership is applicable beginning on September 13, 2019.

FOR FURTHER INFORMATION CONTACT: Laura E. Devlin Dominguez, Assistant Director for Office of the Secretary of Defense Senior Executive Management Office, Office of the Deputy Chief Management Officer, Department of Defense, (703) 693–8373.

SUPPLEMENTARY INFORMATION: The publication of PRB membership is required by 5 U.S.C. 4314(c)(4). In accordance with 5 U.S.C. 4314(c)(4), the following executives are appointed to the Office of the Secretary of Defense PRB with specific PRB panel assignments being made from this group. Executives listed will serve a one-year renewable term, beginning September 13, 2019.

Office of the Secretary of Defense

Appointing Authority—David L. Norquist, Deputy Secretary of Defense
Principal Executive Representative—Sajeel S. Ahmed
Chairperson—Jeffrey R. Register

PRB PANEL MEMBERS

ATKINSON, MICHELLE CRESSWELL	LAYCHAK, MICHAEL R.
BANKS, ROXANNE J.	LEIST JR, MICHAEL N.
BLANKS, JULIE A.	MACSTRAVIC, JAMES A.
BOOTH SR, WILLIAM H.	MAYS, WILLIAM D.
BRUHN, MICHAEL L.	MEANS, LLEWELLYN
BUNN, BRAD	METZ, DANIELLE A.
CADMAN, DAVID S.	MOORE, BLAKE A.
CANNON, MICHAEL O	MOOREFIELD, FREDERICK D.
CONDON, CHRISTINE M.	MUIR, THOMAS M.
EADY, WALTER B.	MULVIHILL, KEVIN M.
GRAFF, DIANA P.	O'DONNELL, CHRISTOPHER C.
GUMAHAD, ARSENIO	SCHLEIEN, STEVEN L.
HANDELMAN, KENNETH B.	SCHLESS, SCOTT R.

PRB PANEL MEMBERS—Continued

HENRY, THOMAS M.	SIKORA, MELISSA A.
HIGGINS, MAUREEN B.	TENAGLIA, JOHN M.
KADIRI, MOBOLA A.	TOLLE, CYNTHIA S.
KAPELLAS, CHRISTOPHER A.	WARK, LAWRENCE J.
KOFFSKY, PAUL S.	

Dated: October 10, 2019.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2019–22611 Filed 10–16–19; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF EDUCATION

[Docket No. ED–2019–ICCD–0131]

Agency Information Collection Activities; Comment Request; Targeted Teacher Shortage Areas Data Collection

AGENCY: Office of Postsecondary Education (OPE), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, ED is proposing a revision of an existing information collection.

DATES: Interested persons are invited to submit comments on or before December 16, 2019.

ADDRESSES: To access and review all the documents related to the information collection listed in this notice, please use *http://www.regulations.gov* by searching the Docket ID number ED–2019–ICCD–0131. Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at *http://www.regulations.gov* by selecting the Docket ID number or via postal mail, commercial delivery, or hand delivery. If the *regulations.gov* site is not available to the public for any reason, ED will temporarily accept comments at *ICDocketMgr@ed.gov.* Please include the docket ID number and the title of the information collection request when requesting documents or submitting comments. *Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted.* Written requests for information or comments submitted by postal mail or delivery should be addressed to the Director of the Information Collection Clearance Division, U.S. Department of Education, 550 12th Street SW, PCP, Room 9086, Washington, DC 20202–0023.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Freddie Cross, 202–453–7224.

SUPPLEMENTARY INFORMATION: The Department of Education (ED), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR) that is described below. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: Targeted Teacher Shortage Areas Data Collection.

OMB Control Number: 1840–0595.

Type of Review: A revision of an existing information collection.

Respondents/Affected Public: State, Local, and Tribal Governments.

Total Estimated Number of Annual Responses: 57.

Total Estimated Number of Annual Burden Hours: 2,793.

Abstract: This request is for approval of reporting requirements that are contained in the Federal Family Education Loan Program (FFELP) regulations (34 CFR 682.210) which address the targeted teacher deferment provision of the Higher Education Act of 1965 as amended by the Higher Education Amendment of 1986, sections 427(a)(2)(C)(vi), 428(b)(1)(M)(vi), and 428(b)(4)(A), which provide for the targeted teacher deferment.

The FFELP (34 CFR 682.210(q)), Paul Douglas Teacher Scholarship Program (34 CFR 653.50(a)), TEACH Grant Program, and Federal Perkins Loan Program (34 CFR 674.53(c)) regulations contain information collection requirements. The Chief State School Officers of each state provide the Secretary annually with a list of proposed teacher shortage areas for that state.

Dated: October 10, 2019.

Kate Mullan,

PRA Coordinator, Information Collection Clearance Program, Information Management Branch, Office of the Chief Information Officer.

[FR Doc. 2019–22602 Filed 10–16–19; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2019–ICCD–0132]

Agency Information Collection Activities; Comment Request; DCIA Aging and Compliance Data Requirements for Guaranty Agencies

AGENCY: Federal Student Aid (FSA), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, ED is proposing a new information collection.

DATES: Interested persons are invited to submit comments on or before December 16, 2019.

ADDRESSES: To access and review all the documents related to the information collection listed in this notice, please use *http://www.regulations.gov* by searching the Docket ID number ED–2019–ICCD–0132. Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at *http://www.regulations.gov* by selecting the Docket ID number or via postal mail, commercial delivery, or hand delivery. If the *regulations.gov* site is not available to the public for any reason, ED will temporarily accept comments at *ICDocketMgr@ed.gov.* Please include the docket ID number and the title of the information collection request when requesting documents or submitting comments. *Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted.* Written requests for information or comments submitted by postal mail or delivery should be addressed to the Director of the Information Collection Clearance Division, U.S. Department of Education, 550 12th Street SW, PCP, Room 9086, Washington, DC 20202–0023.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Beth Grebeldinger, 202–377–4018.

SUPPLEMENTARY INFORMATION: The Department of Education (ED), in

accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR) that is described below. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: DCIA Aging and Compliance Data Requirements for Guaranty Agencies.

OMB Control Number: 1845–NEW.

Type of Review: A new information collection.

Respondents/Affected Public: Private Sector; State, Local, and Tribal Governments.

Total Estimated Number of Annual Responses: 550.

Total Estimated Number of Annual Burden Hours: 1,430.

Abstract: The Department is required to report to the U.S. Department of the Treasury (Treasury) the status and condition of its non-tax debt portfolio in accordance with the requirements of the Debt Collection Improvement Act of 1996 (DCIA) and the Digital Accountability and Transparency Act of 2014 (DATA Act).

The Department is unable to prepare an accurate and compliant Treasury Report based on the data it currently receives from its GAs. The new guidance will require the GAs to: Age debt according to DCIA; report the eligibility of DCIA-aged debt for referral to the Treasury Offset Program (TOP); and report compliance with Form 1099–C reporting.

The new reporting requirements are titled DCIA Aging and Compliance Data Requirements for Guaranty Agencies (the Requirements). The Department plans to issue the Requirements to the GAs by April 1, 2020 for implementation by the first quarter of FY 2021.

Dated: October 11, 2019.

Kate Mullan,

PRA Coordinator, Information Collection Clearance Program, Information Management Branch, Office of the Chief Information Officer.

[FR Doc. 2019–22628 Filed 10–16–19; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Senior Executive Service Performance Review Board

AGENCY: Department of Energy.

ACTION: Designation of Performance Review Board Standing Register.

SUMMARY: This notice provides the Performance Review Board Standing Register for the Department of Energy. This listing supersedes all previously published lists of PRB members.

DATES: This appointment is effective as of September 30, 2019.

SUPPLEMENTARY INFORMATION:

Carter, Brian
Dehaven, Darrel
Isom, Pamela
Johnson Jr., Thomas
Kim, Dong
Kremer, Kevin
Lee, Terri
Lippold, David
Livengood, Joanna
Lushetsky, John
Marlay, Robert
Moore, Johnny
Moreno, Francisco
O'Konski, Peter
Rasar, Kimberly
Reilly, Thomas
Satyapal, Sunita
Srinivasan, Nanda
Tyner, Teresa
Welling, David Craig

Signed in Washington, DC, on October 2, 2019.

Erin S. Moore,

Director, Office of Corporate Executive Management, Office of the Chief Human Capital Officer.

[FR Doc. 2019–22680 Filed 10–16–19; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

International Energy Agency Meetings

AGENCY: Department of Energy.

ACTION: Notice of meetings.

SUMMARY: The Industry Advisory Board (IAB) to the International Energy Agency (IEA) will meet on October 22–23, 2019, at the IEA Headquarters, Room 1, 9 rue de la Fédération, 75015 Paris, France, in connection with a joint meeting of the IEA's Standing Group on Emergency Questions (SEQ) which is scheduled at the same time.

DATES: October 22–23, 2019.

ADDRESS: IEA Headquarters, Room 1, 9 rue de la Fédération, 75015 Paris, France.

FOR FURTHER INFORMATION CONTACT: Thomas Reilly, Assistant General Counsel for International and National Security Programs, Department of Energy, 1000 Independence Avenue SW, Washington, DC 20585, 202–586–5000.

SUPPLEMENTARY INFORMATION: In accordance with section 252(c)(1)(A)(i) of the Energy Policy and Conservation Act (42 U.S.C. 6272(c)(1)(A)(i)) (EPCA), the following notice of meetings is provided:

A meeting of the Industry Advisory Board (IAB) to the International Energy Agency (IEA) will be held at the IEA Headquarters, Room 1, 9 rue de la Fédération, 75015 Paris, France, commencing at 9:30 a.m. on October 22, 2019. The purpose of this notice is to permit attendance by representatives of U.S. company members of the IAB at a meeting of the IEA's Standing Group on Emergency Questions (SEQ), which is scheduled to be held at the same location and time. The IAB will also hold a preparatory meeting among company representatives at the same location at 8:30 a.m. on October 22, 2019. The agenda for this preparatory meeting is to review the agenda for the SEQ meeting.

The agenda of the meeting is under the control of the SEQ and the SOM. It is expected that the SEQ will adopt the following agenda:

Closed SEQ Session—IEA Member Countries Only

1. Adoption of the Agenda
2. Approval of the Summary Record of the 158th Meeting
3. Status of Compliance with IEP Agreement Stockholding Obligations
4. Update on the Ministerial Mandate
5. Update on Accession process of Lithuania

Open SEQ Session—open to Association Countries

6. Mid-term Review of Sweden
7. Gas Security 2019
8. Industry Advisory Board Update
9. Emergency Response Review—Luxembourg

10. Mid-term Review of Switzerland
11. Outreach
12. ERE 10 Notice
13. Oral Reports by Administrations
14. Any Other Business

Schedule of SEQ & SOM Meetings in 2020:

—24–26 March 2020
—23–25 June 2020
—17–19 November 2020

A meeting of the Industry Advisory Board (IAB) to the International Energy Agency (IEA) will be held at the International Energy Agency, 9 rue de la Fédération, 75015 Paris, France, on October 23, 2019, commencing at 09:30 a.m. The purpose of this notice is to permit attendance by representatives of U.S. company members of the IAB at a joint meeting of the IEA's Standing Group on Emergency Questions (SEQ) and the IEA's Standing Group on the Oil Market (SOM), which is scheduled to be held at the same location and time.

The agenda of the SEQ meeting is under the control of the SEQ. It is expected that the SEQ will adopt the following agenda:

Introduction
1. Adoption of the Agenda
2. Approval of Summary Record of 26 June 2019
3. Reports on Recent Oil Market and Policy Developments in IEA Countries
4. Update on the Current Oil Market Situation: followed by Q&A
5. Presentation: ''Perspective from the financial markets on recent oil price volatility'', followed by Q&A
6. Inter-active session on the International Maritime Organisation rules on bunker fuels—Part 1.
7. Inter-active session on the International Maritime Organisation rules on bunker fuels—Part 2.
8. TBD
9. Any Other Business

—Date of the next. SEQ/SOM meeting: 26 March 2020 (TBC). Location IEA, (Room 1)

Discussion of content of next SOM meeting

Close of meeting.

Concluding Remarks

As provided in section 252(c)(1)(A)(ii) of the Energy Policy and Conservation Act (42 U.S.C. 6272(c)(1)(A)(ii)), the meetings of the IAB are open to representatives of members of the IAB and their counsel; representatives of members of the IEA's Standing Group on Emergency Questions and the IEA's Standing Group on the Oil Markets; representatives of the Departments of Energy, Justice, and State, the Federal Trade Commission, the General Accounting Office, Committees of Congress, the IEA, and the European Commission; and invitees of the IAB, the SEQ, the SOM, or the IEA.

Signed in Washington, DC, October 10, 2019.

Thomas Reilly,

Assistant General Counsel for International and National Security Programs.

[FR Doc. 2019–22661 Filed 10–16–19; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Senior Executive Service Performance Review Board

AGENCY: Department of Energy.

ACTION: Designation of Performance Review Board Chair.

SUMMARY: This notice provides the Performance Review Board Chair designee for the Department of Energy. This listing supersedes all previously published lists of Performance Review Board Chair.

DATES: This appointment is effective as of September 30, 2019.

Dennis M. Miotla

Signed in Washington, DC, on October 2, 2019.

Erin S. Moore,

Director, Office of Corporate Executive Management, Office of the Chief Human Capital Officer.

[FR Doc. 2019–22662 Filed 10–16–19; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER19–2619–001.
Applicants: Midcontinent Independent System Operator, Inc.
Description: Tariff Amendment: 2019–10–10_Request for deferral of action on Fast AGC filing to be effective 12/31/9998.
Filed Date: 10/10/19.
Accession Number: 20191010–5021.
Comments Due: 5 p.m. ET 10/31/19.

Docket Numbers: ER20–66–000.
Applicants: PJM Interconnection, L.L.C.
Description: Tariff Cancellation: Notice of Cancellation of ISA/SA No. 3984; Queue No. R52A to be effective 11/11/2019.
Filed Date: 10/9/19.
Accession Number: 20191009–5168.
Comments Due: 5 p.m. ET 10/30/19.

Docket Numbers: ER20–67–000.
Applicants: Evergy Kansas Central, Inc.
Description: § 205(d) Rate Filing: Notice of Succession, Market Based Rate Tariff to be effective 12/9/2019.
Filed Date: 10/10/19.
Accession Number: 20191010–5000.
Comments Due: 5 p.m. ET 10/31/19.

Docket Numbers: ER20–68–000.
Applicants: Evergy Generating, Inc.
Description: § 205(d) Rate Filing: Notice of Succession, Purchase Power Agreement to be effective 12/9/2019.
Filed Date: 10/10/19.
Accession Number: 20191010–5001.
Comments Due: 5 p.m. ET 10/31/19.

Docket Numbers: ER20–69–000.
Applicants: Silver Lake Solar, LLC.
Description: Petition for Limited Waiver of Silver Lake Solar, LLC.
Filed Date: 10/9/19.
Accession Number: 20191009–5185.
Comments Due: 5 p.m. ET 10/23/19.

Docket Numbers: ER20–70–000.
Applicants: Alabama Power Company.
Description: § 205(d) Rate Filing: Charlton Solar Energy Center (Charlton Solar) LGIA Filing to be effective 9/26/2019.
Filed Date: 10/10/19.
Accession Number: 20191010–5038.
Comments Due: 5 p.m. ET 10/31/19.

Docket Numbers: ER20–71–000.
Applicants: Coachella Hills Wind, LLC.
Description: Baseline eTariff Filing: MBR Application to be effective 12/10/2019.
Filed Date: 10/10/19.
Accession Number: 20191010–5039.
Comments Due: 5 p.m. ET 10/31/19.

Docket Numbers: ER20–72–000.
Applicants: Coachella Wind Holdings, LLC.
Description: Baseline eTariff Filing: MBR Application to be effective 12/10/2019.
Filed Date: 10/10/19.
Accession Number: 20191010–5040.
Comments Due: 5 p.m. ET 10/31/19.

Docket Numbers: ER20–73–000.
Applicants: Midcontinent Independent System Operator, Inc.
Description: § 205(d) Rate Filing: 2019–10–11_Attachment L FTR Credit Filing to be effective 6/1/2020.
Filed Date: 10/10/19.
Accession Number: 20191010–5041.
Comments Due: 5 p.m. ET 10/31/19.

Docket Numbers: ER20–74–000.
Applicants: Desert Hot Springs, LLC.
Description: Baseline eTariff Filing: MBR Application to be effective 12/10/2019.

Filed Date: 10/10/19.
Accession Number: 20191010–5042.
Comments Due: 5 p.m. ET 10/31/19.
Docket Numbers: ER20–75–000.
Applicants: Oasis Alta, LLC.
Description: Baseline eTariff Filing: MBR Application to be effective 12/10/2019.
Filed Date: 10/10/19.
Accession Number: 20191010–5043.
Comments Due: 5 p.m. ET 10/31/19.
Docket Numbers: ER20–76–000.
Applicants: Oasis Plains Wind, LLC.
Description: Baseline eTariff Filing: MBR Application to be effective 12/10/2019.
Filed Date: 10/10/19.
Accession Number: 20191010–5044.
Comments Due: 5 p.m. ET 10/31/19.
Docket Numbers: ER20–77–000.
Applicants: Painted Hills Wind Holdings, LLC.
Description: Baseline eTariff Filing: MBR Application to be effective 12/10/2019.
Filed Date: 10/10/19.
Accession Number: 20191010–5046.
Comments Due: 5 p.m. ET 10/31/19.
Docket Numbers: ER20–78–000.
Applicants: San Jacinto Wind II, LLC.
Description: Baseline eTariff Filing: MBR Application to be effective 12/10/2019.
Filed Date: 10/10/19.
Accession Number: 20191010–5047.
Comments Due: 5 p.m. ET 10/31/19.
Docket Numbers: ER20–79–000.
Applicants: Voyager Wind IV Expansion, LLC.
Description: Baseline eTariff Filing: MBR Application to be effective 12/10/2019.
Filed Date: 10/10/19.
Accession Number: 20191010–5048.
Comments Due: 5 p.m. ET 10/31/19.
Docket Numbers: ER20–80–000.
Applicants: Meadow Lake Wind Farm VI LLC,
Description: Baseline eTariff Filing: Reactive Power Compensation Filing to be effective 12/9/2019.
Filed Date: 10/10/19.
Accession Number: 20191010–5064.
Comments Due: 5 p.m. ET 10/31/19.
Docket Numbers: ER20–81–000.
Applicants: Midcontinent Independent System Operator, Inc.
Description: § 205(d) Rate Filing: 2019–10–10_SA 2527 ITC-Consumers Energy 4th Rev GIA (J161 J752) to be effective 9/25/2019.
Filed Date: 10/10/19.
Accession Number: 20191010–5084.
Comments Due: 5 p.m. ET 10/31/19.
Docket Numbers: ER20–82–000.
Applicants: PacifiCorp.
Description: § 205(d) Rate Filing: 3 Phases Renewables (OR D.A.) Rev 2 to be effective 10/1/2019.
Filed Date: 10/10/19.
Accession Number: 20191010–5103.
Comments Due: 5 p.m. ET 10/31/19.

The filings are accessible in the Commission's eLibrary system by clicking on the links or 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: October 10, 2019.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2019–22663 Filed 10–16–19; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER20–64–000]

PGR Lessee L, LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of PGR Lessee L, LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is October 30, 2019.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 5 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426.

The filings in the above-referenced proceeding are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for electronic review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the website that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov.* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: October 10, 2019.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2019–22678 Filed 10–16–19; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER20–65–000]

TWE Bowman Solar Project, LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of TWE Bowman Solar Project, LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426,

in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is October 30, 2019.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 5 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426.

The filings in the above-referenced proceeding are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for electronic review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the website that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov.* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: October 10, 2019.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2019–22675 Filed 10–16–19; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP19–514–000]

Corpus Christi Liquefaction, LLC; Notice of Application To Amend

Take notice that on September 27, 2019, Corpus Christi Liquefaction, LLC (CCL), 700 Milam Street, Suite 1900, Houston, Texas 77002, filed in Docket No. CP19–514–000 an application pursuant to section 3 of the Natural Gas Act (NGA) requesting authorization to increase the total liquefied natural gas (LNG) production capacity of the Liquefaction Project from the currently authorized 767 billion cubic feet per year (Bcf/y) to 875.16 Bcf/y, which represents an increase of 108.16 Bcf/y, in Nueces County, Texas. CCL states that the increase is based on certain enhancements during the engineering, design, and construction process, as well as operational experience to date. CCL states that these enhancements do not involve additional construction of new facilities nor do they require additional LNG vessel transits beyond those already authorized, all as more fully set forth in the application which is on file with the Commission and open to public inspection.

The filing may also be viewed on the web 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. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov* or toll free at (866) 208–3676, or TTY, contact (202) 502–8659.

Any questions regarding the application should be directed to Karri Mahmoud, Cheniere Energy, Inc., 700 Milam Street, Suite 1900, Houston, Texas 77002, (713) 375–5000, *Karri.Mahmoud@cheniere.com;* or Lisa M. Tonery, Orrick, Herrington & Sutcliffe LLP, 51 West 52nd Street, New York, New York 10019–6142, (212) 506–3710, *ltonery@orrick.com.*

Pursuant to section 157.9 of the Commission's rules (18 CFR 157.9), within 90 days of this Notice, the Commission staff will either: Complete its environmental assessment (EA) 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 EA for this proposal. The filing of the EA in the Commission's public record for this proceeding or the issuance of a Notice of Schedule 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.

There are two ways to become involved in the Commission's review of this project. First, any person wishing to obtain legal status by becoming a party to the proceedings for this project should, on or before the comment date stated below, file with the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, a motion to intervene in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.214 or 385.211) and the Regulations under the NGA (18 CFR 157.10). A person obtaining party status will be placed on the service list maintained by the Secretary of the Commission and will receive copies of all documents filed by the applicant and by all other parties. A party must submit five copies of filings made with the Commission and must mail a copy to the applicant and to every other party in the proceeding. Only parties to the proceeding can ask for court review of Commission orders in the proceeding.

However, a person does not have to intervene in order to have comments considered. The second way to participate is by filing with the Secretary of the Commission, as soon as possible, an original and two copies of comments in support of or in opposition to this project. The Commission will consider these comments in determining the appropriate action to be taken, but the filing of a comment alone will not serve to make the filer a party to the proceeding. The Commission's rules require that persons filing comments in opposition to the project provide copies of their protests only to the party or parties directly involved in the protest.

Persons who wish to comment only on the environmental review of this project should submit an original and two copies of their comments to the Secretary of the Commission. Environmental commenters will be placed on the Commission's environmental mailing list, will receive copies of the environmental documents, and will be notified of meetings associated with the Commission's environmental review process. Environmental commenters will not be required to serve copies of filed documents on all other parties. However, the non-party commenters will not receive copies of all documents filed by other parties or issued by the Commission (except for the mailing of environmental documents issued by the Commission) and will not have the right to seek court review of the Commission's final order.

As of the February 27, 2018 date of the Commission's order in Docket No. CP16–4–001, the Commission will apply its revised practice concerning out-of-time motions to intervene in any

new NGA section 3 or section 7 proceeding.[1] Persons desiring to become a party to a certificate proceeding are to intervene in a timely manner. If seeking to intervene out-of-time, the movant is required to show good cause why the time limitation should be waived, and should provide justification by reference to factors set forth in Rule 214(d)(1) of the Commission's Rules and Regulations.[2]

The Commission strongly encourages electronic filings of comments, protests and interventions in lieu of paper using the eFiling link at *http://www.ferc.gov.* Persons unable to file electronically should submit original and five copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426.

Comment Date: 5:00 p.m. Eastern Time on October 31, 2019.

Dated: October 10, 2019.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2019–22677 Filed 10–16–19; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP20–2–000]

National Fuel Gas Supply Corporation; Notice of Application To Amend

Take notice that on October 2, 2019, National Fuel Gas Supply Corporation (National Fuel), 6363 Main Street, Williamsville, New York 14221, filed in Docket No. CP20–2–000 an application pursuant to sections 7(b) and 7(c) of the Natural Gas Act (NGA) for authorization to amend its certificate of public convenience and necessity issued by Commission order on September 6, 2017 (Certificate Order) in Docket No. CP16–28–000, all as more fully set forth in the application which is on file with the Commission and open to public inspection. The 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. For assistance, contact FERC at *FERCOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TYY, (202) 502–8659.

Specifically, National Fuel requests authorization to amend the Certificate Order and to vacate certain authorizations in that order. National Fuel seeks to now abandon by sale to Catalyst Energy, Inc. its Queen Storage Field and Queen Compressor Station, located in Forest and Warren Counties, Pennsylvania. National Fuel also seeks to vacate certain authorizations in the Certificate Order to reflect that it will no longer sell a portion of Line Q, abandon the remaining portion of Line Q, and it will no longer proceed with construction and operation of the Line QP.

Any questions regarding the amendment should be directed to Alice A. Curtiss, Deputy General Counsel, National Fuel Gas Supply Corporation, 6363 Main Street, Williamsville, New York 14221 at (716) 857–7075, or at *curtissa@natfuel.com.*

Pursuant to section 157.9 of the Commission's rules (18 CFR 157.9), within 90 days of this Notice, the Commission staff will 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 environmental assessment (EA) for this proposal. 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 EA.

There are two ways to become involved in the Commission's review of this project. First, any person wishing to obtain legal status by becoming a party to the proceedings for this project should, on or before the comment date stated below file with the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, a motion to intervene in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.214 or 385.211) and the Regulations under the NGA (18 CFR 157.10). A person obtaining party status will be placed on the service list maintained by the Secretary of the Commission and will receive copies of all documents filed by the applicant and by all other parties. A party must submit seven copies of filings made in the proceeding with the Commission and must mail a copy to the applicant and to every other party. Only parties to the proceeding can ask for court review of Commission orders in the proceeding.

However, a person does not have to intervene in order to have comments considered. The second way to participate is by filing with the Secretary of the Commission, as soon as possible, an original and two copies of comments in support of or in opposition to this project. The Commission will consider these comments in determining the appropriate action to be taken, but the filing of a comment alone will not serve to make the filer a party to the proceeding. The Commission's rules require that persons filing comments in opposition to the project provide copies of their protests only to the party or parties directly involved in the protest.

Persons who wish to comment only on the environmental review of this project should submit an original and two copies of their comments to the Secretary of the Commission. Environmental commentors will be placed on the Commission's environmental mailing list, will receive copies of the environmental documents, and will be notified of meetings associated with the Commission's environmental review process. Environmental commentors will not be required to serve copies of filed documents on all other parties. However, the non-party commentors will not receive copies of all documents filed by other parties or issued by the Commission (except for the mailing of environmental documents issued by the Commission) and will not have the right to seek court review of the Commission's final order.

As of the February 27, 2018 date of the Commission's order in Docket No. CP16–4–001, the Commission will apply its revised practice concerning out-of-time motions to intervene in any new NGA section 3 or section 7 proceeding.[1] Persons desiring to become a party to a certificate proceeding are to intervene in a timely manner. If seeking to intervene out-of-time, the movant is required to show good cause why the time limitation should be waived, and should provide justification by reference to factors set forth in Rule 214(d)(1) of the Commission's Rules and Regulations.[2]

The Commission strongly encourages electronic filings of comments, protests and interventions in lieu of paper using the eFiling link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and three copies of the protest or intervention to the Federal Energy regulatory Commission, 888 First Street NE, Washington, DC 20426.

[1] *Tennessee Gas Pipeline Company, L.L.C.,* 162 FERC 61,167 at 50 (2018).

[2] 18 CFR 385.214(d)(1).

[1] *Tennessee Gas Pipeline Company, L.L.C.,* 162 FERC 61,167 at 50 (2018).

[2] 18 CFR 385.214(d)(1).

Comment Date: 5:00 p.m. Eastern Time on October 31, 2019.

Dated: October 10, 2019.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2019–22679 Filed 10–16–19; 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 Pipeline Rate and Refund Report filings:

Filings Instituting Proceedings

Docket Numbers: RP20–52–000.
Applicants: Iroquois Gas Transmission System, L.P.
Description: § 4(d) Rate Filing: 100919 Negotiated Rates—Castleton Commodities Merchant Trading R–4010–10 to be effective 11/1/2019.
Filed Date: 10/9/19.
Accession Number: 20191009–5044.
Comments Due: 5 p.m. ET 10/21/19.

Docket Numbers: RP20–53–000.
Applicants: Iroquois Gas Transmission System, L.P.
Description: § 4(d) Rate Filing: 100919 Negotiated Rates—Castleton Commodities Merchant Trading R–4010–11 to be effective 11/1/2019.
Filed Date: 10/9/19.
Accession Number: 20191009–5045.
Comments Due: 5 p.m. ET 10/21/19.

Docket Numbers: RP20–54–000.
Applicants: Iroquois Gas Transmission System, L.P.
Description: § 4(d) Rate Filing: 100919 Negotiated Rates—Equinor Natural Gas LLC R–7120–11 to be effective 11/1/2019.
Filed Date: 10/9/19.
Accession Number: 20191009–5046.
Comments Due: 5 p.m. ET 10/21/19.

Docket Numbers: RP20–55–000.
Applicants: Iroquois Gas Transmission System, L.P.
Description: § 4(d) Rate Filing: 100919 Negotiated Rates—Equinor Natural Gas LLC R–7120–12 to be effective 11/1/2019.
Filed Date: 10/9/19.
Accession Number: 20191009–5047.
Comments Due: 5 p.m. ET 10/21/19.

Docket Numbers: RP20–56–000.
Applicants: Iroquois Gas Transmission System, L.P.
Description: § 4(d) Rate Filing: 100919 Negotiated Rates—Equinor Natural Gas LLC R–7120–13 to be effective 11/1/2019.
Filed Date: 10/9/19.
Accession Number: 20191009–5048.
Comments Due: 5 p.m. ET 10/21/19.

Docket Numbers: RP20–57–000.
Applicants: Iroquois Gas Transmission System, L.P.
Description: § 4(d) Rate Filing: 100919 Negotiated Rates—Equinor Natural Gas LLC R–7120–14 to be effective 11/1/2019.
Filed Date: 10/9/19.
Accession Number: 20191009–5049.
Comments Due: 5 p.m. ET 10/21/19.

Docket Numbers: RP20–58–000.
Applicants: Colorado Interstate Gas Company, L.L.C.
Description: § 4(d) Rate Filing: Non Conforming TSA Filing—Southwest Energy to Rocky Mtn Midstream to be effective 10/1/2019.
Filed Date: 10/9/19.
Accession Number: 20191009–5138.
Comments Due: 5 p.m. ET 10/21/19.

The filings are accessible in the Commission's eLibrary system by clicking on the links or 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: October 10, 2019.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2019–22670 Filed 10–16–19; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2413–124]

Georgia Power Company; Notice of Availability of Environmental Assessment

In accordance with the National Environmental Policy Act of 1969 and the Federal Energy Regulatory Commission's (Commission) regulations, 18 CFR part 380, the Office of Energy Projects has reviewed the application for license for the Wallace Dam Pumped Storage Project, and has prepared an Environmental Assessment (EA) for the project. The project is located on the Oconee River, in Hancock, Putnam, Greene, and Morgan Counties, Georgia, and it occupies 493.7 acres of federal land administered by the U.S. Forest Service.

The EA contains Commission staff's analysis of the potential environmental effects of the project. The EA concludes that licensing the project, with appropriate environmental protective measures, would not constitute a major federal action that would significantly affect the quality of the human environment.

A copy of the EA is available for review at the Commission in the Public Reference Room, or 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. For assistance, contact FERC Online Support at *FERCOnlineSupport@ferc.gov,* (866) 208–3676 (toll free), or 202–502–8659 (TTY).

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, contact FERC Online Support.

Any comments should be filed within 30 days from the date of this notice.

The Commission strongly encourages electronic filing. Please file comments 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. In lieu of electronic filing, please send a paper copy to: Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. The first page of any filing should include docket number P–2413–124.

For further information, contact Allan Creamer at 202–502–8365, or by email at *allan.creamer@ferc.gov.*

Dated: October 10, 2019.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2019–22674 Filed 10–16–19; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–10001–22–OAR]

Acid Rain Program: Excess Emissions Penalty Inflation Adjustments

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of annual adjustment factors.

SUMMARY: The Acid Rain Program requires sources that do not meet their annual Acid Rain emissions limitations for sulfur dioxide (SO_2) or nitrogen oxides (NO_X) to pay inflation-adjusted excess emissions penalties. This document provides notice of the annual adjustment factors used to calculate excess emissions penalties for compliance years 2019 and 2020.

FOR FURTHER INFORMATION CONTACT: Jason Kuhns at (202) 564–3236 or *kuhns.jason@epa.gov.*

SUPPLEMENTARY INFORMATION: The Acid Rain Program limits SO_2 and NO_X emissions from fossil fuel-fired electricity generating units. All affected sources must hold allowances sufficient to cover their annual SO_2 mass emissions, and certain coal-fired units must meet annual average NO_X emission rate limits. Under 40 CFR 77.6, any source that does not meet these requirements must pay an excess emissions penalty without demand to the EPA Administrator. The automatic penalty is computed as the number of excess tons of SO_2 or NO_X emitted times a per-ton penalty amount of $2,000 times an annual adjustment factor, which must be published in the **Federal Register**.

The annual adjustment factor used to compute excess emissions penalties for compliance year 2019 is 2.0236, resulting in an automatic penalty amount of $4,047 per excess ton of SO_2 or NO_X emitted in 2019. In accordance with 40 CFR 77.6(b) and 72.2, this annual adjustment factor is determined from values of the Consumer Price Index for All Urban Consumers (CPI–U) for August 1989 and August 2018.

The annual adjustment factor used to compute excess emissions penalties for compliance year 2020 is 2.0591, resulting in an automatic penalty amount of $4,118 per excess ton of SO_2 or NO_X emitted in 2020. This annual adjustment factor is determined from values of the CPI–U for August 1989 and August 2019.

Dated: September 25, 2019.

Reid P. Harvey,

Director, Clean Air Markets Division, Office of Atmospheric Programs, Office of Air and Radiation.

[FR Doc. 2019–22696 Filed 10–16–19; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL DEPOSIT INSURANCE CORPORATION

Sunshine Act Meetings

TIME AND DATE: Pursuant to the provisions of the ''Government in the Sunshine Act'' (5 U.S.C. 552b), notice is hereby given that at 10:43 p.m. on Tuesday, October 15, 2019, the Board of Directors of the Federal Deposit Insurance Corporation met in closed session to consider matters related to the Corporation's supervision, corporate, and resolution activities.

PLACE: The meeting was held in the Board Room located on the sixth floor of the FDIC Building located at 550 17th Street NW, Washington, DC.

STATUS: The meeting was closed to the public.

MATTERS TO BE CONSIDERED: In calling the meeting, the Board determined, on motion of Director Martin J. Gruenberg, seconded by Kathleen L. Kraninger (Director, Consumer Financial Protection Bureau), and concurred in by Director Joseph M. Otting (Comptroller of the Currency) and Chairman Jelena McWilliams, that Corporation business required its consideration of the matters which were to be the subject of this meeting on less than seven days' notice to the public; that no earlier notice of the meeting was practicable; that the public interest did not require consideration of the matters in a meeting open to public observation; and that the matters could be considered in a closed meeting by authority of subsections (c)(4), (c)(6), (c)(8), (c)(9)(A)(ii), and (c)(9)(B) of the ''Government in the Sunshine Act'' (5 U.S.C. 552b(c)(4), (c)(6), (c)(8), (c)(9)(A)(ii), and (c)(9)(B).

CONTACT PERSON FOR MORE INFORMATION: Requests for further information concerning the meeting may be directed to Robert E. Feldman, Executive Secretary of the Corporation, at 202–898–7043.

Dated at Washington, DC, on October 15, 2019.

Federal Deposit Insurance Corporation.

Robert E. Feldman,

Executive Secretary.

[FR Doc. 2019–22775 Filed 10–15–19; 4:15 pm]

BILLING CODE 6714–01–P

FEDERAL ELECTION COMMISSION

Sunshine Act Meetings

TIME AND DATE: Tuesday, October 22, 2019 at 10:00 a.m.

PLACE: 1050 First Street NE, Washington, DC.

STATUS: This meeting will be closed to the public.

MATTERS TO BE CONSIDERED: Matters concerning participation in civil actions or proceedings or arbitration.

CONTACT PERSON FOR MORE INFORMATION: Judith Ingram, Press Officer, Telephone: (202) 694–1220.

Vicktoria J. Allen,

Acting Deputy Secretary of the Commission.

[FR Doc. 2019–22811 Filed 10–15–19; 4:15 pm]

BILLING CODE 6715–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–3263]

Request for Nominations for Voting Members on the Tobacco Products Scientific Advisory Committee

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is requesting nominations for members to serve on the Tobacco Products Scientific Advisory Committee, in the Center for Tobacco Products. FDA seeks to include the views of women and men, members of all racial and ethnic groups, and individuals with and without disabilities on its advisory committees and, therefore, encourages nominations of appropriately qualified candidates from these groups.

DATES: Nominations received on or before December 16, 2019 will be given first consideration for membership on the Tobacco Products Scientific Advisory Committee. Nominations received after December 16, 2019 will be considered for nomination to the committee as later vacancies occur.

ADDRESSES: All nominations for membership should be sent electronically by logging into the FDA Advisory Nomination Portal: *https://www.accessdata.fda.gov/scripts/FACTRSPortal/FACTRS/index.cfm,* or by mail to Advisory Committee Oversight and Management Staff, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5103, Silver Spring, MD 20993–0002.

FOR FURTHER INFORMATION CONTACT: *Regarding all nomination questions for membership, the primary contact is:* Janice O'Connor, Office of Science, Center for Tobacco Products, Food and Drug Administration, Document Control Center, 10903 New Hampshire Ave., Bldg. 71, Rm. G335, Silver Spring, MD 20993–0002, 1–877–287–1373 (choose Option 5), email: *TPSAC@fda.hhs.gov.*

Information about becoming a member on an FDA advisory committee can also be obtained by visiting FDA's website at: *http://www.fda.gov/AdvisoryCommittees/default.htm.*

SUPPLEMENTARY INFORMATION: FDA is requesting nomination for voting members on the Tobacco Products Scientific Advisory Committee.

I. General Description of the Committee Duties

The Tobacco Products Scientific Advisory Committee advises the Commissioner of Food and Drugs (the Commissioner) or designee in discharging responsibilities related to the regulation of tobacco products. The committee reviews and evaluates safety, dependence, or health issues relating to tobacco products and provides appropriate advice, information, and recommendations to the Commissioner.

II. Criteria for Voting Members

The committee consists of 12 members including the Chair. Members and the Chair are selected by the Commissioner or designee from among individuals knowledgeable in the fields of medicine, medical ethics, science, or technology involving the manufacture, evaluation, or use of tobacco products. Almost all non-Federal members of this committee serve as Special Government Employees. The committee includes nine technically qualified voting members, selected by the Commissioner or designee. The nine voting members include seven members who are physicians, dentists, scientists, or healthcare professionals practicing in the areas of oncology, pulmonology, cardiology, toxicology, pharmacology, addiction, or any other relevant specialty. The nine voting members also include one member who is an officer or employee of a State or local government or of the Federal Government, and one member who is a representative of the general public. Members will be invited to serve for terms of up to 4 years.

III. Nomination Procedures

Any interested person may nominate one or more qualified individuals for membership on the advisory committee. Self-nominations are also accepted. Nominations must include a current, complete résumé or curriculum vitae for each nominee, including current business address and/or home address, telephone number, and email address if available. Nominations must also specify the advisory committee for which the nominee is recommended. Nominations must also acknowledge that the nominee is aware of the nomination unless self-nominated. FDA will ask potential candidates to provide detailed information concerning such matters related to financial holdings, employment, and research grants and/or contracts to permit evaluation of possible sources of conflicts of interest.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to advisory committees.

Dated: October 10, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–22685 Filed 10–16–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–3263]

Request for Nominations of a Nonvoting Representative of the Interest of the Tobacco Manufacturing Industry on the Tobacco Products Scientific Advisory Committee

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is requesting nominations for a nonvoting representative of the interests of the tobacco manufacturing industry to serve on the Tobacco Products Scientific Advisory Committee (TPSAC), in the Center for Tobacco Products. FDA seeks to include the views of women and men, members of all racial and ethnic groups, and individuals with and without disabilities on its advisory committees and, therefore encourages nominations of appropriately qualified candidates from these groups. A nominee may either be self-nominated or nominated by an organization.

In addition, FDA is requesting that any industry organizations interested in participating in the selection of a nonvoting representative of the interests of the tobacco manufacturing industry to serve on the TPSAC notify FDA in writing. Nominations will be accepted for either the representative to serve on TPSAC or for the selection group effective with this notice.

DATES: Nomination materials for prospective candidates should be sent to FDA by November 18, 2019. Concurrently, any industry organization interested in participating in the selection of an appropriate nonvoting member to represent the interests of the tobacco manufacturing industry must send a letter stating that interest to FDA by November 18, 2019, (see sections I and II of this document for further details).

ADDRESSES: All nominations for nonvoting representatives of the interests of the tobacco manufacturing industry may be submitted electronically by accessing the FDA Advisory Committee Membership Nomination Portal at: *https://www.accessdata.fda.gov/scripts/FACTRSPortal/FACTRS/index.cfm,* or by mail to Advisory Committee Oversight and Management Staff, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5103, Silver Spring, MD 20993–0002.

All statements of interest from industry organizations interested in participating in the selection process of nonvoting representatives of the interests of the tobacco manufacturing industry nomination should be sent to Janice O'Connor (see **FOR FURTHER INFORMATION CONTACT**).

FOR FURTHER INFORMATION CONTACT: Janice O'Connor, Office of Science, Center for Tobacco Products, Food and Drug Administration, Document Control Center, 10903 New Hampshire Ave., Bldg. 71, Rm. G335, Silver Spring, MD 20993–0002, 1–877–287–1373 (choose Option 5), email: *TPSAC@fda.hhs.gov.*

Information about becoming a member of an FDA advisory committee can also be obtained by visiting FDA's website at: *http://www.fda.gov/AdvisoryCommittees/default.htm.*

SUPPLEMENTARY INFORMATION: FDA is requesting nominations for a nonvoting representative of the interests of the tobacco manufacturing industry on the Tobacco Products Scientific Advisory Committee (TPSAC).

I. General Description of the Committee Duties

The TPSAC advises the Commissioner of Food and Drugs (the Commissioner) or designee in discharging responsibilities related to the regulation of tobacco products. The TPSAC reviews and evaluates safety, dependence, or health issues relating to tobacco products and provides

appropriate advice, information, and recommendations to the Commissioner.

II. Nomination Procedure

Individuals may self-nominate and/or an organization may nominate one or more individuals to serve as a nonvoting representative of the interests of the tobacco manufacturing industry. Nominations must include a current résumé or curriculum vitae for each nominee, including current business address and/or home address, telephone number, and email address, if available. Nominations must specify the advisory committee for which the nominee is recommended. Nominations must also acknowledge that the nominee is aware of the nomination unless self-nominated. The nomination should be sent to the FDA Advisory Committee Membership Nomination Portal (see **ADDRESSES**) within 30 days of publication of this document (see **DATES**). FDA will forward all nominations to the organizations expressing interest in participating in the selection process. (Persons who nominate themselves as nonvoting industry representatives will not participate in the selection process.)

III. Selection Procedure

The Agency is also seeking names of organizations to participate in the selection of the nonvoting representative of the interests of the tobacco manufacturing industry. Any industry organization interested in participating in the selection of an appropriate nonvoting member to represent industry interests should send a letter stating that interest to the FDA contact (see **FOR FURTHER INFORMATION CONTACT**) within 30 days of publication of this document (see **DATES**). Within the subsequent 30 days, FDA will send a letter to each organization that has expressed an interest in participating in the selection group, attaching a complete list of all organizations participating in selection; and a list of all non-voting nominees along with their current résumés. The letter will also state that it is the responsibility of the interested organizations on the selection group to confer with one another and to select a candidate and an alternative as backup, within 60 days after the receipt of the FDA letter, to serve as the nonvoting member to represent industry interests for the TPSAC. The interested organizations are not bound by the list of nominees in selecting a candidate. However, if no individual is selected within 60 days, the Commissioner will select the nonvoting member to represent industry interests.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to advisory committees.

Dated: October 10, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–22683 Filed 10–16–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0108]

Prescription Drug User Fee Act Waivers, Reductions, and Refunds for Drug and Biological Products; Guidance for Industry; 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 final guidance for industry entitled ''Prescription Drug User Fee Act Waivers, Reductions, and Refunds for Drug and Biological Products.'' This guidance provides recommendations to applicants planning to request a waiver or reduction in user fees. This guidance finalizes the draft guidance for industry of the same title issued in June 2018.

DATES: The announcement of the guidance is published in the **Federal Register** on October 17, 2019.

ADDRESSES: You may submit submit either electronic or written comments on Agency guidances 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–2011–D–0108 for ''Prescription Drug User Fee Act Waivers, Reductions, and Refunds for Drug and Biological Products.'' 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.

- 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.gpo.gov/fdsys/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.

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 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; or to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist the office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Keith Verrett, Division of User Fee Management and Budget Formulation, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Bldg., Rm. 2179, Silver Spring, MD 20993, 301–796–7900, *CDERCollections@fda.hhs.gov;* or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave. Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Prescription Drug User Fee Act Waivers, Reductions, and Refunds for Drug and Biological Products.'' This guidance provides recommendations to applicants regarding requests for waivers, reductions, or refunds of user fees assessed under sections 735 and 736 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 379g and 379h). This guidance describes the types of waivers, reductions, and refunds permitted under the user fee provisions of the FD&C Act and the procedures for submitting requests for waivers, reductions, refunds, as well as requests for reconsiderations or appeals. The guidance also provides additional clarification on certain issues such as user fee exemptions for orphan drugs and FDA's current thinking on considerations relevant to eligibility for user fee waivers, reductions, and refunds under the applicable statutory provisions.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Prescription Drug User Fee Act Waivers, Reductions, and Refunds for Drug and Biological Products.'' 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.

This guidance is not subject to Executive Order 12866.

II. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collection of information of this guidance has been approved under OMB control number 0910–0693. The collection of information associated with Form FDA 3397 has been approved under OMB control number 0910–0297. The collections of information associated with new drug applications or biologics license applications have been approved under OMB control numbers 0910–0001 and 0910–0338, respectively. See section X of the guidance document.

III. Electronic Access

Persons with access to the internet may obtain the guidance at either *https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances, https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs,* or *https://www.regulations.gov.*

Dated: October 10, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–22690 Filed 10–16–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Meeting of the Council on Graduate Medical Education

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: In accordance with the Federal Advisory Committee Act, this notice announces that the Council on Graduate Medical Education (COGME or Council) will hold public meetings for the 2020 calendar year (CY). Information about COGME, agendas, and materials for these meetings can be found on the COGME website at *https://www.hrsa.gov/advisory-committees/graduate-medical-edu/index.html.*

DATES: April 28–29, 2020, 8:30 a.m.–5:00 p.m. Eastern Time (ET) and 8:30 a.m.–2:00 p.m. ET; July 17, 2020, 10:00 a.m.–5:00 p.m. ET; December 8–9, 2020, 8:30 a.m.–5:00 p.m. ET and 8:30 a.m.–2:00 p.m.

ADDRESSES: The meetings scheduled on April 28–29, 2020, and December 8–9, 2020, will be held in-person at 5600 Fishers Lane, Room 5E29, Rockville, Maryland 20857. The meeting scheduled on July 17, 2020, will be held by teleconference/Adobe Connect webinar. Instructions for joining the meetings either in person or remotely will be posted on the COGME website 30 business days before the date of the meeting. For meeting information updates, go to the COGME website meeting page at *https://www.hrsa.gov/advisory-committees/graduate-medical-edu/meetings/index.html.*

FOR FURTHER INFORMATION CONTACT: Kennita Carter, MD, Senior Advisor and Designated Federal Official (DFO), Division of Medicine and Dentistry, Bureau of Health Workforce (BHW), HRSA, 5600 Fishers Lane, 15N116, Rockville, Maryland 20857; 301–945–9505; or *BHWCOGME@hrsa.gov.*

SUPPLEMENTARY INFORMATION: COGME makes recommendations to the Secretary of HHS (Secretary) and Congress on policy, program development, and other matters of significance as specified by section 762 of Title VII of the Public Health Service (PHS) Act. Issues addressed by COGME include the supply and distribution of the physician workforce in the United States, including any projected shortages or excesses; foreign medical school graduates; the nature and financing of undergraduate and graduate

medical education; appropriation levels for certain programs under Title VII of the PHS Act and deficiencies in databases of the supply and distribution of the physician workforce and postgraduate programs for training physicians. COGME submits reports to the Secretary of HHS, the Senate Committee on Health, Education, Labor and Pensions, and the House of Representatives Committee on Energy and Commerce. Additionally, COGME encourages entities providing graduate medical education to conduct activities to voluntarily achieve the recommendations of the Council.

Agenda items are subject to change as priorities dictate. During the CY 2020 COGME meetings, COGME will discuss topics surrounding the rural health workforce. Refer to the COGME website listed above for all current and updated information concerning the CY 2020 COGME meetings, including draft agendas and meeting materials that will be posted before the meeting. An agenda will be posted on the website at least 14 calendar days before the meeting.

Members of the public will have the opportunity to provide comments. Public participants may submit written statements in advance of the scheduled meetings. Oral comments will be honored in the order they are requested and may be limited as time allows. Requests to submit a written statement or make oral comments to the COGME should be sent to Kennita Carter using the contact information above at least 5 business days before the meeting dates.

Individuals who need special assistance or another reasonable accommodation should notify Dr. Kennita Carter using the contact information listed above at least 10 business days before the meeting they wish to attend. Since all in person meetings occur in a federal government building, attendees must go through a security check to enter the building. Non-U.S. Citizen attendees must notify HRSA of their planned attendance at least 20 business days prior to the meeting in order to facilitate their entry into the building. All attendees are required to present government-issued identification prior to entry.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2019–22649 Filed 10–16–19; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Meeting of the Advisory Committee on Training and Primary Care Medicine and Dentistry

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: In accordance with the Federal Advisory Committee Act, this notice announces that the Advisory Committee on Training and Primary Care Medicine and Dentistry (ACTPCMD) will hold public meetings for the 2020 calendar year (CY). Information about ACTPCMD, agendas, and materials for these meetings can be found on the ACTPCMD website at *https://www.hrsa.gov/advisory-committees/primarycare-dentist/index.html.*

DATES: January 8–9, 2020, 8:30 a.m.–5:00 p.m. Eastern Time (ET) and 8:30 a.m.–2:00 p.m. ET; and August 4, 2020, 10:00 a.m.–5:00 p.m. ET.

ADDRESSES: The meeting scheduled on January 8–9, 2020, will be held in-person at 5600 Fishers Lane, Room 5E29, Rockville, Maryland 20857. The meeting scheduled on August 4, 2020, will be held by teleconference/Adobe Connect webinar. Instructions for joining the meetings either in person or remotely will be posted on the ACTPCMD website 30 business days before the date of the meeting. For meeting information updates, go to the ACTPCMD website meeting page at *https://www.hrsa.gov/advisory-committees/primarycare-dentist/meetings.html.*

FOR FURTHER INFORMATION CONTACT: Kennita Carter, MD, Designated Federal Official (DFO) Division of Medicine and Dentistry, Bureau of Health Workforce (BHW), HRSA, 5600 Fishers Lane, 15N116, Rockville, Maryland 20857; 301–945–9505; or *BHWACTPCMD@hrsa.gov.*

SUPPLEMENTARY INFORMATION: ACTPCMD provides advice and recommendations to the Secretary of HHS (Secretary) on policy, program development, and other matters of significance concerning the activities under Section 747 of Title VII of the Public Health Service (PHS) Act, as it existed upon the enactment of Section 749 of the PHS Act in 1998. ACTPCMD prepares an annual report describing the activities of the committee, including findings and recommendations made by the committee concerning the activities under Section 747, as well as training programs in oral health and dentistry. The annual report is submitted to the Secretary as well as the Chairman and ranking members of the Senate Committee on Health, Education, Labor and Pensions and the House of Representatives Committee on Energy and Commerce. ACTPCMD develops, publishes, and implements performance measures and guidelines for longitudinal evaluations of programs authorized under Title VII, Part C of the PHS Act, and recommends appropriation levels for programs under this Part.

During ACTPCMD's CY 2020 meetings, the committee will discuss matters concerning policy, program development, and other matters of significance concerning medicine and dentistry activities. Agenda items are subject to change as priorities dictate. Refer to the ACTPCMD website listed above for all current and updated information concerning the CY 2020 meetings, including draft agendas and meeting materials that will be posted before the meeting. An agenda will be posted on the website at least 14 calendar days before each meeting.

Members of the public will have the opportunity to provide comments. Public participants may submit written statements in advance of the scheduled meetings. Oral comments will be honored in the order they are requested and may be limited as time allows. Requests to submit a written statement or make oral comments to the ACTPCMD should be sent to Kennita Carter using the contact information above at least 5 business days before the meeting dates.

Individuals who need special assistance or another reasonable accommodation should notify Kennita Carter using the contact information listed above at least 10 business days before the meeting they wish to attend. Since all in-person meetings occur in a federal government building, attendees must go through a security check to enter the building. Non-U.S. Citizen attendees must notify HRSA of their planned attendance at least 20 business days prior to the meeting in order to facilitate their entry into the building. All attendees are required to present government-issued identification prior to entry.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2019–22650 Filed 10–16–19; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: Evaluation of the Maternal and Child Health Bureau Pediatric Mental Health Care Access (PMHCA) Program and the Maternal and Child Health Bureau Screening and Treatment for Maternal Depression and Related Behavioral Disorders Program, OMB No. 0906–xxxx, New

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this ICR should be received no later than December 16, 2019.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 14N136B, 5600 Fishers Lane, Rockville, Maryland 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at (301) 443–1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information request collection title for reference.

Information Collection Request Title: Evaluation of Maternal and Child Health Bureau Pediatric Mental Health Care Access Program and the Maternal and Child Health Bureau Screening and Treatment for Maternal Depression and Related Behavioral Disorders Program, OMB No. 0906–xxxx—New.

Abstract: HRSA's Maternal and Child Health Bureau Pediatric Mental Health Care Access (PMHCA) and Maternal Depression and Related Behavioral Disorders (MDRBD) programs aim to increase identification of behavioral health conditions by screening specified populations (*e.g.,* children, adolescents, young adults, and pregnant and postpartum women, especially those living in rural, isolated, and underserved areas); providing clinical behavioral health consultation; care coordination support (*e.g.,* communication/collaboration, accessing resources, referral services) and training to health care providers; and increasing access to clinical interventions including by telehealth. Provider education and training will support the knowledge and skills acquisition needed to accomplish this goal. PMHCA program is authorized by the Public Health Service Act, § 330M (42 U.S.C. 254c–19), as amended. The MDRBD program is authorized by the Public Health Service Act, § 317L–1 (42 U.S.C. 247b–13a), as amended. In order to evaluate progress made toward the programs' goals, this data collection will use four instruments: Health Care Provider (HCP) Survey, Practice-Level Survey, Program Implementation Survey, and Program Implementation Semi-Structured Interview.

Need and Proposed Use of the Information: This information is needed to evaluate the PMHCA and MDRBD Programs by providing HRSA with the necessary information to guide future policy decisions regarding increasing health care providers capacity to address patient's behavioral health and access to behavioral health services. Specifically, data collected for the evaluation will be used to study the efforts of awardee programs to achieve key awardee outcomes (*e.g.,* increase in access to behavioral health services; providers trained; available community-based resources, including counselors or family service providers) and to measure whether and to what extent awardee programs are associated with changes in these key awardee outcomes. The evaluation will also examine changes over time, within a state and/or across the PMCHA and MDRBD programs, with regard to (1) enrolled providers/practices related to screening, referral, and care coordination for behavioral health conditions; (2) provision of behavioral health services for mental health conditions in primary care settings by enrolled health care providers; (3) use of consultative services; and (4) facilitation of access to behavioral health services for mental health conditions.

Likely Respondents: Both HCP and Practice-Level Survey responses will be collected from health care providers and practices that are participating in the PMCHA and MDRBD programs. Likely respondents include:

- *HCP Surveys:* Physicians, nurse practitioners, physician assistants, nurse midwives (for MDBRD), other health care professionals (*e.g.,* behavioral health providers, case coordinators, nurses, social workers)
- *Practice-Level Surveys:* Practice managers (*e.g.,* office managers, office leadership, nurse champions)
- *Program Implementation Surveys and Semi-Structured Interviews:* PMHCA and MDRBD cooperative agreement-funded Project Directors/Principal Investigators

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

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Tota burden hours
Health Care Provider Survey	13,035	3	39,105	0.17	6,648
Practice-Level Survey	4,165	3	12,495	0.25	3,124
Program Implementation Survey	28	3	84	0.50	42

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Tota burden hours
Program Implementation Semi-Structured Interview	28	1	28	1.00	28
Total	17,256		51,712		9,842

HRSA specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions, (2) the accuracy of the estimated burden, (3) ways to enhance the quality, utility, and clarity of the information to be collected, and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2019–22636 Filed 10–16–19; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Advancing Translational Sciences; Notice of Closed Meeting

Pursuant to section 10(d) 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 Center for Advancing Translational Sciences Special Emphasis Panel; Platform Delivery Technologies for Nucleic Acid Therapeutics.

Date: November 13–14, 2019.

Time: 8:30 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, One Democracy Plaza, 6701 Democracy Boulevard, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Jing Chen, Ph.D., Scientific Review Officer, Office of Scientific Review, National Center for Advancing Translational Sciences (NCATS), National Institutes of Health, 6701 Democracy Blvd., Democracy 1, Room 1080, Bethesda, MD 20892–4874, *chenjing@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.350, B—Cooperative Agreements; 93.859, Biomedical Research and Research Training, National Institutes of Health, HHS)

Dated: October 10, 2019.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–22572 Filed 10–16–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director, National Institutes of Health; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Office of AIDS Research Advisory Council, November 7, 2019 from 8:30 a.m. to 4:30 p.m., National Institutes of Health, 5601 Fishers Lane, Room 1D13, Rockville, MD 20852 which was published in the **Federal Register** on February 15, 2019, 84 FR 4495.

This meeting notice is amended to change the meeting date from November 7, 2019 to October 28, 2019 at the National Institutes of Health, 5601 Fishers Lane, Room 1D13, Rockville, MD 20852. The meeting is open to the public.

Dated: October 10, 2019.

Tyeshia M. Roberson,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–22571 Filed 10–16–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Eye Institute; Notice of Closed Meeting

Pursuant to section 10(d) 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 Eye Institute Special Emphasis Panel; NEI Genetic Epidemiology and Secondary Data Analysis Applications.

Date: November 4–5, 2019.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Eye Institute, National Institutes of Health, 6700 B Rockledge Drive, Suite 3400, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Brian Hoshaw, Ph.D., Acting Review Chief, National Eye Institute, National Institutes of Health, Division of Extramural Research, 6700 B Rockledge Drive, Suite 3400, Rockville, MD 20892, (301) 451–2020, *hoshawb@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.867, Vision Research, National Institutes of Health, HHS)

Dated: October 10, 2019.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–22573 Filed 10–16–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Current List of HHS-Certified Laboratories and Instrumented Initial Testing Facilities Which Meet Minimum Standards To Engage in Urine Drug Testing for Federal Agencies

Correction

In notice document 2019–21176, beginning on page 52117 in the issue of Tuesday, October 1, 2019, make the following corrections:

1. On page 52117, in the third column, on the second line, ''Quiver Road, Leone, KS'' should read ''Quivira Road, Lenexa, KS''.

2. On the same page, in the same column, on the eighth line, ''Desert Ox'' should read ''Desert Tox''.

3. On the same page, in the same column, on the eleventh line, ''Drug,Scan'' should read ''DrugScan''.

[FR Doc. C1–2019–21176 Filed 10–16–19; 8:45 am]

BILLING CODE 1505–01–D

DEPARTMENT OF THE INTERIOR

Geological Survey

[GX19 EN05ESB0500; OMB Control Number 1028–0096/Renewal]

Agency Information Collection Activities: Request for Comments; Department of the Interior Regional Climate Adaptation Science Centers

AGENCY: U.S. Geological Survey, Interior.

ACTION: Notice of Information Collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, we, the U.S. Geological Survey (USGS) are proposing to renew an information collection.

DATES: Interested persons are invited to submit comments on or before December 16, 2019.

ADDRESSES: Send your comments on this information collection request (ICR) by mail to U.S. Geological Survey, Information Collections Officer, 12201 Sunrise Valley Drive MS 159, Reston, VA 20192; or by email to *gs-info_collections@usgs.gov.* Please reference OMB Control Number 1028–0096 in the subject line of your comments.

FOR FURTHER INFORMATION CONTACT: To request additional information about this ICR, contact Doug Beard, Chief of the USGS National Climate Adaptation Science Center, by email at *dbeard@usgs.gov,* or by telephone at 703–648–5212.

SUPPLEMENTARY INFORMATION: In accordance with the Paperwork Reduction Act of 1995, we provide the general public and other Federal agencies with an opportunity to comment on new, proposed, revised, and continuing collections of information. This helps us assess the impact of our information collection requirements and minimize the public's reporting burden. It also helps the public understand our information collection requirements and provide the requested data in the desired format.

We are soliciting comments on the proposed ICR that is described below. We are especially interested in public comment addressing the following issues: (1) Is the collection necessary to the proper functions of the USGS; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the USGS enhance the quality, utility, and clarity of the information to be collected; and (5) how might the USGS minimize the burden of this collection on the respondents, including through the use of information technology.

Comments that you submit in response to this notice are a matter of public record. We will include or summarize each comment in our request to OMB to approve this ICR. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you may ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Abstract: The U.S. Geological Survey (USGS) manages eight Department of the Interior (DOI) Regional Climate Adaptation Science Centers (CASCs). Each CASC involves a cooperative agreement with a host institution. The host institution agreements are periodically re-competed, requiring collection of information from potential host institutions. In addition, this information collection addresses quarterly and annual reporting required of host institutions.

Title of Collection: Department of the Interior Regional Climate Adaptation Science Centers.

OMB Control Number: 1028–0096.

Form Number: N/A.

Type of Review: Extension of a currently approved collection.

Respondents/Affected Public: Institutions that are expected to propose to serve as CASC host or partner institutions include state, local government, and tribal entities, including academic institutions. Existing host institutions are state academic institutions.

Total Estimated Number of Annual Respondents: The USGS expects to request proposals for a maximum of three CASCs in any year, and to receive an average of 5 proposals per CASC-request, for a total of 15 proposals in any single year. The USGS expects to enter into hosting agreements with a minimum of eight CASC host institutions.

Total Estimated Number of Annual Responses: The USGS would request quarterly financial statements and annual progress reports covering host agreements from eight institutions. In addition, the USGS expects to have in place approximately 40 cooperative agreements per year addressing specific research projects funded under these hosting agreements. Each of these 40 agreements requires quarterly financial statements and one annual progress report.

Estimated Completion Time per Response: Each proposal for CASC hosting is expected to take 200 hours to complete. The time required to complete quarterly and annual reports for any specific host cooperative agreement or research project agreement is expected to total 2.5 hours per report.

Total Estimated Number of Annual Burden Hours: A maximum of 3120 hours in years when proposals are requested, and 120 hours in those years with only quarterly and annual reporting.

Respondent's Obligation: Required to Obtain or Retain a Benefit.

Frequency of Collection: Information will be collected one time every five years (approximately) for each CASC, to enable re-competition of CASC hosting agreements. In addition, host institutions are required to fill four quarterly financial statements and one annual progress report.

Total Estimated Annual Nonhour Burden Cost: There are no ''non-hour cost'' burdens associated with this collection of information.

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 authority for this action is the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq*).

Thomas Beard,

Chief, National Climate Adaptation Science Center.

[FR Doc. 2019–22610 Filed 10–16–19; 8:45 am]

BILLING CODE 4338–11–P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

[190A2100DD/AAKC001030/A0A501010.999900]

HEARTH Act Approval of Menominee Indian Tribe of Wisconsin Regulations

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice.

SUMMARY: On July 25, 2019, the Bureau of Indian Affairs (BIA) approved the Menominee Indian Tribe of Wisconsin (Tribe) Leasing Regulations under the Helping Expedite and Advance Responsible Tribal Homeownership Act of 2012 (HEARTH Act). With this approval, the Tribe is authorized to enter into agricultural, residential, business, and other authorized purposes leases without further BIA approval.

FOR FURTHER INFORMATION CONTACT: Ms. Sharlene Round Face, Bureau of Indian Affairs, Division of Real Estate Services, 1849 C Street NW, MS 4624–MIB, Washington, DC at (505) 563–3132.

SUPPLEMENTARY INFORMATION:

I. Summary of the HEARTH Act

The HEARTH Act makes a voluntary, alternative land leasing process available to Tribes, by amending the Indian Long-Term Leasing Act of 1955, 25 U.S.C. 415. The HEARTH Act authorizes Tribes to negotiate and enter into agricultural and business leases of Tribal trust lands with a primary term of 25 years, and up to two renewal terms of 25 years each, without the approval of the Secretary of the Interior (Secretary). The HEARTH Act also authorizes Tribes to enter into leases for residential, recreational, religious or educational purposes for a primary term of up to 75 years without the approval of the Secretary. Participating Tribes develop Tribal leasing regulations, including an environmental review process, and then must obtain the Secretary's approval of those regulations prior to entering into leases. The HEARTH Act requires the Secretary to approve Tribal regulations if the Tribal regulations are consistent with the Department of the Interior's (Department) leasing regulations at 25 CFR part 162 and provide for an environmental review process that meets requirements set forth in the HEARTH Act. This notice announces that the Secretary, through the Assistant Secretary—Indian Affairs, has approved the Tribal regulations for the Menominee Indian Tribe of Wisconsin.

II. Federal Preemption of State and Local Taxes

The Department's regulations governing the surface leasing of trust and restricted Indian lands specify that, subject to applicable Federal law, permanent improvements on leased land, leasehold or possessory interests, and activities under the lease are not subject to State and local taxation and may be subject to taxation by the Indian Tribe with jurisdiction. See 25 CFR 162.017. As explained further in the preamble to the final regulations, the Federal government has a strong interest in promoting economic development, self-determination, and Tribal sovereignty. 77 FR 72440, 72447–48 (December 5, 2012). The principles supporting the Federal preemption of State law in the field of Indian leasing and the taxation of lease-related interests and activities applies with equal force to leases entered into under Tribal leasing regulations approved by the Federal government pursuant to the HEARTH Act.

Section 5 of the Indian Reorganization Act, 25 U.S.C. 5108, preempts State and local taxation of permanent improvements on trust land. *Confederated Tribes of the Chehalis Reservation* v. *Thurston County,* 724 F.3d 1153, 1157 (9th Cir. 2013) (citing *Mescalero Apache Tribe* v. *Jones,* 411 U.S. 145 (1973)). Similarly, section 5108 preempts State taxation of rent payments by a lessee for leased trust lands, because ''tax on the payment of rent is indistinguishable from an impermissible tax on the land.'' *See Seminole Tribe of Florida* v. *Stranburg,* No. 14–14524, *13–*17, n.8 (11th Cir. 2015). In addition, as explained in the preamble to the revised leasing regulations at 25 CFR part 162, Federal courts have applied a balancing test to determine whether State and local taxation of non-Indians on the reservation is preempted. *White Mountain Apache Tribe* v. *Bracker,* 448 U.S. 136, 143 (1980). The *Bracker* balancing test, which is conducted against a backdrop of ''traditional notions of Indian self- government,'' requires a particularized examination of the relevant State, Federal, and Tribal interests. We hereby adopt the *Bracker* analysis from the preamble to the surface leasing regulations, 77 FR at 72447–48, as supplemented by the analysis below.

The strong Federal and Tribal interests against State and local taxation of improvements, leaseholds, and activities on land leased under the Department's leasing regulations apply equally to improvements, leaseholds, and activities on land leased pursuant to Tribal leasing regulations approved under the HEARTH Act. Congress's overarching intent was to ''allow Tribes to exercise greater control over their own land, support self-determination, and eliminate bureaucratic delays that stand in the way of homeownership and economic development in Tribal communities.'' 158 Cong. Rec. H. 2682 (May 15, 2012). The HEARTH Act was intended to afford Tribes ''flexibility to adapt lease terms to suit [their] business and cultural needs'' and to ''enable [Tribes] to approve leases quickly and efficiently.'' *Id.* at 5–6.

Assessment of State and local taxes would obstruct these express Federal policies supporting Tribal economic development and self-determination, and also threaten substantial Tribal interests in effective Tribal government, economic self-sufficiency, and territorial autonomy. *See Michigan* v. *Bay Mills Indian Community,* 134 S. Ct. 2024, 2043 (2014) (Sotomayor, J., concurring) (determining that ''[a] key goal of the Federal Government is to render Tribes more self-sufficient, and better positioned to fund their own sovereign functions, rather than relying on Federal funding''). The additional costs of State and local taxation have a chilling effect on potential lessees, as well as on a tribe that, as a result, might refrain from exercising its own sovereign right to impose a Tribal tax to support its infrastructure needs. *See id.* at 2043–44 (finding that State and local taxes greatly discourage Tribes from raising tax revenue from the same sources because the imposition of double taxation would impede Tribal economic growth).

Similar to BIA's surface leasing regulations, Tribal regulations under the HEARTH Act pervasively cover all aspects of leasing. *See* 25 U.S.C. 415(h)(3)(B)(i) (requiring Tribal regulations be consistent with BIA surface leasing regulations). Furthermore, the Federal government remains involved in the Tribal land leasing process by approving the Tribal leasing regulations in the first instance and providing technical assistance, upon request by a tribe, for the development of an environmental review process. The Secretary also retains authority to take any necessary

actions to remedy violations of a lease or of the Tribal regulations, including terminating the lease or rescinding approval of the Tribal regulations and reassuming lease approval responsibilities. Moreover, the Secretary continues to review, approve, and monitor individual Indian land leases and other types of leases not covered under the Tribal regulations according to the Part 162 regulations.

Accordingly, the Federal and Tribal interests weigh heavily in favor of preemption of State and local taxes on lease-related activities and interests, regardless of whether the lease is governed by Tribal leasing regulations or Part 162. Improvements, activities, and leasehold or possessory interests may be subject to taxation by the Menominee Indian Tribe of Wisconsin.

Dated: July 25, 2019.

Tara Sweeney,

Assistant Secretary—Indian Affairs.

[FR Doc. 2019–22681 Filed 10–16–19; 8:45 am]

BILLING CODE 4337–15–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–PWRO–TUSK–28830; PPPWTUSK00, PPMPSPD1Z.YM0000]

Tule Springs Fossil Beds National Monument Advisory Council Notice of Public Meeting

AGENCY: National Park Service, Interior.

ACTION: Meeting notice.

SUMMARY: In accordance with the Federal Advisory Committee Act of 1972, the National Park Service is hereby giving notice that the Tule Springs Fossil Beds National Monument Advisory Council (Council) will meet as indicated below.

DATES: The meeting will be held on Monday, November 4, 2019, at 5:00 p.m. (PACIFIC).

ADDRESSES: The meeting will be held at the Federal Interagency Office Building, 4701 N Torrey Pines Road, Las Vegas, Nevada 89130–2301.

FOR FURTHER INFORMATION CONTACT: Further information concerning the meeting may be obtained from Diane Keith, Superintendent, Tule Springs Fossil Beds National Monument, 601 Nevada Way, Boulder City, Nevada 89005, via telephone at (702) 515–5462, or email at *tusk_information@nps.gov.*

SUPPLEMENTARY INFORMATION: The Council was established pursuant to Section 3092(a)(6) of Public Law 113–291 and in accordance with the provisions of the Federal Advisory Committee Act (5 U.S.C. Appendix 1–16). The purpose of the Council is to advise the Secretary of the Interior with respect to the preparation and implementation of the management plan.

Purpose of the Meeting: The Council agenda will include the status of the park's Foundation Document and General Management Plan, the Desert National Wildlife Refuge Visitor Center exhibit installation, Project CARE, subcommittee projects, and a presentation by the Las Vegas Wash Coordination Committee.

The meeting is open to the public. Interested persons may make oral/written presentations to the Council during the business meeting or file written statements. Such requests should be made to the Superintendent prior to the meeting.

Public Disclosure of Comments: Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Authority: 5 U.S.C. Appendix 2.

Michael Shelton,

Program Analyst, Office of Policy.

[FR Doc. 2019–22657 Filed 10–16–19; 8:45 am]

BILLING CODE 4312–52–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–1180]

Institution of Investigation

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that a complaint was filed with the U.S. International Trade Commission on August 9, 2019, under section 337 of the Tariff Act of 1930, as amended, on behalf of Innovation Sciences LLC of Plano, Texas. A supplement to the complaint was filed on August 26, 2019. The complaint alleges violations of section 337 based upon the importation into the United States, the sale for importation, and the sale within the United States after importation of certain wireless communication devices, and related components thereof by reason of infringement of certain claims of U.S. Patent No. 10,136,179 (''the '179 patent'') and U.S. Patent No. 10,104,425 (''the '425 patent''). The complaint further alleges that an industry in the United States exists as required by the applicable Federal Statute.

The complainant requests that the Commission institute an investigation and, after the investigation, issue a limited exclusion order and a cease and desist orders.

ADDRESSES: The complaint, except for any confidential information contained therein, is available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street SW, Room 112, Washington, DC 20436, telephone (202) 205–2000. Hearing impaired individuals are advised that information on this matter can be obtained 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 at *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*.

FOR FURTHER INFORMATION CONTACT: Pathenia M. Proctor, The Office of Unfair Import Investigations, U.S. International Trade Commission, telephone (202) 205–2560.

SUPPLEMENTARY INFORMATION:

Authority: The authority for institution of this investigation is contained in section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, and in section 210.10 of the Commission's Rules of Practice and Procedure, 19 CFR 210.10 (2019).

Scope of Investigation: Having considered the complaint, the U.S. International Trade Commission, on October 9, 2019, Ordered That—

(1) Pursuant to subsection (b) of section 337 of the Tariff Act of 1930, as amended, an investigation be instituted to determine whether there is a violation of subsection (a)(1)(B) of section 337 in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain products identified in paragraph (2) by reason of infringement of one or more of claims 1–3, 5, 6, 9, 11, 12, and 14–18 of the '179 patent and claims 14–18 and 45–48 of the '425 patent; and whether an industry in the United States exists as

required by subsection (a)(2) of section 337;

(2) Pursuant to section 210.10(b)(1) of the Commission's Rules of Practice and Procedure, 19 CFR 210.10(b)(1), the plain language description of the accused products or category of accused products, which defines the scope of the investigation, is ''smart cellular phones, smart thermostats, and smart home control and monitoring systems with their associated wireless security sensors (door and window, smoke and fire, motion and sound, leak and freeze), wireless controllers (door locks, lighting, home appliances), and smart video cameras (indoor and outdoor cameras, doorbell cameras), which may be configured to serve as (or with) smart hubs for communicating with, monitoring, and/or controlling such wireless smart devices, systems, and/or appliances in the home or office, and can control the communication of signals/content between those wireless smart devices, systems, and/or appliances'';

(3) For the purpose of the investigation so instituted, the following are hereby named as parties upon which this notice of investigation shall be served:

(a) The complainant is:

Innovation Sciences LLC, 5800 Legacy Circle, Suite 311, Plano, TX 75024.

(b) The respondents are the following entities alleged to be in violation of section 337, and are the parties upon which the complaint is to be served:

Resideo Technologies, Inc., 901 East Sixth Street, Austin, TX 78702.

HTC Corporation, 23 Xinghua Road, Tayouan, 330, Republic of China, Taiwan.

HTC America, Inc., 308 Occidental Avenue S., Suite 300, Seattle, WA 98104.

(c) The Office of Unfair Import Investigations, U.S. International Trade Commission, 500 E Street SW, Suite 401, Washington, DC 20436; and

(4) For the investigation so instituted, the Chief Administrative Law Judge, U.S. International Trade Commission, shall designate the presiding Administrative Law Judge.

Responses to the complaint and the notice of investigation must be submitted by the named respondents in accordance with section 210.13 of the Commission's Rules of Practice and Procedure, 19 CFR 210.13. Pursuant to 19 CFR 201.16(e) and 210.13(a), such responses will be considered by the Commission if received not later than 20 days after the date of service by the Commission of the complaint and the notice of investigation. Extensions of time for submitting responses to the complaint and the notice of investigation will not be granted unless good cause therefor is shown.

Failure of a respondent to file a timely response to each allegation in the complaint and in this notice may be deemed to constitute a waiver of the right to appear and contest the allegations of the complaint and this notice, and to authorize the administrative law judge and the Commission, without further notice to the respondent, to find the facts to be as alleged in the complaint and this notice and to enter an initial determination and a final determination containing such findings, and may result in the issuance of an exclusion order or a cease and desist order or both directed against the respondent.

By order of the Commission.

Issued: October 10, 2019.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2019–22606 Filed 10–16–19; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–1162]

Certain Touch-Controlled Mobile Devices, Computers, and Components Thereof; Commission Determination Not To Review an Initial Determination Amending the Complaint and Notice of Investigation To Substitute Respondents Dell Inc. and Dell Products LP for Respondent Dell Technologies Inc.

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission (''Commission'') has determined not to review an initial determination (''ID'') (Order No. 12) that grants an unopposed motion to amend the complaint and notice of investigation to substitute new respondents Dell Inc. and Dell Products LP for original respondent Dell Technologies Inc. in the above-identified investigation.

FOR FURTHER INFORMATION CONTACT: Ron Traud, Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone 202–205–3427. Copies of non-confidential documents filed in connection with this investigation are or will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone 202–205–2000. General information concerning the Commission may also be obtained by accessing its internet server at *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.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal, telephone 202–205–1810.

SUPPLEMENTARY INFORMATION: The Commission instituted this investigation on June 24, 2019, based on a complaint filed by Neodron Ltd. of Dublin, Ireland (''Neodron''). 84 FR 29545 (June 24, 2019). The complaint, as amended, alleges violations of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337 (''section 337''), based upon the importation into the United States, the sale for importation, and the sale within the United States after importation of certain touch-controlled mobile devices, computers, and components thereof by reason of infringement of certain claims of U.S. Patent Nos. 8,432,173; 8,791,910; 9,024,790; and 9,372,580. *Id.* The amended complaint further alleges that an industry in the United States exists as required by section 337. *Id.* The notice of investigation named as respondents Amazon.com, Inc. of Seattle, Washington; Dell Technologies Inc. of Round Rock, Texas; HP Inc. of Palo Alto, California; Lenovo Group Ltd. of Beijing, China; Lenovo (United States) Inc. of Morrisville, North Carolina; Microsoft Corporation of Redmond, Washington; Motorola Mobility LLC of Chicago, Illinois; Samsung Electronics Co., Ltd. of Suwon, South Korea; and Samsung Electronics America, Inc. of Ridgefield Park, New Jersey. *Id.* The Office of Unfair Import Investigations was not named as a party to the investigation. *Id.*

On September 23, 2019, Neodron filed an unopposed motion seeking leave to amend the complaint and notice of investigation to substitute new respondents Dell Inc. and Dell Products LP, both of Round Rock, Texas, for original respondent Dell Technologies Inc.

On September 25, 2019, the ALJ issued Order No. 12, the subject ID, which grants the motion. The ID finds that Neodron's motion complies with 19 CFR 210.14(b)(1) and that granting the motion will not prejudice the public interest or the rights of the parties. No petitions for review were filed.

The Commission has determined not to review the subject ID.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in part 210 of the Commission's Rules of Practice and Procedure (19 CFR part 210).

By order of the Commission.

Issued: October 11, 2019.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2019–22647 Filed 10–16–19; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—Consortium for Battery Innovation

Notice is hereby given that, on September 13, 2019, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (''the Act''), Consortium for Battery Innovation (''CBI'') has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in its membership. The notifications were filed for the purpose of extending the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, Abertax Technologies LTD, Paola, MALTA; Ahlstrom-Munksjöo, Mathi, ITALY; Gridtential Energy, Santa Clara, CA; and Wirtz Manufacturing Co. Inc., Port Huron, MI, have been added as parties to this venture.

No other changes have been made in either the membership or planned activity of the group research project. Membership in this group research project remains open, and CBI intends to file additional written notifications disclosing all changes in membership.

On May 24, 2019, CBI filed its original notification pursuant to Section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to Section 6(b) of the Act on June 21, 2019 (84 FR 29241).

Suzanne Morris,

Chief, Premerger and Division Statistics Unit, Antitrust Division.

[FR Doc. 2019–22618 Filed 10–16–19; 8:45 am]

BILLING CODE 4410–11–P

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—Advanced Media Workflow Association, Inc.

Notice is hereby given that, on September 13, 2019, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (''the Act''), Advanced Media Workflow Association, Inc. has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in its membership. The notifications were filed for the purpose of extending the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, Etere Pte Ltd, Singapore, SINGAPORE; Tamura Corporation, Tokyo, JAPAN; and Phillip Nguyen (individual member), Folsom, CA, have been added as parties to this venture.

Also, Signiant, Lexington, MA; TVNZ, Auckland, NEW ZEALAND; and Telestream, LLC, Nevada City, CA, have withdrawn as parties to this venture.

No other changes have been made in either the membership or planned activity of the group research project. Membership in this group research project remains open, and Advanced Media Workflow Association, Inc. intends to file additional written notifications disclosing all changes in membership.

On March 28, 2000, Advanced Media Workflow Association, Inc. filed its original notification pursuant to Section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to Section 6(b) of the Act on June 29, 2000 (65 FR 40127).

The last notification was filed with the Department on June 21, 2019. A notice was published in the **Federal Register** pursuant to Section 6(b) of the Act on July 17, 2019 (84 FR 34200).

Suzanne Morris,

Chief, Premerger and Division Statistics Unit, Antitrust Division.

[FR Doc. 2019–22614 Filed 10–16–19; 8:45 am]

BILLING CODE 4410–11–P

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—National Fire Protection Association

Notice is hereby given that, on September 6, 2019, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (''the Act''), National Fire Protection Association (''NFPA'') has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing additions or changes to its standards development activities. The notifications were filed for the purpose of extending the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, NFPA has provided an updated and current list of its standards development activities, related technical committee and conformity assessment activities. Information concerning NFPA regulations, technical committees, current standards, standards development and conformity assessment activities are publicly available at *nfpa.org*.

On September 20, 2004, NFPA filed its original notification pursuant to Section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to Section 6(b) of the Act on October 21, 2004 (69 FR 61869).

The last notification was filed with the Department on June 20, 2019. A notice was published in the **Federal Register** pursuant to Section 6(b) of the Act on July 17, 2019 (84 FR 34200).

Suzanne Morris,

Chief, Premerger and Division Statistics Unit, Antitrust Division.

[FR Doc. 2019–22617 Filed 10–16–19; 8:45 am]

BILLING CODE 4410–11–P

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—OpenJS Foundation

Notice is hereby given that, on September 19, 2019, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (''the Act''), OpenJS Foundation (''OpenJS Foundation'') has filed written notifications simultaneously with the

Attorney General and the Federal Trade Commission disclosing changes in its membership. The notifications were filed for the purpose of extending the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, Vincit California, Inc., San Francisco, CA, has been added as a party to this venture.

Also, XNSIO, Bengaluru, INDIA, has withdrawn as a party to this venture.

No other changes have been made in either the membership or planned activity of the group research project. Membership in this group research project remains open, and OpenJS Foundation intends to file additional written notifications disclosing all changes in membership.

On August 17, 2015, OpenJS Foundation filed its original notification pursuant to Section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to Section 6(b) of the Act on September 28, 2015 (80 FR 58297).

The last notification was filed with the Department on July 12, 2019. A notice was published in the **Federal Register** pursuant to Section 6(b) of the Act on August 1, 2019 (84 FR 37680).

Suzanne Morris,

Chief, Premerger and Division Statistics Unit, Antitrust Division.

[FR Doc. 2019–22616 Filed 10–16–19; 8:45 am]

BILLING CODE 4410–11–P

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—Pistoia Alliance, Inc.

Notice is hereby given that, on September 10, 2019, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.,* (''the Act''), Pistoia Alliance, Inc. has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in its membership. The notifications were filed for the purpose of extending the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, Rainer Fuchs (individual member), Sudbury, MA; Cambridge Quantum Computing Limited, London, UNITED KINGDOM; David Dorsett (individual member), Pennington, NJ; PERCAYAI LLC, St. Louis, MO; Zapata Computing Inc., Cambridge, MA; Thomas Liener (individual member), Innsbruck, AUSTRIA; Action Duchenne, London, UNITED KINGDOM; Collaborative Drug Discovery Inc., Burlingame, CA; Scinapsis Analytics Inc. d/b/a BenchSci, Toronto, CANADA; and Revathi Nathaniel (individual member), Dallas, TX, have been added as parties to this venture.

Also, Transformative AI Limited, London, UNITED KINGDOM; Data2Discovery, Bloomington, IN; and Digipharm, Zug, SWITZERLAND, have withdrawn as parties to this venture.

No other changes have been made in either the membership or planned activity of the group research project. Membership in this group research project remains open, and Pistoia Alliance, Inc. intends to file additional written notifications disclosing all changes in membership.

On May 28, 2009, Pistoia Alliance, Inc. filed its original notification pursuant to Section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to Section 6(b) of the Act on July 15, 2009 (74 FR 34364).

The last notification was filed with the Department on June 26, 2019. A notice was published in the **Federal Register** pursuant to Section 6(b) of the Act on July 17, 2019 (84 FR 34201).

Suzanne Morris,

Chief, Premerger and Division Statistics Unit, Antitrust Division.

[FR Doc. 2019–22608 Filed 10–16–19; 8:45 am]

BILLING CODE 4410–11–P

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—Cooperative Research Group on ROS-Industrial Consortium Americas

Notice is hereby given that, on September 10, 2019, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (''the Act''), Southwest Research Institute—Cooperative Research Group on ROS-Industrial Consortium-Americas (''RIC-Americas'') has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in its membership. The notifications were filed for the purpose of extending the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, Advanced Robotics for Manufacturing (ARM), Pittsburgh, PA, and Siemens Energy, Inc., Orlando, FL, have been added as parties to this venture.

No other changes have been made in either the membership or planned activity of the group research project. Membership in this group research project remains open, and RIC-Americas intends to file additional written notifications disclosing all changes in membership.

On April 30, 2014, RIC-Americas filed its original notification pursuant to Section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to Section 6(b) of the Act on June 9, 2014 (79 FR 32999).

The last notification was filed with the Department on August 1, 2019. A notice was published in the **Federal Register** pursuant to Section 6(b) of the Act on September 4, 2019 (84 FR 46565).

Suzanne Morris,

Chief, Premerger and Division Statistics Unit Antitrust Division.

[FR Doc. 2019–22609 Filed 10–16–19; 8:45 am]

BILLING CODE 4410–11–P

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—3D PDF Consortium, Inc.

Notice is hereby given that, on September 6, 2019, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.,* (''the Act''), 3D PDF Consortium, Inc. (''3D PDF'') has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in its membership. The notifications were filed for the purpose of extending the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, Jean-François Blanchette (individual member), Los Angeles, CA; and KOM Software, Ottawa, CANADA, have been added as parties to this venture.

No other changes have been made in either the membership or planned activity of the group research project. Membership in this group research project remains open, and 3D PDF intends to file additional written notifications disclosing all changes in membership.

On March 27, 2012, 3D PDF filed its original notification pursuant to Section

6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to Section 6(b) of the Act on April 20, 2012 (77 FR 23754).

The last notification was filed with the Department on July 3, 2019. A notice was published in the **Federal Register** pursuant to Section 6(b) of the Act on August 1, 2019 (84 FR 37681).

Suzanne Morris,

Chief, Premerger and Division Statistics Unit, Antitrust Division.

[FR Doc. 2019–22615 Filed 10–16–19; 8:45 am]

BILLING CODE 4410–11–P

DEPARTMENT OF JUSTICE

Foreign Claims Settlement Commission

Privacy Act of 1974; System of Records

AGENCY: Foreign Claims Settlement Commission of the United States, Department of Justice.

ACTION: Notice of a new system of records.

SUMMARY: Pursuant to the Privacy Act of 1974, the Foreign Claims Settlement Commission of the United States (Commission), Department of Justice, proposes to establish a new system of records to enable the Commission to carry out its statutory responsibility to receive, examine, adjudicate and render final decisions with respect to claims for compensation of individuals. The system will include documentation provided by the claimants as well as background material that will assist the Commission in the processing of their claims. The system will also include the final decision of the Commission regarding each claim.

DATES: In accordance with 5 U.S.C. 552a(e)(4) and (11), this system of records notice is effective upon publication, with the exception of the routine uses that are subject to a 30-day period in which to comment, described below. Therefore, please submit any comments by November 18, 2019.

ADDRESSES: The public is invited to submit any comments via email at *info.fcsc@usdoj.gov* or by mail to the Foreign Claims Settlement Commission, 441 G Street NW, Room 6330, Washington, DC 20579.

FOR FURTHER INFORMATION CONTACT: Jeremy LaFrancois, Chief Administrative Counsel, Foreign Claims Settlement Commission, U.S. Department of Justice, 441 G Street NW, Room 6330, Washington, DC 20579, or by telephone at (202) 616–6975.

SUPPLEMENTARY INFORMATION: The Foreign Claims Settlement Commission of the United States (Commission) is authorized, pursuant to 22 U.S.C. 1621 et. seq., 50 U.S.C. 1701 note and 50 U.S.C. App. 2004 and 2005, to adjudicate claims to determine the eligibility of individuals for and the appropriate amount of compensation.

The system of records covered by this notice is necessary for the Commission's adjudication of claims pursuant to its authority under the aforementioned statutes. These records shall form the basis upon which the Commission will determine an individual's eligibility for and amount of compensation.

In accordance with 5 U.S.C. 552a(r), the Commission has provided a report to OMB and the Congress on the new system of records.

Dated: October 10, 2019.

Jeremy R. LaFrancois,

Chief Administrative Counsel.

SYSTEM NAME AND NUMBER:

Claims Received and Adjudicated by the Foreign Claims Settlement Commission JUSTICE/FCSC–33.

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

Offices of the Foreign Claims Settlement Commission, 441 G Street NW Room 6330, Washington, DC 20579 and Washington National Records Center, 4205 Suitland Road, Washington, DC 20409.

SYSTEM MANAGER(S):

Chief Administrative Counsel, Foreign Claims Settlement Commission, 441 G Street NW Room 6330, Washington, DC 20579. Telephone: (202) 616–6975. Fax: (202) 616–6993. Email *Jeremy.r.lafrancois@usdoj.gov.*

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Authority to establish and maintain this system is contained in 5 U.S.C. 301 and 44 U.S.C. 3101, which authorize the Chairman of the Commission to create and maintain federal records of agency activities, and is further described in 22 U.S.C. 1622e, which vests all non-adjudicatory functions, powers and duties in the Chairman of the Commission.

PURPOSE(S) OF THE SYSTEM:

This system shall consolidate the following Systems of Records: FCSC–1 Indexes of Claimants (Alphabetical); FCSC–3 Certifications of Awards; FCSC–4 China, Claims Against; FCSC–5 Civilian Internees (Vietnam); FCSC–8 Cuba, Claims Against; FCSC–17 Prisoners of War (Vietnam); FCSC–19 Soviet Union, Claims Against; FCSC–25 Egypt, Claims Against; FCSC–26 Albania, Claims Against; FCSC–27 Germany, Holocaust Survivors' Claims Against; FCSC–28 Iraq, Registration of Potential Claims Against; FCSC–29 Libya, Claims Against; FCSC–29 Claims of less than $250,000 Against Iran; FCSC–30 Iraq, Claims Against; FCSC–31 Claims Referred by the Department of State; FCSC–32 Claims Arising under the Guam World War II Loyalty Recognition Act. This system will enable the Commission to carry out its statutory responsibility to determine the validity and amount of claims authorized to be adjudicated pursuant to pursuant to 22 U.S.C. 1621 et. seq., 50 U.S.C. 1701 note and 50 U.S.C. App. 2004 and 2005.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Individuals who file claims pursuant to a duly authorized Commission claims program.

CATEGORIES OF RECORDS IN THE SYSTEM:

Claim information, including name and address of claimant and representative, if any; date and place of birth or naturalization; nature of claim; description of loss or injury including medical records; and other evidence establishing entitlement to compensation.

RECORD SOURCE CATEGORIES:

The primary document source is the claimant upon whom the record is maintained. The collection may also include documents obtained from legal databases (*e.g.,* Westlaw and/or Lexis), Congressional records, and the records of other Federal agencies (*e.g.,* the Social Security Agency, Department of State, etc.)

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b), all or a portion of the records contained in this system of records may be disclosed as a routine use pursuant to 5 U.S.C. 552a(b)(3) under the circumstances or for the purposes described below, to the extent such disclosures are compatible with the purposes for which the information was collected.

a. Upon the issuance of a final decision awarding compensation, the Commission will certify its decision and other necessary personal information to the Department of the Treasury in order to process payment of the claim.

b. To contractors, grantees, experts, consultants, students, and others performing or working on a contract, service, grant, cooperative agreement, or other assignment for the federal government, when necessary to accomplish a Commission function related to this system of records;

c. To a Member of Congress or staff acting upon the Member's behalf when the Member or staff requests the information on behalf of, and at the request of, the individual who is the subject of the record;

d. Where a record, either alone or in conjunction with other information, indicates a violation or potential violation of law—criminal, civil, or regulatory in nature—the relevant records may be referred to the appropriate federal, state, local, territorial, tribal, or foreign law enforcement authority or other appropriate entity charged with the responsibility for investigating or prosecuting such violation or charged with enforcing or implementing such law;

e. In an appropriate proceeding before the Commission, or before a court, grand jury, or administrative or adjudicative body, when the Department of Justice and/or the Commission determines that the records are arguably relevant to the proceeding; or in an appropriate proceeding before an administrative or adjudicative body when the adjudicator determines the records to be relevant to the proceeding;

f. To a former employee of the Commission for purposes of: Responding to an official inquiry by a federal, state, or local government entity or professional licensing authority, in accordance with applicable Commission regulations; or facilitating communications with a former employee that may be necessary for personnel-related or other official purposes where the Commission requires information and/or consultation from the former employee regarding a matter within that person's former area of responsibility;

g. To the National Archives and Records Administration for purposes of records management inspections conducted under the authority of 44 U.S.C. 2904 and 2906;

h. To appropriate agencies, entities, and persons when (1) the Commission suspects or has confirmed that there has been a breach of the system of records; (2) the Commission has determined that as a result of the suspected or confirmed breach there is a risk of harm to the individuals, the Commission (including its information systems, programs, and operations), the Federal Government, or national security; and (3) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with the Commission's efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm;

i. To another Federal agency or Federal entity, when the Commission determines that information from this system of records is reasonably necessary to assist the recipient agency or entity in (1) responding to a suspected or confirmed breach or (2) preventing, minimizing, or remedying the risk of harm to individuals, the recipient agency or entity (including its information systems, programs, and operations), the Federal Government, or national security, resulting from a suspected or confirmed breach;

j. To such recipients and under such circumstances and procedures as are mandated by federal statute or treaty.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

Paper records maintained in file folders at the Commission's office and the National Records Center. Electronic records are located on the Department of Justice Servers.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

Records maintained in this system of records will be retrieved by claim number and/or decision number. An alphabetical index may be used by the Commission for identification of a claim by claimants' name.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

Records are maintained under 5 U.S.C. 301. The Commission maintains record schedules with the National Archives and Records Administration for each authorized claims program.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

Paper records are under security safeguards at both the Commission's office and the National Records Center. Such safeguards include storage in a central location within a limited access building and a further limited access suite. Accordingly, access is limited to Commission and Record Center employees and contractors with appropriate security clearances. The electronic records are safeguarded by the DOJ JCON security procedures. Access to the Commission's data requires a password and is limited to Commission employees and contractors with appropriate security clearances.

RECORD ACCESS PROCEDURES:

The Commission's record access procedures are set forth in 45 CFR 503.5. That section provides that (a) Any individual requesting access to a record or information on himself or herself in person must appear at the offices of the Foreign Claims Settlement Commission, 441 G Street NW Room 6330, Washington, DC, between the hours of 9 a.m. and 5:00 p.m., Monday through Friday, and (1) Provide information sufficient to identify the record, *e.g.,* the individual's own name, claim and decision number, date and place of birth, etc.; (2) Provide identification sufficient to verify the individual's identity, *e.g.,* driver's license, Medicare card, or other government issued identification; and (3) Any individual requesting access to records or information pertaining to himself or herself may be accompanied by a person of the individual's own choosing while reviewing the records or information. If an individual elects to be so accompanied, advance notification of the election will be required along with a written statement authorizing disclosure and discussion of the record in the presence of the accompanying person at any time, including the time access is granted. (b) Any individual making a request for access to records or information pertaining to himself or herself by mail must address the request to the Privacy Officer, Foreign Claims Settlement Commission, 441 G Street NW Room 6330, Washington, DC 20579, and must provide information acceptable to the Commission to verify the individual's identity. (c) Responses to requests under this section normally will be made within ten (10) days of receipt (excluding Saturdays, Sundays, and legal holidays). If it is not possible to respond to requests within that period, an acknowledgment will be sent to the individual within ten (10) days of receipt of the request (excluding Saturdays, Sundays, and legal holidays).

CONTESTING RECORD PROCEDURES:

(a) Any individual may request amendment of a record pertaining to himself or herself according to the procedure in paragraph (b) of this section, except in the case of records described under paragraph (d) of this section. (b) After inspection by an individual of a record pertaining to himself or herself, the individual may file a written request, presented in person or by mail, with the Administrative Officer, for an amendment to a record. The request must specify the particular portions of the record to be amended, the desired amendments and the reasons therefor.

(c) Not later than ten (10) days (excluding Saturdays, Sundays, and legal holidays) after the receipt of a request made in accordance with this section to amend a record in whole or in part, the Administrative Officer will: (1) Make any correction of any portion of the record which the individual believes is not accurate, relevant, timely or complete and thereafter inform the individual of such correction; or (2) Inform the individual, by certified mail return receipt requested, of the refusal to amend the record, setting forth the reasons therefor, and notify the individual of the right to appeal that determination as provided under 45 CFR 503.8. (d) The provisions for amending records do not apply to evidence presented in the course of Commission proceedings in the adjudication of claims, nor do they permit collateral attack upon what has already been subject to final agency action in the adjudication of claims in programs previously completed by the Commission pursuant to statutory time limitations.

NOTIFICATION PROCEDURES:

The Commission's notification procedures are set forth in 45 CFR 503.5. That section provides that (a) Any individual requesting access to a record or information on himself or herself in person must appear at the offices of the Foreign Claims Settlement Commission, 441 G Street NW Room 6330, Washington, DC, between the hours of 9 a.m. and 5:00 p.m., Monday through Friday, and (1) Provide information sufficient to identify the record, *e.g.,* the individual's own name, claim and decision number, date and place of birth, etc.; (2) Provide identification sufficient to verify the individual's identity, *e.g.,* driver's license, Medicare card, or other government issued identification; and (3) Any individual requesting access to records or information pertaining to himself or herself may be accompanied by a person of the individual's own choosing while reviewing the records or information. If an individual elects to be so accompanied, advance notification of the election will be required along with a written statement authorizing disclosure and discussion of the record in the presence of the accompanying person at any time, including the time access is granted. (b) Any individual making a request for access to records or information pertaining to himself or herself by mail must address the request to the Privacy Officer, Foreign Claims Settlement Commission, 441 G Street NW Room 6330, Washington, DC 20579, and must provide information acceptable to the Commission to verify the individual's identity. (c) Responses to requests under this section normally will be made within ten (10) days of receipt (excluding Saturdays, Sundays, and legal holidays). If it is not possible to respond to requests within that period, an acknowledgment will be sent to the individual within ten (10) days of receipt of the request (excluding Saturdays, Sundays, and legal holidays).

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

HISTORY:

None.

[FR Doc. 2019–22496 Filed 10–16–19; 8:45 am]

BILLING CODE 4410–BA–P

DEPARTMENT OF JUSTICE

Notice of Lodging of Proposed Consent Decree Under the Comprehensive Environmental Response, Compensation and Liability Act

On October 9, 2019, the Department of Justice lodged a proposed consent decree with the United States District Court for the District of Massachusetts in *United States* v. *Textron Inc., and Whittaker Corporation,* Civil Action No. 19–cv–12097–RGS.

The proposed consent decree would resolve the claims of the United States for injunctive relief and recovery of response costs against the defendants under sections 106 and 107 of the Comprehensive Environmental Response, Compensation, and Liability Act (''CERCLA'') relating to the Nuclear Metals, Inc. Superfund Site in Concord, Massachusetts.

The consent decree requires the settling defendants, Textron Inc. and Whittaker Corporation, to pay approximately $8,000 toward the United States Environmental Protection Agency's (''EPA's'') past response costs, contribute approximately $2 million into a trust account, and perform the remedial action for this Site using funds from the trust account. The consent decree also requires the settling federal agencies, the U.S. Army and the U.S. Department of Energy, to pay approximately $390,000 toward EPA's past response costs and contribute approximately $101 million into the trust account to be used by the settling defendants to perform the remedial action for this Site.

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. *Textron Inc., and Whittaker Corporation,* D.J. Ref. No. 90–11–2–07237/12. 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: *http://www.usdoj.gov/enrd/Consent_Decrees.html.* 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 $121.25 (25 cents per page reproduction cost) payable to the United States Treasury. For a copy without the exhibits, the cost is $12.50.

Jeffrey Sands,

Assistant Section Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 2019–22637 Filed 10–16–19; 8:45 am]

BILLING CODE 4410–15–P

DEPARTMENT OF JUSTICE

[OMB Number 1110–New]

Agency Information Collection Activities; Proposed eCollection eComments Requested; New Collection

AGENCY: Federal Bureau of Investigation (FBI), Department of Justice.

ACTION: 30-Day Notice.

SUMMARY: The Department of Justice, Federal Bureau of Investigation, is submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995.

DATES: The Department of Justice encourages public comment and will accept input until November 18, 2019.

FOR FURTHER INFORMATION CONTACT: If you have additional comments especially on the estimated public

burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact Tonya Odom, Federal Bureau of Investigation, 935 Pennsylvania Ave NW, Washington, DC 20535, 202–324–3000, *atodom@fbi.gov.* Written comments and/or suggestions can also be sent to the Office of Management and Budget, Office of Information and Regulatory Affairs, Attention Department of Justice Desk Officer, Washington, DC 20503 or sent to *OIRA_submissions@omb.eop.gov.*

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

➢ Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the FBI, including whether the information will have practical utility;

➢ 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;

➢ Evaluate whether and if so how the quality, utility, and clarity of the information to be collected can be enhanced; and

➢ 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 submission of responses.

Overview of this Information Collection:

1. *Type of Information Collection:* New Collection.

2. *The Title of the Form/Collection:* FBI Special Agent Application Process Review Form.

3. *The agency form number, if any, and the applicable component of the Department sponsoring the collection:* ''There is no agency form number for this collection.'' The applicable component within the Department of Justice is the Federal Bureau of Investigation (FBI).

4. *Affected public who will be asked or required to respond, as well as a brief abstract:* Individuals; Anyone who has filled out any part of the FBI Special Agent Application in the previous three years will be asked to complete a brief voluntary survey recalling their experience and preparation tactics for the application process. This information is being collected by the Federal Bureau of Investigation for the purpose of improving the ease of the application process, eliminating any systematic barriers to success for applicants, and better understanding how to recruit and retain qualified applicants.

5. *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* We estimate roughly 40,000 individuals have applied to the Special Agent position at the FBI in the previous 3 years, we will solicit this entire population to participate in the voluntary survey though it is unlikely all 40,000 WILL respond. The survey will take approximately 10 minutes to complete.

6. An estimate of the total public burden (in hours) associated with the collection: 6,667 total hours of public burden, 10 minutes per survey for 40,000 respondents.

If additional information is required contact: Melody Braswell, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE, 3E.405A, Washington, DC 20530.

Dated: October 11, 2019.

Melody Braswell,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2019–22631 Filed 10–16–19; 8:45 am]

BILLING CODE 4410–02–P

MILLENNIUM CHALLENGE CORPORATION

[MCC FR 19–09]

Notice of Open Meeting

AGENCY: Millennium Challenge Corporation.

ACTION: Notice.

SUMMARY: In accordance with the requirements of the Federal Advisory Committee Act, the Millennium Challenge Corporation (MCC) Economic Advisory Council was established as a discretionary advisory committee on October 5, 2018. The MCC Economic Advisory Council serves MCC in an advisory capacity only and provides advice and guidance to MCC economists, evaluators, leadership of the Department of Policy and Evaluation, and senior MCC leadership regarding relevant trends in development economics, applied economic and evaluation methods, poverty analytics, as well as modeling, measuring, and evaluating development interventions. In doing so, an overarching purpose of the MCC Economic Advisory Council is to sharpen MCC's analytical methods and capacity in support of continuing development effectiveness. It also serves as a sounding board and reference group for assessing and advising on strategic policy innovations and methodological directions in MCC.

DATES: Friday, November 1st, 2019, from 9:00 a.m.–2:00 p.m. EDT which includes a break for lunch.

ADDRESSES: The meeting will be held at the Millennium Challenge Corporation, 1099 14th St. NW, Suite 700 Washington, DC 20005.

FOR FURTHER INFORMATION CONTACT: Brian Epley, 202.772.6515 *MCCEACouncil@mcc.gov* or visit *www.mcc.gov/about/org-unit/economic-advisory-council.*

SUPPLEMENTARY INFORMATION:

Agenda. During this meeting of the MCC Economic Advisory Council, members will be provided an overview of MCC's work and the context and function of the MCC Economic Advisory Council within MCC's mission, including amendments to the bylaws for the MCC Economic Advisory Council and a determination of a chairperson. The MCC Economic Advisory Council will also discuss issues related to MCC's core functions, including the following topics: (i) Balancing cost-recovery and social objectives with user charges and tariff policy; (ii) improving early beneficiary analysis to inform investment decision-making; and (iii) opportunities and challenges in MCC's use of results-based financing.

Public Participation: The meeting will be open to the public. Members of the public may file written statement(s) before or after the meeting. If you plan to attend, please submit your name and affiliation no later than Wednesday, October 30, 2019 to *MCCEACouncil@mcc.gov* to be placed on an attendee list.

Dated: October 11, 2019.

Jeanne M. Hauch,

VP/General Counsel and Corporate Secretary.

[FR Doc. 2019–22671 Filed 10–16–19; 8:45 am]

BILLING CODE 9211–03–P

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice: (19–068)]

NASA International Space Station Advisory Committee; Meeting

AGENCY: National Aeronautics and Space Administration (NASA).

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, as amended, the National Aeronautics and Space Administration announces a meeting of the NASA International Space Station (ISS) Advisory Committee. The purpose of the meeting is to review all aspects related to the safety and operational readiness of the ISS, and to assess the possibilities for using the ISS for future space exploration.

DATES: Monday, November 18, 2019, 11:00 a.m.–12:00 p.m., Eastern Time.

ADDRESSES: NASA Headquarters, Glennan Conference Room (1Q39), 300 E Street SW, Washington, DC 20546. Note: 1Q39 is located on the first floor of NASA Headquarters.

FOR FURTHER INFORMATION CONTACT: Mr. Patrick Finley, Office of International and Interagency Relations, (202) 358–5684, NASA Headquarters, Washington, DC 20546–0001.

SUPPLEMENTARY INFORMATION: This meeting will be open to the public up to the seating capacity of the room. This meeting is also accessible via teleconference. To participate telephonically, please contact Mr. Finley (202) 358–5684; before 4:30 p.m., Eastern Time, November 14, 2019. You will need to provide your name, affiliation, and phone number.

Attendees will be requested to sign a register and to comply with NASA security requirements, including the presentation of a valid picture ID to Security before access to NASA Headquarters. Foreign nationals attending this meeting will be required to provide a copy of their passport and visa in addition to providing the following information no less than 10 working days prior to the meeting: Full name; gender; date/place of birth; citizenship; visa information (number, type, expiration date); passport information (number, country, expiration date); employer/affiliation information (name of institution, address, country, telephone); title/position of attendee; and home address to Mr. Finley via email at *patrick.t.finley@nasa.gov* or by telephone at (202) 358–5684. U.S. citizens and permanent residents (green card holders) are requested to submit their name and affiliation at least three working days prior to the meeting to Mr. Finley.

It is imperative that the meeting be held on this date to accommodate the scheduling priorities of the key participants.

Patricia Rausch,

Advisory Committee Management Officer, National Aeronautics and Space Administration.

[FR Doc. 2019–22688 Filed 10–16–19; 8:45 am]

BILLING CODE 7510–13–P

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice: (19–069)]

NASA Applied Sciences Advisory Committee; Meeting

AGENCY: National Aeronautics and Space Administration.

ACTION: ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, as amended, the National Aeronautics and Space Administration (NASA) announces a meeting of the Applied Sciences Advisory Committee. This Committee reports to the Director, Earth Science Division, Science Mission Directorate, NASA Headquarters. The meeting will be held for the purpose of soliciting, from the scientific community and other persons, scientific and technical information relevant to program planning.

DATES: Tuesday, November 12, 2019, 11:00 a.m.–2:00 p.m.; and Friday, November 15, 2019, 2:00 p.m.–4:00 p.m., Eastern Time.

FOR FURTHER INFORMATION CONTACT: Ms. KarShelia Henderson, Science Mission Directorate, NASA Headquarters, Washington, DC 20546, (202) 358–2355, fax (202) 358–2779, or *khenderson@nasa.gov.*

SUPPLEMENTARY INFORMATION: The meeting will be available telephonically and by WebEx. You must use a touch-tone phone to participate in this meeting. Any interested person may dial the USA toll free conference call number 1–888–946–9423, passcode 4935973, to participate in this meeting by telephone on both days. The WebEx link is *https://nasaenterprise.webex.com/;* the meeting number on November 12 is 908 667 679, password is 2Tn4Svh?, and the meeting number on November 15 is 904 495 351, password is Kq2prmN$.

The agenda for the meeting includes the following topics:

—Earth Science and Applied Sciences Program Updates
—Private Sector and Applications
—Applications Guidebook
—Technical Content Strategy

The agenda will be posted on the Applied Sciences Advisory Committee web page: *https://science.nasa.gov/science-committee/subcommittees/nac-earth-science-subcommittee/advisory-groups*

It is imperative that the meeting be held on this date to accommodate the scheduling priorities of the key participants.

Patricia Rausch,

Advisory Committee Management Officer, National Aeronautics and Space Administration.

[FR Doc. 2019–22693 Filed 10–16–19; 8:45 am]

BILLING CODE 7510–13–P

NATIONAL CREDIT UNION ADMINISTRATION

Agency Information Collection Activities: Proposed Collection; Comment Request; Supervisory Committee Audits and Verifications

AGENCY: National Credit Union Administration (NCUA).

ACTION: Notice and request for comment.

SUMMARY: The National Credit Union Administration (NCUA), as part of a continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to comment on the following extension of a currently approved collection, as required by the Paperwork Reduction Act of 1995.

DATES: Written comments should be received on or before November 18, 2019 to be assured of consideration.

ADDRESSES: Send comments regarding the burden estimate, or any other aspect of this information collection, including suggestions for reducing the burden, to (1) Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: Desk Officer for NCUA, New Executive Office Building, Room 10235, Washington, DC 20503, or email at *OIRA_Submission@OMB.EOP.gov* and (2) NCUA PRA Clearance Officer, 1775 Duke Street, Suite 5080, Alexandria, VA 22314, or email at *PRAComments@ncua.gov.*

FOR FURTHER INFORMATION CONTACT: Copies of the submission may be obtained by contacting Mackie Malaka at (703) 548–2704, emailing *PRAComments@ncua.gov,* or viewing the entire information collection request at *www.reginfo.gov.*

SUPPLEMENTARY INFORMATION:

OMB Number: 3133–0059.

Title: Supervisory Committee Audits and Verifications.

Type of Review: Revision of a currently approved collection.

Abstract: Title 12 CFR part 715 prescribes the responsibilities of the supervisory committee to obtain an audit of the credit union and verification of member accounts as outlined in Section 115 of the Federal Credit Union Act, 12 U.S.C. 1761d. A supervisory committee audit is required at least once every calendar year covering the period since the last audit and to conduct a verification of members' accounts not less frequently than once every two years. The information is used by both the credit union and the NCUA to ensure through audit testing that the credit union's assets, liabilities, equity, income, and expenses exist, are properly valued, controlled and meet ownership, disclosure and classification requirements of sound financial reporting. A written report on the audit must be made to the board of directors and, if requested, NCUA. Working papers must be maintained and made available to NCUA. Independence requirements must be met; standards governing verifications and the methods used to verify member's passbooks and accounts are set forth. Section 741.202 makes these requirements applicable to federally insured state-chartered credit unions.

Affected Public: Private Sector: Businesses or other for-profits.

Estimated No. of Respondents: 5,308.

Estimated Annual Frequency: 4.16.

Estimated Total Annual Responses: 22,086.

Estimated Average Hours: 0.57.

Estimated Total Annual Burden Hours: 12,549.

Reason for Change: Adjustments are due to the decline in the number of FICUs due to industry consolidation from mergers and liquidations; the time per response was reduced to remove the regulatory burden reported under the PRA to only reflect the information collection burden associated with a recordkeeping requirement, and capture a disclosure requirement not previously reported.

By Gerard Poliquin, Secretary of the Board, the National Credit Union Administration, on October 11, 2019.

Dated: October 11, 2019.

Mackie I. Malaka,

NCUA PRA Clearance Officer.

[FR Doc. 2019–22686 Filed 10–16–19; 8:45 am]

BILLING CODE 7535–01–P

NATIONAL SCIENCE FOUNDATION

Agency Information Collection Activities: Comment Request; Grantee Reporting Requirements for Prediction of and Resilience Against Extreme Events (PREEVENTS)

AGENCY: National Science Foundation.

ACTION: Notice.

SUMMARY: The National Science Foundation (NSF) is announcing plans to renew this collection. In accordance with the requirements of the Paperwork Reduction Act of 1995, we are providing opportunity for public comment on this action. After obtaining and considering public comment, NSF will prepare the submission requesting Office of Management and Budget (OMB) clearance of this collection for no longer than 3 years.

COMMENTS: 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; (c) ways to enhance the quality, utility, and clarity of the information on respondents, including through the use of automated collection techniques or other forms of information technology; and (d) 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.

DATES: Written comments on this notice must be received by December 16, 2019 to be assured consideration. Comments received after that date will be considered to the extent practicable. Send comments to address below.

FOR FURTHER INFORMATION CONTACT: Suzanne H. Plimpton, Reports Clearance Officer, National Science Foundation, 2415 Eisenhower Avenue, Suite W18200, Alexandria, Virginia 22314; telephone (703) 292–7556; or send email to *splimpto@nsf.gov.* Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339, which is accessible 24 hours a day, 7 days a week, 365 days a year (including Federal holidays).

SUPPLEMENTARY INFORMATION:

Title of Collection: Grantee Reporting Requirements for Prediction of and Resilience against Extreme Events (PREEVENTS).

OMB Number: 3145–0244.

Expiration Date of Approval: January 31, 2020.

Type of Request: Intent to seek approval to renew an information collection.

Proposed Project: NSF and the Directorate for Geosciences (GEO) have long supported basic research in scientific and engineering disciplines necessary to understand natural hazards and extreme events. The Prediction of and Resilience against Extreme Events (PREEVENTS) program is one element of the NSF-wide Risk and Resilience activity, which has the overarching goal of improving predictability and risk assessment, and increasing resilience, in order to reduce the impact of extreme events on our life, society, and economy. PREEVENTS provides an additional mechanism to support research and related activities that will improve our understanding of the fundamental processes underlying natural hazards and extreme events in the geosciences.

PREEVENTS is intended to encourage new scientific directions in the domains of natural hazards and extreme events. PREEVENTS will consider proposals for conferences that will foster development of interdisciplinary or multidisciplinary communities required to address complex questions surrounding natural hazards and extreme events. Such proposals are called PREEVENTS Track 1 proposals.

In addition to standard NSF annual and final report requirements, PIs for all PREEVENTS Track 1 awards will be required to submit to NSF a public report that summarizes the conference activities, attendance, and outcomes; describes scientific and/or technical challenges that remain to be overcome in the areas discussed during the conference; and identifies specific next steps to advance knowledge in the areas of natural hazards and extreme events that were considered during the conference. These reports will be made publicly available via the NSF website, and are intended to foster nascent interdisciplinary or multidisciplinary communities and to enable growth of new scientific directions.

Use of the Information: NSF will use the information to understand and evaluate the outcomes of the conference, to foster growth of new scientific communities, and to evaluate the progress of the PREEVENTS program.

Estimate of Burden: 40 hours per award for 5–10 conference awards for a total of 200–400 hours.

Respondents: Universities and Colleges; Non-profit, non-academic organizations; For-profit organizations;

NSF-funded Federally Funded Research and Development Centers (FFRDCs).

Estimated Number of Responses per Report: One from each five to ten Track 1 awardees.

Dated: October 10, 2019.

Suzanne H. Plimpton,

Reports Clearance Officer, National Science Foundation.

[FR Doc. 2019–22604 Filed 10–16–19; 8:45 am]

BILLING CODE 7555–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2019–0104]

Information Collection: NRC Form 212, Qualifications Investigation, Professional, Technical and Administrative Positions

AGENCY: Nuclear Regulatory Commission.

ACTION: Renewal of existing information collection; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) invites public comment on the renewal of Office of Management and Budget (OMB) approval for an existing collection of information. The information collection is entitled, NRC Form 212, ''Qualifications Investigation, Professional, Technical and Administrative Positions.''

DATES: Submit comments by December 16, 2019. 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:

- *Federal Rulemaking Website:* Go to *https://www.regulations.gov/* and search for Docket ID NRC–2019–0104. Address questions about NRC docket IDs to Anne Frost; telephone: 301–287–9232; email: *Anne.Frost@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *Mail comments to:* David Cullison, Office of the Chief Information Officer, Mail Stop: T6–A10M, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

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: David Cullison, Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–2084; email: *Infocollects.Resource@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2019–0104 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–2019–0104. A copy of the collection of information and related instructions may be obtained without charge by accessing Docket ID NRC–2019–0104 on this website.
- *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.* A copy of the collection of information and related instructions may be obtained without charge by accessing ADAMS Package Accession ML19186A402. The supporting statement is available in ADAMS under Accession ML19283B472.
- *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.
- *NRC's Clearance Officer:* A copy of the collection of information and related instructions may be obtained without charge by contacting NRC's Clearance Officer, David Cullison, Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–2084; email: *Infocollects.Resource@nrc.gov.*

B. Submitting Comments

Please include Docket ID NRC–2019–0104 in the subject line of your comment submission, in order to ensure that the NRC is able to make your comment submission available to the public in this docket.

The NRC cautions you not to include identifying or contact information in comment submissions 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, and 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. Background

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the NRC is requesting public comment on its intention to request the OMB's approval for the information collection summarized below.

1. *The title of the information collection:* NRC Form 212, ''Qualifications Investigation, Professional, Technical and Administrative Positions.''
2. *OMB approval number:* 3150–0033.
3. *Type of submission:* Extension.
4. *The form number, if applicable:* NRC Form 212.
5. *How often the collection is required or requested:* On occasion. The forms are collected for every new hire to the NRC.
6. *Who will be required or asked to respond:* Former employers, supervisors, and other references indicated on job applications are asked to complete the NRC Form 212.
7. *The estimated number of annual responses:* 500.
8. *The estimated number of annual respondents:* 500.
9. *The estimated number of hours needed annually to comply with the information collection requirement or request:* 250 hours.
10. *Abstract:* Information requested on NRC Form 212, ''Qualifications Investigation, Professional, Technical, and Administrative Positions'' is used to determine the qualifications and suitability of external applicants for employment with the NRC. The completed form may be used to examine, rate and/or assess the prospective employee's qualifications. The information regarding the qualifications of applicants for employment is reviewed by professional

personnel of the Office of the Chief Human Capital Officer, in conjunction with other information in the NRC files, to determine the qualifications of the applicant for appointment to the position under consideration.

III. Specific Requests for Comments

The NRC is seeking comments that address the following questions:

1. Is the proposed collection of information necessary for the NRC to properly perform its functions? Does the information have practical utility?
2. Is the estimate of the burden of the information collection accurate?
3. Is there a way to enhance the quality, utility, and clarity of the information to be collected?
4. How can the burden of the information collection on respondents be minimized, including the use of automated collection techniques or other forms of information technology?

Dated at Rockville, Maryland, this 11th day of October, 2019.

For the Nuclear Regulatory Commission.

David C. Cullison,

NRC Clearance Officer, Office of the Chief Information Officer.

[FR Doc. 2019–22691 Filed 10–16–19; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2018–0233]

Information Collection: NRC Forms 540 and 540A, Uniform Low-Level Radioactive Waste Manifest (Shipping Paper) and Continuation Page

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of submission to the Office of Management and Budget; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) has recently submitted a request for renewal of an existing collection of information to the Office of Management and Budget (OMB) for review. The information collection is entitled, ''NRC Forms 540 and 540A, Uniform Low-Level Radioactive Waste Manifest (Shipping Paper) and Continuation Page.''

DATES: Submit comments by November 18, 2019. 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: Submit comments directly to the OMB reviewer at: OMB Office of Information and Regulatory Affairs (3150–0164), Attn: Desk Officer for the Nuclear Regulatory Commission, 725 17th Street NW, Washington, DC 20503; email: *oira_submission@omb.eop.gov.*

FOR FURTHER INFORMATION CONTACT: David Cullison, NRC Clearance Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–2084; email: *Infocollects.Resource@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2018–0233 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–2018–0233. A copy of the collection of information and related instructions may be obtained without charge by accessing Docket ID NRC–2018–0233 on this website.
- *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.* A copy of NRC Forms 540 and 540A and related instructions may be obtained without charge by accessing ADAMS Accession Nos. ML18313A144, ML18313A145, and ML071870172, respectively. The supporting statement is available in ADAMS under Accession No. ML19233A065.
- *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.
- *NRC's Clearance Officer:* A copy of the collection of information and related instructions may be obtained without charge by contacting the NRC's Clearance Officer, David Cullison, Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–2084; email: *Infocollects.Resource@nrc.gov.*

B. Submitting Comments

The NRC cautions you not to include identifying or contact information in comment submissions that you do not want to be publicly disclosed in your comment submission. All comment submissions are posted at *https://www.regulations.gov/* and entered into ADAMS. Comment submissions are not routinely edited to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the OMB, 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 comment submissions are not routinely edited to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. Background

Under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the NRC recently submitted a request for renewal of an existing collection of information to OMB for review entitled, ''NRC Forms 540 and 540A, Uniform Low-Level Radioactive Waste Manifest (Shipping Paper) and Continuation Page.'' The NRC hereby informs potential respondents that an agency may not conduct or sponsor, and that a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

The NRC published a **Federal Register** notice with a 60-day comment period on this information collection on July 3, 2019 (84 FR 31927).

1. *The title of the information collection:* ''NRC Forms 540 and 540A, Uniform Low-Level Radioactive Waste Manifest (Shipping Paper) and Continuation Page.''
2. *OMB approval number:* 3150–0164.
3. *Type of submission:* Extension.
4. *The form number if applicable:* NRC Forms 540 and 540A.
5. *How often the collection is required or requested:* Forms are used by shippers when radioactive waste is shipped. Quarterly or less frequent reporting is made to Agreement States depending on specific license conditions. No reporting is made to the NRC.
6. *Who will be required or asked to respond:* All NRC or Agreement State low-level waste facilities licensed pursuant to part 61 of title 10 of the *Code of Federal Regulations* (10 CFR) or equivalent Agreement State regulations. All generators, collectors, and processors of low-level waste intended for disposal at a low-level waste facility must complete the appropriate forms.

7. *The estimated number of annual responses:* 5,740.

8. *The estimated number of annual respondents:* 220.

Note that the NRC does not collect or retain data on manifest forms and the forms are not sent to or received by the NRC. The estimates provided in items seven and eight above are from the previous form renewal Notice. The NRC did not receive any public comment on the previous renewal suggesting that these estimates should be revised.

9. *An estimate of the total number of hours needed annually to comply with the information collection requirement or request:* 4,305.

10. *Abstract:* NRC Forms 540 and 540A provide a set of standardized forms to meet Department of Transportation (DOT), NRC, and State requirements. The forms were developed by the NRC at the request of low-level waste industry groups. The forms provide uniformity and efficiency in the collection of information contained in manifests which are required to control transfers of low-level radioactive waste intended for disposal at a land disposal facility. The NRC Form 540 contains information needed to satisfy DOT shipping paper requirements in 49 CFR part 172, and the waste tracking requirements of the NRC in 10 CFR part 20.

Dated at Rockville, Maryland, this 11th day of October, 2019.

For the Nuclear Regulatory Commission.

David C. Cullison,

NRC Clearance Officer, Office of the Chief Information Officer.

[FR Doc. 2019–22633 Filed 10–16–19; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2018–0235]

Information Collection: NRC Forms 542 and 542A, Uniform Low-Level Radioactive Waste Manifest (Index and Regional Compact Tabulation) and Continuation Page

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of submission to the Office of Management and Budget; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) has recently submitted a request for renewal of an existing collection of information to the Office of Management and Budget (OMB) for review. The information collection is entitled, ''NRC Forms 542 and 542A, Uniform Low-Level Radioactive Waste Manifest (Index and Regional Compact Tabulation) and Continuation Page.''

DATES: Submit comments by November 18, 2019. 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: Submit comments directly to the OMB reviewer at: OMB Office of Information and Regulatory Affairs (3150–0165), Attn: Desk Officer for the Nuclear Regulatory Commission, 725 17th Street NW, Washington, DC 20503; email: *oira_submission@omb.eop.gov.*

FOR FURTHER INFORMATION CONTACT: David Cullison, NRC Clearance Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–2084; email: *Infocollects.Resource@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2018–0235 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–2018–0235. A copy of the collection of information and related instructions may be obtained without charge by accessing Docket ID NRC–2018–0235 on this website.
- *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.* A copy of NRC Forms 542 and 542A and related instructions may be obtained without charge by accessing ADAMS Accession No. ML18313A148, ML18313A149, and ML071870172, respectively. The supporting statement is available in ADAMS under Accession No. ML19240A377.
- *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.
- *NRC's Clearance Officer:* A copy of the collection of information and related instructions may be obtained without charge by contacting the NRC's Clearance Officer, David Cullison, Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–2084; email: *Infocollects.Resource@nrc.gov.*

B. Submitting Comments

The NRC cautions you not to include identifying or contact information in comment submissions that you do not want to be publicly disclosed in your comment submission. All comment submissions are posted at *https://www.regulations.gov/* and entered into ADAMS. Comment submissions are not routinely edited to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the OMB, 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 comment submissions are not routinely edited to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. Background

Under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the NRC recently submitted a request for renewal of an existing collection of information to OMB for review entitled, ''NRC Forms 542 and 542A, Uniform Low-Level Radioactive Waste Manifest (Index and Regional Compact Tabulation) and Continuation Page.'' The NRC hereby informs potential respondents that an agency may not conduct or sponsor, and that a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

The NRC published a **Federal Register** notice with a 60-day comment period on this information collection on July 3, 2019 (84 FR 31930).

1. *The title of the information collection:* ''NRC Forms 542 and 542A, Uniform Low-Level Radioactive Waste Manifest (Index and Regional Compact Tabulation) and Continuation Page.''

2. *OMB approval number:* 3150–0165.

3. *Type of submission:* Extension.

4. *The form number if applicable:* NRC Forms 542 and 542A.

5. *How often the collection is required or requested:* Forms are used by shippers when radioactive waste is shipped. Quarterly or less frequent reporting is made to Agreement States

depending on specific license conditions. No reporting is made to the NRC.

6. *Who will be required or asked to respond:* All NRC or Agreement State low-level waste facilities licensed pursuant to part 61 of title 10 of the *Code of Federal Regulations* (10 CFR) or equivalent Agreement State regulations. All generators, collectors, and processors of low-level waste intended for disposal at a low-level waste facility must complete the appropriate forms.

7. *The estimated number of annual responses:* 756.

8. *The estimated number of annual respondents:* 22.

Note that the NRC does not collect or retain data on manifest forms and the forms are not sent to or received by the NRC. The estimates provided in items seven and eight above are from the previous form renewal Notice. The NRC did not receive any public comment on the previous renewal suggesting that these estimates should be revised.

9. *An estimate of the total number of hours needed annually to comply with the information collection requirement or request:* 567.

10. *Abstract:* NRC Forms 542 and 542A, provide a set of standardized forms to meet Department of Transportation, NRC, and State requirements. The forms were developed by NRC at the request of low-level waste industry groups. The forms provide uniformity and efficiency in the collection of information contained in manifests which are required to control transfers of low-level radioactive waste intended for disposal at a land disposal facility. The NRC Form 542, completed by waste collectors or processors, contains information which facilitates tracking the identity of the waste generator. That tracking becomes more complicated when the waste forms, dimensions, or packaging are changed by the waste processor. Each container of waste shipped from a waste processor may contain waste from several different generators. The information provided on the NRC Form 542 permits the States and Compacts to know the original generators of low-level waste, as authorized by the Low-Level Radioactive Waste Policy Amendments Act of 1985, so they can ensure that waste is disposed of in the appropriate Compact.

Dated at Rockville, Maryland, this 11th day of October, 2019.

For the Nuclear Regulatory Commission.

David C. Cullison,

NRC Clearance Officer, Office of the Chief Information Officer.

[FR Doc. 2019–22632 Filed 10–16–19; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2018–0234]

Information Collection: NRC Forms 541 and 541A, Uniform Low-Level Radioactive Waste Manifest (Container and Waste Description) and Continuation Page

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of submission to the Office of Management and Budget; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) has recently submitted a request for renewal of an existing collection of information to the Office of Management and Budget (OMB) for review. The information collection is entitled, ''NRC Forms 541 and 541A, Uniform Low-Level Radioactive Waste Manifest (Container and Waste Description) and Continuation Page.''

DATES: Submit comments by November 18, 2019. 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: Submit comments directly to the OMB reviewer at: OMB Office of Information and Regulatory Affairs (3150–0166), Attn: Desk Officer for the Nuclear Regulatory Commission, 725 17th Street NW, Washington, DC 20503; email: *oira_submission@omb.eop.gov*.

FOR FURTHER INFORMATION CONTACT: David Cullison, NRC Clearance Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–2084; email: *Infocollects.Resource@nrc.gov*.

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2018–0234 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–2018–0234. A copy of the collection of information and related instructions may be obtained without charge by accessing Docket ID NRC–2018–0234 on this website.
- *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*. A copy of NRC Forms 541 and 541A and related instructions may be obtained without charge by accessing ADAMS Accession Nos. ML18313A146, ML18313A147, and ML071870172, respectively. The supporting statement is available in ADAMS under Accession No. ML19240B715.
- *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.
- *NRC's Clearance Officer:* A copy of the collection of information and related instructions may be obtained without charge by contacting the NRC's Clearance Officer, David Cullison, Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–2084; email: *Infocollects.Resource@nrc.gov*.

B. Submitting Comments

The NRC cautions you not to include identifying or contact information in comment submissions that you do not want to be publicly disclosed in your comment submission. All comment submissions are posted at *https://www.regulations.gov/* and entered into ADAMS. Comment submissions are not routinely edited to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the OMB, 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 comment submissions are not routinely edited to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. Background

Under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the NRC recently

submitted a request for renewal of an existing collection of information to OMB for review entitled, ''NRC Forms 541 and 541A, Uniform Low-Level Radioactive Waste Manifest (Container and Waste Description) and Continuation Page.'' The NRC hereby informs potential respondents that an agency may not conduct or sponsor, and that a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

The NRC published a **Federal Register** notice with a 60-day comment period on this information collection on July 3, 2019 (84 FR 31931).

1. *The title of the information collection:* ''NRC Forms 541 and 541A, Uniform Low-Level Radioactive Waste Manifest (Container and Waste Description) and Continuation Page.''

2. *OMB approval number:* 3150–0166.

3. *Type of submission:* Extension.

4. *The form number if applicable:* NRC Forms 541 and 541A.

5. *How often the collection is required or requested:* Forms are used by shippers when radioactive waste is shipped. Quarterly or less frequent reporting is made to Agreement States depending on specific license conditions. No reporting is made to the NRC.

6. *Who will be required or asked to respond:* All NRC or Agreement State low-level waste facilities licensed pursuant to part 61 of title 10 of the *Code of Federal Regulations* (10 CFR) or equivalent Agreement State regulations. All generators, collectors, and processors of low-level waste intended for disposal at a low-level waste facility must complete the appropriate forms.

7. *The estimated number of annual responses:* 5,600.

8. *The estimated number of annual respondents:* 220.

Note that the NRC does not collect or retain data on manifest forms and the forms are not sent to or received by the NRC. The estimates provided in items seven and eight above are from the previous form renewal Notice. The NRC did not receive any public comment on the previous renewal suggesting that these estimates should be revised.

9. *An estimate of the total number of hours needed annually to comply with the information collection requirement or request:* 18,480.

10. *Abstract:* NRC Forms 541 and 541A provide a set of standardized forms to meet Department of Transportation, NRC, and State requirements. The forms were developed by the NRC at the request of low-level waste industry groups. The forms provide uniformity and efficiency in the collection of information contained in manifests which are required to control transfers of low-level radioactive waste intended for disposal at a land disposal facility. The NRC Form 541 contains information needed by disposal site facilities to safely dispose of low-level waste and information to meet NRC and State requirements regulating these activities.

Dated at Rockville, Maryland, this 11th day of October, 2019.

For the Nuclear Regulatory Commission.

David C. Cullison,

NRC Clearance Officer, Office of the Chief Information Officer.

[FR Doc. 2019–22630 Filed 10–16–19; 8:45 am]

BILLING CODE 7590–01–P

POSTAL REGULATORY COMMISSION

[Docket No. MC2020–8; Order No. 5271]

Mail Classification Schedule

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is acknowledging a recent Postal Service filing concerning changes to the Priority Mail Express International (PMEI) product description in the Mail Classification Schedule. This document informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* November 7, 2019.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov.* Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Introduction

On October 9, 2019, the Postal Service filed a notice of changes to product descriptions pursuant to Commission rule 39 CFR 3020.90.[1] The Postal Service seeks to make changes to Priority Mail Express International (PMEI) product descriptions in the Mail Classification Schedule (MCS). Notice at 1. The changes are intended to take effect on January 26, 2020. *Id.*

II. Summary of Changes

The Postal Service states that ''[t]he purpose of these minor modifications is to establish changes to PMEI relating to the list of destination countries offered at a discount at retail, as provided in section 2305.6 of the MCS.'' *Id.* The Postal Service avers that the proposed changes satisfy the requirements of 39 CFR 3020.90 because the changes should result in a more accurate representation of the Postal Service's offerings by informing postal retail customers of the destinations and weight steps eligible for the PMEI discount, the Notice is filed no later than 15 days prior to the intended effective date, and the changes merely revise the MCS without otherwise changing product offerings, or the prices or price groups. *Id.* at 1–2. The Postal Service also asserts that the proposed changes do not significantly change the user experience for any product and that there is no evidence that the changes will significantly impact competitors. *Id.* at 2.

III. Notice of Commission Action

Pursuant to 39 CFR 3020.91, the Commission has posted the Notice on its website and invites comments on whether the Postal Service's filings are consistent with 39 CFR part 3020, subpart E. Comments are due no later than November 7, 2019. The filing can be accessed via the Commission's website (*http://www.prc.gov*).

The Commission appoints Katrina R. Martinez to represent the interests of the general public (Public Representative) in this docket.

IV. Ordering Paragraphs

It is ordered:

1. The Commission establishes Docket No. MC2020–8 to consider matters raised by the Notice.

2. Comments by interested persons are due by November 7, 2019.

3. Pursuant to 39 U.S.C. 505, Katrina R. Martinez is appointed to serve as an officer of the Commission (Public Representative) to represent the interests of the general public in this proceeding.

4. The Commission directs the Secretary of the Commission to arrange for prompt publication of this notice in the **Federal Register**.

[1] Notice of United States Postal Service of Filing Minor Changes to a Product Description, October 9, 2019 (Notice).

By the Commission.

Darcie S. Tokioka,

Acting Secretary.

[FR Doc. 2019–22576 Filed 10–16–19; 8:45 am]

BILLING CODE 7710–FW–P

POSTAL REGULATORY COMMISSION

[Docket No. CP2020–5; Order No. 5272]

Competitive Price Adjustment

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is recognizing a recently filed Postal Service document with the Commission concerning changes in rates of general applicability for competitive products. The changes are scheduled to take effect January 26, 2020. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* October 25, 2019.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov.* Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Introduction and Overview

On October 9, 2019, the Postal Service filed notice with the Commission concerning changes in rates of general applicability for competitive products.[1] The Postal Service represents that, as required by 39 CFR 3015.2(b), the Notice includes an explanation and justification for the changes, the effective date, and a schedule of the changed rates. *See* Notice at 1. The changes are scheduled to take effect on January 26, 2020. *Id.*

Attached to the Notice is Governors' Decision No. 19–3, which states the new prices are in accordance with 39 U.S.C. 3632 and 3633 and 39 CFR 3015.2.[2] The Governors' Decision provides an analysis of the competitive products' price changes intended to demonstrate that the changes comply with 39 U.S.C. 3633 and 39 CFR part 3015. Governors' Decision No. 19–3 at 1. The attachment to the Governors' Decision sets forth the price changes and includes draft Mail Classification Schedule (MCS) language for competitive products of general applicability.

The Governors' Decision includes two additional attachments:

- A partially redacted table showing FY 2020 projected volumes, revenues, attributable costs, contribution, and cost coverage for each product, assuming implementation of the new prices on January 26, 2020.
- A partially redacted table showing FY 2020 projected volumes, revenues, attributable costs, contribution, and cost coverage for each product, assuming a hypothetical implementation of the new prices on October 1, 2019.

The Notice also includes an application for non-public treatment of the attributable costs, contribution, and cost coverage data in the unredacted version of the annex to the Governors' Decision, as well as the supporting materials for the data. Notice at 1–2.

Planned price adjustments. The Governors' Decision includes an overview of the Postal Service's planned price changes, which is summarized in the table below.

TABLE I–1—PROPOSED PRICE CHANGES

Product name	Average price increase (percent)
Domestic Competitive Products	
Priority Mail Express	3.5
Retail	3.8
Commercial Base	2.2
Commercial Plus	2.2
Priority Mail	4.1
Retail	4.9
Commercial Base	2.8
Commercial Plus	3.0
Parcel Select:	
Traditional	2.5
Lightweight	4.2
Parcel Return Service	4.9
Return Sectional Center Facility	4.9
Return Delivery Unit	4.9
First-Class Package Service	2.6
Retail	3.9
Commercial	2.2
Retail Ground	3.9
Domestic Extra Services	
Premium Forwarding Service Enrollment Fee	0.9–5.3
Adult Signature Service:	
Basic	3.9
Person-Specific	3.6
Address Enhancement Services	0.4–3.8
Competitive Post Office Box	10.4
Package Intercept Service	3.9
International Competitive Products	
Global Express Guaranteed	0.0
Priority Mail Express International	2.0
Priority Mail International	6.0
International Priority Airmail	5.9
International Priority Airmail M-Bags	5.9
International Surface Air Lift	5.9
International Surface Air Lift M-Bags	5.9
Airmail M-Bags	6.0
First-Class Package International Service	9.9
International Ancillary Services and Special Services	
International Ancillary Services	2.7

Source: *See* Governors' Decision No. 19–3 at 2–6 (showing percentage increases for products other than Adult Signature Service and new prices for Adult Signature Service); Mail Classification Schedule section 2645.1.2 (showing existing prices for Adult Signature Service).

II. Initial Administrative Actions

The Commission establishes Docket No. CP2020–5 to consider the Postal Service's Notice. Interested persons may express views and offer comments on whether the planned changes are consistent with 39 U.S.C. 3632, 3633, and 3642, 39 CFR part 3015, and 39 CFR 3020 subparts B and E. Comments are due no later than October 25, 2019. For specific details of the planned price changes, interested persons are encouraged to review the Notice, which is available on the Commission's website at *www.prc.gov.*

Pursuant to 39 U.S.C. 505, Curtis E. Kidd is appointed to serve as Public Representative to represent the interests of the general public in this docket.

III. Ordering Paragraphs

It is ordered:

[1] United States Postal Service Notice of Changes in Rates of General Applicability for Competitive Products, October 9, 2019 (Notice). Pursuant to 39 U.S.C. 3632(b)(2), the Postal Service is obligated to publish the Governors' Decision and record of proceedings in the **Federal Register** at least 30 days before the effective date of the new rates.

[2] Notice, Decision of the Governors of the United States Postal Service on Changes in Rates of General Applicability for Competitive Products (Governors' Decision No. 19–3), at 1 (Governors' Decision No. 19–3).

1. The Commission establishes Docket No. CP2020–5 to provide interested persons an opportunity to express views and offer comments on whether the planned changes are consistent with 39 U.S.C. 3632, 3633, and 3642, 39 CFR part 3015, and 39 CFR 3020 subparts B and E.

2. Comments are due no later than October 25, 2019.

3. Pursuant to 39 U.S.C. 505, the Commission appoints Curtis E. Kidd to serve as an officer of the Commission (Public Representative) to represent the interests of the general public in this docket.

4. The Secretary shall arrange for publication of this order in the **Federal Register**.

By the Commission.

Darcie S. Tokioka,

Acting Secretary.

[FR Doc. 2019–22587 Filed 10–16–19; 8:45 am]

BILLING CODE 7710–FW–P

POSTAL REGULATORY COMMISSION

[Docket No. MC2020–7; Order No. 5270]

Mail Classification Schedule

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is acknowledging a recent Postal Service filing concerning classification changes to the Mail Classification Schedule related to International Mail. This document informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* November 7, 2019.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov.* Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Introduction

On October 9, 2019, the Postal Service filed a notice of classification changes pursuant to Commission rule 39 CFR 3020.90.[1] The Postal Service seeks to make changes in the Mail Classification Schedule (MCS) governing International Mail. Notice at 1. The changes are intended to take effect on January 26, 2020, simultaneously with the implementation of the planned market dominant price changes filed in Docket No. R2020–1 [2] and the planned competitive price changes filed in Docket No. CP2020–5.[3] Notice at 1.

II. Summary of Changes

The Postal Service states that ''[t]he purpose of these minor modifications is to make changes to the country price list for international mail . . . in order to conform to official sources and improve the accuracy of the product descriptions in the MCS.'' *Id.* The Postal Service avers that the proposed changes satisfy the requirements of 39 CFR 3020.90 because the changes should result in a more accurate representation of the Postal Service's current offerings and should allow mailers to more precisely locate pertinent information, the Notice is filed more than 15 days prior to the intended effective date, and the changes merely make revisions concerning one possible destination for certain products listed in the MCS without otherwise changing those products or their prices or price groups. *Id.* at 1–2. The Postal Service also asserts that the proposed changes do not significantly change the user experience for any product and that there is no evidence that the changes will significantly impact competitors. *Id.* at 2.

III. Notice of Commission Action

Pursuant to 39 CFR 3020.91, the Commission has posted the Notice on its website and invites comments on whether the Postal Service's filings are consistent with 39 CFR part 3020, subpart E. Comments are due no later than November 7, 2019. The filing can be accessed via the Commission's website (*http://www.prc.gov*).

The Commission appoints Katrina R. Martinez to represent the interests of the general public (Public Representative) in this docket.

IV. Ordering Paragraphs

It is ordered:

1. The Commission establishes Docket No. MC2020–7 to consider matters raised by the Notice.

2. Comments by interested persons are due by November 7, 2019.

3. Pursuant to 39 U.S.C. 505, Katrina R. Martinez is appointed to serve as an officer of the Commission (Public Representative) to represent the interests of the general public in this proceeding.

4. The Commission directs the Secretary of the Commission to arrange for prompt publication of this notice in the **Federal Register**.

By the Commission.

Darcie S. Tokioka,

Acting Secretary.

[FR Doc. 2019–22577 Filed 10–16–19; 8:45 am]

BILLING CODE 7710–FW–P

[1] Notice of United States Postal Service of Minor Classification Changes, October 9, 2019 (Notice).

[2] Docket No. R2020–1, United States Postal Service Notice of Market-Dominant Price Change, October 9, 2019.

[3] Docket No. CP2020–5, United States Postal Service Notice of Changes in Rates of General Applicability for Competitive Products, October 9, 2019.

POSTAL REGULATORY COMMISSION

[Docket No. R2020–1; Order No. 5273]

Market Dominant Price Adjustment

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recently filed Postal Service notice of inflation-based rate adjustments affecting market dominant domestic and international products and services, along with temporary mailing promotions and numerous proposed classification changes. The adjustments and other changes are scheduled to take effect January 26, 2020. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* October 29, 2019.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov.* Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Introduction and Overview

On October 9, 2019, the Postal Service filed a notice of inflation-based price adjustments affecting market dominant domestic and international products and services, along with temporary mailing promotions and numerous

proposed classification changes to the Mail Classification Schedule (MCS).[1] The intended effective date is January 26, 2020. Notice at 1. The Notice, which was filed pursuant to 39 U.S.C. 3622 and 39 CFR part 3010, triggers a notice-and-comment proceeding.[2]

Contents of filing. The Postal Service's filing consists of the Notice, which the Postal Service represents addresses the data and information required under 39 CFR 3010.12; four attachments (Attachments A–D) to the Notice; and seven sets of workpapers filed as library references.

Attachment A presents the proposed price and related product description changes to the MCS. Notice, Attachment A. Attachments B and C address workshare discounts and the price cap calculation, respectively. *Id.* Attachments B and C. Attachment D presents the promotions schedule. *Id.* Attachment D.

Several library references present supporting financial documentation for the five classes of mail. Notice at 4–5 nn.9–11. The Postal Service filed one library reference pertaining to the two international mail products within First-Class Mail (Outbound Single-Piece First-Class Mail International and Inbound Letter Post) under seal and applied for non-public treatment of those materials.[3]

Planned price adjustments. The Postal Service's planned percentage changes by class are, on average, as follows:

Market dominant class	Planned price adjustment (%)
First-Class Mail	1.919
USPS Marketing Mail	1.891
Periodicals	1.900
Package Services	1.892
Special Services	1.905

Id. at 4.

Price adjustments for products within classes vary from the average. *See, e.g., id.* at 7, 22 (Table 5 showing range for First-Class Mail products and Table 7 showing range for USPS Marketing Mail products). Most of the planned adjustments entail increases to market dominant rates and fees; however, in a few instances, the Postal Service proposes either no adjustment or a decrease. *See id.* at 7.

Proposed classification changes. The Postal Service proposes numerous classification changes in its Notice and identifies the impact on the MCS in Attachment A. *Id.* at 37–39; *id.* Attachment A.

Calendar year 2020 promotions. The Postal Service seeks approval for the following six promotions for the indicated periods:

Tactile, Sensory and Interactive Mailpiece Engagement Promotion (February 1–July 31, 2020);

- Emerging and Advanced Technology Promotion (March 1–August 31, 2020);
- Earned Value Reply Mail Promotion (April 1–June 30, 2020);
- Personalized Color Transpromo Promotion (July 1–December 31, 2020);
- Mobile Shopping Promotion (August 1–December 31, 2020); and
- Informed Delivery Promotion (September 1–November 30, 2020).

Id. Attachment D.

II. Initial Administrative Actions

Pursuant to 39 CFR 3010.11(a), the Commission establishes Docket No. R2020–1 to consider the planned price adjustments for market dominant postal products and services, as well as the related classification changes, identified in the Notice. The Commission invites comments from interested persons on whether the Postal Service's filing is consistent with the applicable statutory and regulatory requirements, including 39 U.S.C. 3622 and 39 CFR part 3010. The Commission further notes that any issues specifically related to Docket No. R2019–1 First-Class Mail rates and the *Carlson* decision will be addressed in a separate order in Docket No. R2019–1 and will not be adjudicated as part of the instant proceeding. Comments are due no later than October 29, 2019.[4]

The public portions of the Postal Service's filing are available for review on the Commission's website (*http://www.prc.gov*). Comments and other material filed in this proceeding will be available for review on the Commission's website, unless the information contained therein is subject to an application for non-public treatment. The Commission's rules on non-public materials (including access to documents filed under seal) appear in 39 CFR part 3007.

Pursuant to 39 U.S.C. 505, the Commission appoints Anne C. O'Connor to represent the interests of the general public (Public Representative) in this proceeding.

III. Ordering Paragraphs

It is ordered:

1. The Commission establishes Docket No. R2020–1 to consider the planned price adjustments for market dominant postal products and services, as well as the related classification changes, identified in the Postal Service's October 9, 2019 Notice.

2. Comments on the planned price adjustments and related classification changes are due no later than October 29, 2019.

3. Pursuant to 39 U.S.C. 505, Anne C. O'Connor is appointed to serve as an officer of the Commission (Public Representative) to represent the interests of the general public in this proceeding.

4. The Commission directs the Secretary of the Commission to arrange for prompt publication of this notice in the **Federal Register**.

By the Commission.

Darcie S. Tokioka,

Acting Secretary.

[FR Doc. 2019–22651 Filed 10–16–19; 8:45 am]

BILLING CODE 7710–FW–P

[1] United States Postal Service Notice of Market-Dominant Price Change, October 9, 2019 (Notice).

[2] This is a Type 1–B proceeding. *See* 39 CFR part 3010, subparts A–C for additional information.

[3] *See* USPS Notice of Filing USPS–LR–R2020–1/NP1, October 9, 2019, Attachment 1.

[4] The Commission is mindful of the Comments on Procedure of the National Postal Policy Council, the Greeting Card Association, and the Major Mailers Association, October 10, 2019 and the United States Postal Service Response to Procedural Schedule Comments, October 10, 2019. The Commission continues to use the 20-day comment period as set forth in 39 CFR 3010.11(a)(5); however, the Commission notes that in order to sufficiently address the issues identified in the *Carlson* decision, its determination may exceed the 14-day deadline set forth in 39 CFR 3010.11(d). *See Carlson* v. *Postal Regulatory Commission,* No. 18–1328, slip op. (D.C. Cir. Sept. 13, 2019).

SECURITIES AND EXCHANGE COMMISSION

[SEC File No. 270–601, OMB Control No. 3235–0673]

Submission for OMB Review; Comment Request

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736.

Extension: Rule 15c3–5.

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (''PRA'') (44 U.S.C. 3501 *et seq.*) (''PRA''), the Securities and Exchange Commission (''Commission'') has submitted to the Office of Management and Budget (''OMB'') a request for approval of extension of the previously approved collection of information provided for in Rule 15c3–5 (17 CFR 240.15c3–5) under the Securities Exchange Act of 1934 (15 U.S.C. 78a *et seq.*) (''Exchange Act'').

Rule 15c3–5 under the Exchange Act requires brokers or dealers with access to trading directly on an exchange or alternative trading system (''ATS''),

including those providing sponsored or direct market access to customers or other persons, to implement risk management controls and supervisory procedures reasonably designed to manage the financial, regulatory, and other risks of this business activity.

The rule requires brokers or dealers to establish, document, and maintain certain risk management controls and supervisory procedures as well as regularly review such controls and procedures, and document the review, and remediate issues discovered to assure overall effectiveness of such controls and procedures. Each such broker or dealer is required to preserve a copy of its supervisory procedures and a written description of its risk management controls as part of its books and records in a manner consistent with Rule 17a–4(e)(7) under the Exchange Act. Such regular review is required to be conducted in accordance with written procedures and is required to be documented. The broker or dealer is required to preserve a copy of such written procedures, and documentation of each such review, as part of its books and records in a manner consistent with Rule 17a–4(e)(7) under the Exchange Act, and Rule 17a–4(b) under the Exchange Act, respectively.

In addition, the Chief Executive Officer (or equivalent officer) is required to certify annually that the broker or dealer's risk management controls and supervisory procedures comply with the rule, and that the broker-dealer conducted such review. Such certifications are required to be preserved by the broker or dealer as part of its books and records in a manner consistent with Rule 17a–4(b) under the Exchange Act. Compliance with Rule 15c3–5 is mandatory.

Respondents consist of broker-dealers with access to trading directly on an exchange or ATS. The Commission estimates that there are currently 570 respondents. To comply with Rule 15c3–5, these respondents will spend a total of approximately 91,200 hours per year (160 hours per broker-dealer × 570 broker-dealers = 91,200 hours). At an average internal cost per burden hour of approximately $358.51, the resultant total related internal cost of compliance for these respondents is $32,696,340 per year (91,200 burden hours multiplied by approximately $358.51/hour). In addition, for hardware and software expenses, the Commission estimates that the average annual external cost would be approximately $20,500 per broker-dealer, or $11,685,000 in the aggregate ($20,500 per broker-dealer × 570 brokers and dealers = $11,685,000).

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information under the PRA unless it displays a currently valid OMB control number.

The public may view background documentation for this information collection at the following website: *www.reginfo.gov.* Comments should be directed to: (i) Desk Officer for the Securities and Exchange Commission, Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10102, New Executive Office Building, Washington, DC 20503, or by sending an email to: *Lindsay.M.Abate@omb.eop.gov;* and (ii) Charles Riddle, Acting Director/Chief Information Officer, Securities and Exchange Commission, c/o Candace Kenner, 100 F Street NE, Washington, DC 20549, or by sending an email to: *PRA_Mailbox@sec.gov.* Comments must be submitted to OMB within 30 days of this notice.

Dated: October 10, 2019.

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2019–22580 Filed 10–16–19; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–87279; File No. SR–PEARL–2019–28]

Self-Regulatory Organizations; MIAX PEARL, LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Exchange Rule 519, MIAX PEARL Order Monitor

October 10, 2019.

Pursuant to the provisions of 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 October 3, 2019, MIAX PEARL, LLC (''MIAX PEARL'' or the ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') a proposed rule change as described in Items I and II 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

The Exchange is filing a proposal to amend Exchange Rule 519, MIAX PEARL Order Monitor (''MOM'').

The text of the proposed rule change is available on the Exchange's website at *http://www.miaxoptions.com/rule-filings/pearl* at MIAX PEARL's principal office, 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 Exchange Rule 519, MIAX PEARL Order Monitor (''MOM'') to remove a term in the Exchange's rule which creates an ambiguity concerning the application of the rule. Specifically, subsection (4) of paragraph (a), Limit Orders to Sell, provides that ''[f]or options with a National Best Bid (''NBB'') equal to or greater than $0.25 the System[3] will reject an incoming limit order that has a limit price equal to or less than the NBB by the lesser of (i) $2.50, or (ii) 50% of the NBB price.'' The second provision of the rule provides that, ''[f]or options with an NBB of $0.25 or less the System will accept any incoming limit order.''

The statements an NBB ''equal to or greater than $0.25'' and ''an NBB of $0.25 or less'' both contemplate the NBB being equal to $0.25. The operation of the rule requires a bifurcation at $0.25 and only one action (accepting or rejecting an incoming order) can occur when the NBB is equal to $0.25. The desired behavior by the Exchange, for limit orders to sell, is to accept an order at any price when the NBB is equal to $0.25 or less. Therefore the Exchange proposes to remove the phrase ''equal to or'' from the first sentence in the rule.

The new proposed rule text will provide that, ''[f]or options with a National Best Bid (''NBB'') greater than $0.25 the System will reject an

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] The term ''System'' means the automated trading system used by the Exchange for the trading of securities. *See* Exchange Rule 100.

incoming limit order that has a limit price equal to or less than the NBB by the lesser of (i) $2.50, or (ii) 50% of the NBB price. For options with an NBB of $0.25 or less the System will accept any incoming limit order.

The Exchange believes its proposed change provides additional detail and clarity to the Exchange's rule and eliminates any inadvertent ambiguity in the rule text concerning order protections for incoming limit orders to sell.

2. Statutory Basis

MIAX PEARL believes that its proposed rule change is consistent with Section 6(b) of the Act [4] in general, and furthers the objectives of Section 6(b)(5) of the Act [5] in particular, in that it is 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 mechanisms of a free and open market and a national market system and, in general, to protect investors and the public interest.

The Exchange believes its proposal promotes just and equitable principles of trade, removes impediments to and perfects the mechanisms of a free and open market and a national market system, and in general, protects investors and the public interest by providing clarity and precision in the Exchange's rule text. Additionally, the proposed change is consistent with the current System behavior as described in the Exchange's User Manual.[6]

The Exchange believes that the proposed change to the rule text provides further clarification to Members,[7] investors, and the public, regarding the Exchange's handling of limit orders to sell. The Exchange believes it is in the interest of investors and the public to accurately describe the behavior of the Exchange's System in its rules as this information may be used by investors to make decisions concerning the submission of their orders. Transparency and clarity are consistent with the Act because it removes impediments to and helps perfect the mechanism of a free and open market and a national market system, and, in general, protects investors and the public interest by accurately describing the behavior of the Exchange's System.

The Exchange believes that the proposed change promotes just and equitable principles of trade and removes impediments to and perfects the mechanism of a free and open market and a national market system and, in general, protects investors and the public interest by providing additional detail and clarity in the Exchange's rules. Further, the Exchange's proposal provides transparency and clarity in the rule and is consistent with the Act because it removes impediments to and helps perfect the mechanism of a free and open market and a national market system, and, in general, protects investors and the public interest by accurately describing the behavior of the Exchange's System. In particular, the Exchange believes that the proposed rule change will provide greater clarity to Members and the public regarding the Exchange's Rules, and it is in the public interest for rules to be accurate and concise so as to eliminate the potential for confusion.

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. The proposed rule change is designed to remove an unintentional ambiguity introduced in a prior rule change.[8]

The Exchange does not believe that the proposed rule change will impose any burden on inter-market competition as the Rules apply equally to all Exchange Members. The proposed rule change is not a competitive filing and is intended to improve the clarity and precision of the Exchange's rule text.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days after the date of the filing, or such shorter time as the Commission may designate, it has become effective pursuant to 19(b)(3)(A) of the Act [9] and Rule 19b–4(f)(6) [10] thereunder.

A proposed rule change filed under Rule 19b–4(f)(6) [11] normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b–4(f)(6)(iii),[12] the Commission may designate a shorter time if such action is consistent with protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay. The Exchange believes that waiver is consistent with the protection of investors and the public interest because it would remove any ambiguity in the Exchange's rule concerning its handling of limit orders to sell. The Commission believes that waiver of the 30-day operative delay is consistent with the protection of investors and the public interest because the proposal does not raise any new or novel issues and makes a non-substantive change to clarify the rule text. Accordingly, the Commission designates the proposed rule change to be operative on upon filing.[13]

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 shall institute proceedings to determine whether the proposed rule 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

[4] 15 U.S.C. 78f(b).

[5] 15 U.S.C. 78f(b)(5).

[6] MIAX PEARL User's Manual, August 2019, p 14, *https://www.miaxoptions.com/exchange-functionality-data/pearl.*

[7] The term ''Member'' means an individual or organization approved to exercise the trading rights associated with a Trading Permit. Members are deemed ''members'' under the Exchange Act. *See* Exchange Rule 100.

[8] *See* Securities Exchange Release No. 84887 (December 20, 2018), 83 FR 67452 (December 28, 2018) (SR–PEARL–2018–25).

[9] 15 U.S.C. 78s(b)(3)(A).

[10] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[11] 17 CFR 240.19b–4(f)(6).

[12] 17 CFR 240.19b–4(f)(6).

[13] For purposes only of waiving the 30-day operative delay, the Commission also has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

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 (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–PEARL–2019–28 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–PEARL–2019–28. 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 (*http://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. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–PEARL–2019–28 and should be submitted on or before November 7, 2019.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[14]

Jill M. Peterson,

Assistant Secretary.

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[14] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–87292; File No. SR–NYSEArca–2019–70]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend the NYSE Arca Equities Fees and Charges

October 11, 2019.

Pursuant to Section 19(b)(1) [1] of the Securities Exchange Act of 1934 (the ''Act'') [2] and Rule 19b–4 thereunder,[3] notice is hereby given that, on October 1, 2019, NYSE Arca, Inc. (''NYSE Arca'' or the ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''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

The Exchange proposes to amend the NYSE Arca Equities Fees and Charges (''Fee Schedule'') to (1) modify the requirements associated with the Step Up Tier 4, and (2) adopt a new pricing tier, Tape B Step Up Tier. The Exchange proposes to implement the fee changes effective October 1, 2019. The proposed rule change is available on the Exchange's website at *www.nyse.com,* at the principal office of the Exchange, 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 self-regulatory organization 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 those 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 parts of such statements.

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend the Fee Schedule to (1) modify the volume requirements applicable to ETP Holders (including Market Makers) to qualify for the per share credits for orders that provide displayed liquidity under the Step Up Tier 4,[4] and (2) adopt a new pricing tier, the Tape B Step Up Tier.

The proposed changes respond to the current competitive environment where order flow providers have a choice of where to direct liquidity-providing orders by offering further incentives for ETP Holders [5] to send additional displayed liquidity to the Exchange.

The Exchange proposes to implement the fee changes effective October 1, 2019.

Background

The Commission has repeatedly expressed its preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. 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.'' [6]

As the Commission itself recognized, the market for trading services in NMS stocks has become ''more fragmented and competitive.'' [7] Indeed, equity trading is currently dispersed across 13 exchanges,[8] 31 alternative trading systems,[9] and numerous broker-dealer internalizers and wholesalers, all competing for order flow. Based on publicly-available information for

[4] *See* Securities Exchange Act Release No. 85311 (March 14, 2019), 84 FR 10348 (March 20, 2019) (SR–NYSEArca–2019–10).

[5] All references to ETP Holders in connection with the Step Up Tier 4 and the Tape B Step Up Tier include Market Makers.

[6] *See* Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005).

[7] *See* Securities Exchange Act Release No. 51808, 84 FR 5202, 5253 (February 20, 2019) (File No. S7–05–18) (Final Rule).

[8] *See* Cboe U.S Equities Market Volume Summary, available at *https://markets.cboe.com/us/equities/market_share. See generally https://www.sec.gov/fast-answers/divisionsmarketregmrexchangesshtml.html.*

[9] *See* FINRA ATS Transparency Data, *available at https://otctransparency.finra.org/otctransparency/AtsIssueData.* A list of alternative trading systems registered with the Commission is *available at https://www.sec.gov/foia/docs/atslist.htm.*

August 2019, no single exchange has more than 19% market share (whether including or excluding auction volume).[10] Therefore, no exchange possesses significant pricing power in the execution of equity order flow. More specifically, in August 2019, the Exchange had 8.2% market share of executed volume of equity trades (excluding auction volume).[11]

The Exchange believes that the ever-shifting market share among the exchanges from month to month demonstrates that market participants can move order flow, or discontinue or reduce use of certain categories of products. While it is not possible to know a firm's reason for shifting order flow, the Exchange believes that one such reason is because of fee changes at any of the registered exchanges or non-exchange venues to which a firm routes order flow. With respect to non-marketable order flow that would provide displayed liquidity on an Exchange against which market makers can quote, ETP Holders can choose from any one of the 13 currently operating registered exchanges to route such order flow. Accordingly, competitive forces constrain exchange transaction fees that relate to orders that would provide displayed liquidity on an exchange.

Proposed Rule Change

The proposed rule change is designed to be available to all ETP Holders on the Exchange and is intended to provide ETP Holders an opportunity to receive an enhanced rebate by executing more of their orders on the Exchange. The Exchange currently provides credits to ETP Holders who submit orders that provide displayed liquidity on the Exchange. The Exchange currently has multiple levels of credits for orders that provide displayed liquidity that are based on the amount of volume of such orders that ETP Holders send to the Exchange.

As described in greater detail below, the Exchange proposes the following change:

• Modify the volume requirements applicable to ETP Holders to qualify for the Step Up Tier 4 by lowering the percentage threshold that an ETP Holder must meet, and modify the baseline month over which the minimum threshold requirement must be met; and

• A new pricing tier that provides an incremental credit between $0.0002 per share and $0.0004 per share to ETP Holders that provide liquidity in Tape B Securities when such providing volume is at least 0.50% of the US Tape B CADV and such volume in Tape B Securities as a percentage of US Tape B CADV is an increase of 20% or more over the ETP Holder's providing ADV as a percentage of US Tape B CADV in the third quarter (''3Q'') of 2019.

Step Up Tier 4

In this competitive environment, the Exchange has already established Step Up Tiers 1–4, which are designed to encourage ETP Holders that provide displayed liquidity on the Exchange to increase that order flow, which would benefit all ETP Holders by providing greater execution opportunities on the Exchange. In order to provide an incentive for ETP Holders to direct providing displayed order flow to the Exchange, the credits increase in the various tiers based on increased levels of volume directed to the Exchange.

Currently, the following credits are available to ETP Holders that provide increased levels of displayed liquidity on the Exchange:

Tier	*Credit for providing displayed liquidity*
Step Up Tier	$0.0030 (Tape A). $0.0023 (Tape B). $0.0031 (Tape C).
Step Up Tier 2	$0.0028 (Tape A and C). $0.0022 (Tape B).
Step Up Tier 3	$0.0025 (Tape A and C). $0.0022 (Tape B).
Step Up Tier 4	$0.0033 (Tape A and C). $0.0034 (Tape B).

Under the Step Up Tier 4, if an ETP Holder increases its providing liquidity on the Exchange by a specified percentage over the level that such ETP Holder provided liquidity in January 2019, it is eligible to earn higher credits for providing displayed liquidity. Specifically, to qualify for the credits under the Step Up Tier 4, an ETP Holder must directly execute providing average daily volume (ADV) per month that is an increase of no less than 0.70% of US CADV[12] for that month over the ETP Holder's providing ADV in January 2019, taken as a percentage of US CADV.

Currently, if an ETP Holder meets these Step Up Tier 4 qualifications, such ETP Holder is eligible to earn a credit of:

• $0.0033 per share for orders that provide displayed liquidity to the Book in Tape A and Tape C Securities, and

• $0.0034 per share for orders that provide displayed liquidity to the Book in Tape B Securities.[13]

With this proposed rule change, the Exchange proposes to modify the volume requirements applicable to ETP Holders to qualify for the Step Up Tier 4 by lowering the percentage threshold that an ETP Holder must meet, from a minimum of 0.70% of US CADV for the billing month to a minimum of 0.55% of US CADV for the billing month. Additionally, the Exchange proposes to modify the baseline month over which the minimum threshold requirement must be met from January 2019 to September 2019.

The purpose of the proposed rule change is to increase the incentive for order flow providers to send liquidity-providing orders to the Exchange. As described above, ETP Holders with liquidity-providing orders have a choice of where to send those orders. The Exchange believes that, if it reduces the requirement to qualify for a tiered credit, more ETP Holders will choose to route their liquidity-providing orders to the Exchange to qualify for the credit.

The Exchange does not know how much order flow ETP Holders choose to route to other exchanges or to off-exchange venues. While the Step Up Tier 4 pricing tier is available to all ETP Holders, to date, not one ETP Holder has qualified for it.[14] Without having a view of ETP Holders' activity on other markets and off-exchange venues, the Exchange has no way of knowing whether this proposed rule change would result in any ETP Holders qualifying for the Step Up Tier 4 credit. The Exchange cannot predict with certainty how many ETP Holders would avail themselves of this opportunity but additional liquidity-providing orders would benefit all market participants because it would provide greater execution opportunities on the Exchange.

The Exchange is not proposing to amend any of the credits payable under the Step Up Tier 4.

[10] *See* Cboe Global Markets U.S. Equities Market Volume Summary, available at *http://markets.cboe.com/us/equities/market_share/.*

[11] *See id.*

[12] US CADV means the United States Consolidated Average Daily Volume for transactions reported to the Consolidated Tape, excluding odd lots through January 31, 2014 (except for purposes of Lead Market Maker pricing), and excludes volume on days when the market closes early and on the date of the annual reconstitution of the Russell Investments Indexes. Transactions that are not reported to the Consolidated Tape are not included in US CADV. *See* Fee Schedule, footnote 3.

[13] *See* Securities Exchange Act Release No. 86122 (June 17, 2019), 84 FR 29258 (June 21, 2019) (SR–NYSEArca–2019–43).

[14] As of July 24, 2019, there are 165 ETP Holders on the Exchange that could qualify for the Exchange's Step Up pricing tiers.

Tape B Step Up Tier

The Exchange proposes to adopt a new pricing tier, Tape B Step Up Tier, that would offer an incremental credit to ETP Holders that qualify for the tier. As proposed, an ETP Holder that sends orders that add liquidity in Tape B Securities would receive the following:

- An incremental credit of $0.0002 per share when an ETP Holder's providing ADV in Tape B Securities during the billing month is at least 0.50% of the US Tape B CADV and the ETP Holder's providing ADV in Tape B Securities during the billing month as a percentage of US Tape B CADV is at least 20% more but less than 30% of the ETP Holder's providing ADV as a percentage of US Tape B CADV in 3Q 2019;
- An incremental credit of $0.0003 per share when an ETP Holder's providing ADV in Tape B Securities during the billing month is at least 0.50% of the US Tape B CADV and the ETP Holder's providing ADV in Tape B Securities during the billing month as a percentage of US Tape B CADV is at least 30% more but less than 40% of the ETP Holder's providing ADV as a percentage of US Tape B CADV in 3Q 2019; and
- An incremental credit of $0.0004 per share when an ETP Holder's providing ADV in Tape B Securities during the billing month is at least 0.50% of the US Tape B CADV and the ETP Holder's providing ADV in Tape B Securities during the billing month as a percentage of US Tape B CADV is at least 40% more than the ETP Holder's providing ADV as a percentage of US Tape B CADV in 3Q 2019.

The proposed incremental credit would be payable in addition to the ETP Holder's Tiered or Basic Rate credit(s); provided, however, that such combined credit(s) in Tape B Securities shall not exceed $0.0032 per share.

For example, assume an ETP Holder has providing ADV of 0.80% of Tape B CADV in Tape B securities in the baseline period of third quarter of 2019. Further assume that the same ETP Holder has providing ADV of 0.96% of Tape B in the billing month, which is at least 20% more but less than 30% of the ETP Holder's baseline ADV of 0.80% of Tape B CADV. Therefore, the ETP Holder in the above example would qualify to receive an incremental credit of $0.0002 per share. If instead, the same ETP Holder had providing ADV of Tape B CADV of 1.04% of Tape B in the billing month, then that ETP Holder would qualify for an incremental credit of $0.0003 per share, as 1.04% is at least 30% more but less than 40% of the ETP Holder's baseline ADV of 0.80% of Tape B CADV.[15] If instead, the same ETP Holder had providing ADV of Tape B CADV of 1.12% of Tape B in the billing month, then that ETP Holder would qualify for an incremental credit of $0.0004 per share, as 1.12% is at least 40% more than the ETP Holder's baseline ADV of 0.80% of Tape B CADV.[16]

As noted above, the Exchange operates in a competitive environment, particularly as it relates to attracting non-marketable, providing liquidity that would be displayed on the Exchange. Because, as proposed, the tier requires an ETP Holder to increase the volume of its liquidity-providing orders over that ETP Holder's 3Q 2019 baseline, the Exchange believes that the proposed incremental credit would provide an incentive for ETP Holders to route additional liquidity to the Exchange in order to qualify for it.

The proposed rule change is designed to incentivize ETP Holders to increase the orders sent to the Exchange that would provide liquidity, which would support the quality of price discovery and transparency on the Exchange. The Exchange believes that by correlating the level of the credits to the level of executed providing volume on the Exchange, the Exchange's fee structure would incentivize ETP Holders to submit more displayed, liquidity-providing orders to the Exchange that are likely to be executed (*i.e.,* are not orders that are intended to be displayed, but are priced such that they are not likely to be executed), thereby increasing the potential for incoming marketable orders submitted to the Exchange to receive an execution.

The proposed changes are not otherwise intended to address any other issues, and the Exchange is not aware of any significant problems that market participants would have in complying with the proposed changes.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,[17] in general, and furthers the objectives of Sections 6(b)(4) and (5) of the Act,[18] in particular, because it provides for the equitable allocation of reasonable dues, fees, and other charges among its members, issuers and other persons using its facilities and does not unfairly discriminate between customers, issuers, brokers or dealers.

The Proposed Fee Change is Reasonable

As discussed above, the Exchange operates in a highly fragmented and competitive market. 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.'' [19]

As the Commission itself recognized, the market for trading services in NMS stocks has become ''more fragmented and competitive.'' [20] Indeed, equity trading is currently dispersed across 13 exchanges,[21] 31 alternative trading systems,[22] and numerous broker-dealer internalizers and wholesalers, all competing for order flow. Based on publicly-available information, no single exchange has more than 19% market share (whether including or excluding auction volume).[23] Therefore, no exchange possesses significant pricing power in the execution of equity order flow. More specifically, as noted earlier, the Exchange averaged less than 9% market share of executed volume of equity trades (excluding auction volume) for August 2019.

The Exchange believes that the ever-shifting market share among the exchanges from month to month demonstrates that market participants can shift order flow, or discontinue to reduce use of certain categories of

[15] The ETP Holder would also qualify for the existing Tape B Tier 2 credit of $0.0028 by meeting the 1.0% of the US Tape B CADV requirement, for a total credit of $0.0031 per share ($0.0028 per share Tape B Tier 2 credit plus the proposed $0.0003 per share Tape B Step Up Tier credit).

[16] The ETP Holder would also qualify for the existing Tape B Tier 2 credit of $0.0028 by meeting the 1.0% of the US Tape B CADV requirement, for a total credit of $0.0032 per share ($0.0028 per share Tape B Tier 2 credit plus the proposed $0.0004 per share Tape B Step Up Tier credit).

[17] 15 U.S.C. 78f(b).

[18] 15 U.S.C. 78f(b)(4) and (5).

[19] *See* Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005).

[20] *See* Securities Exchange Act Release No. 51808, 84 FR 5202, 5253 (February 20, 2019) (File No. S7–05–18) (Final rule).

[21] *See* Cboe Global Markets, U.S Equities Market Volume Summary, available at *https://markets.cboe.com/us/equities/market_share/.*

[22] *See* FINRA ATS Transparency Data, *available at https://otctransparency.finra.org/otctransparency/AtsIssueData.* A list of alternative trading systems registered with the Commission is *available at https://www.sec.gov/foia/docs/atslist.htm.*

[23] *See* Cboe Global Markets U.S. Equities Market Volume Summary, available at *http://markets.cboe.com/us/equities/market_share/.*

products, in response to fee changes. With respect to non-marketable order which provide liquidity on an Exchange, ETP Holders can choose from any one of the 13 currently operating registered exchanges to route such order flow. Accordingly, competitive forces reasonably constrain exchange transaction fees that relate to orders that would provide displayed liquidity on an exchange. Stated otherwise, changes to exchange transaction fees can have a direct effect on the ability of an exchange to compete for order flow.

Given this competitive environment, the proposal represents a reasonable attempt to attract additional order flow to the Exchange.

The Exchange believes the proposed change to lower the volume requirements under the Step Up Tier 4 is reasonable because it would allow ETP Holders an additional opportunity to meet the requirement of the pricing tier to receive per share credits payable under the Step Up Tier 4, thereby encouraging the submission of additional liquidity to a national securities exchange. Submission of additional liquidity to the Exchange would promote price discovery and transparency and enhance order execution opportunities for ETP Holders from the substantial amounts of liquidity present on the Exchange. All ETP Holders would benefit from the greater amounts of liquidity that will be present on the Exchange, which would provide greater execution opportunities. The Exchange believes that the proposed change to modify the baseline month from January 2019 to September 2019 is reasonable given the trend of recent trading on the Exchange. The Exchange's market share in January 2019, the original baseline month adopted under the Step Up Tier 4, was 9.0%, and has declined to 8.2% in August 2019.[24] The Exchange believes modifying the baseline month would allow ETP Holders to more easily qualify for the pricing tier as it would need to submit lesser number of orders to qualify for the tier.

Because no ETP Holder to date has qualified for the Step Up Tier 4, the Exchange believes the proposed lower volume requirements are reasonable as they would provide an additional incentive for ETP Holders to qualify for this established tier and direct their order flow to the Exchange and provide meaningful added levels of displayed liquidity, thereby contributing to the depth and market quality on the Exchange.

The Exchange believes the proposed Tape B Step Up Tier would provide an incentive for ETP Holders to route additional liquidity-providing orders to the Exchange in Tape B Securities. As noted above, the Exchange operates in a highly competitive environment, particularly for attracting order flow that provides displayed liquidity on an exchange. The Exchange believes it is reasonable to provide a higher credit for orders that provide additional liquidity. Similarly, the Exchange believes that it is reasonable to provide an incremental credit to ETP Holders that meet the requirements of the Tape B Step Up Tier that add additional liquidity in Tape B Securities on the Exchange.

Since the proposed Tape B Step Up Tier would be new with a requirement for increased providing volume over the baseline month, no ETP Holder currently qualifies for the proposed pricing tier. The Exchange believes that a number of ETP Holders could qualify for the proposed higher credit but without a view of ETP Holder activity on other exchanges and off-exchange venues, the Exchange has no way of knowing whether the proposed rule change would result in any ETP Holder qualifying for the tier. The Exchange believes the proposed higher credit is reasonable as it would provide an additional incentive for ETP Holders to direct their order flow to the Exchange and provide meaningful added levels of liquidity in order to qualify for the higher credit, thereby contributing to depth and market quality on the Exchange.

The Exchange notes that volume-based incentives and discounts have been widely adopted by exchanges,[25] including the Exchange,[26] and are reasonable, equitable and non-discriminatory because they are open to all ETP Holders on an equal basis and provide additional credits that are reasonably related to the value to an exchange's market quality and associated higher levels of market activity.

On the backdrop of the competitive environment in which the Exchange currently operates, the proposed rule change is a reasonable attempt to increase liquidity on the Exchange and improve the Exchange's market share relative to its competitors.

The Proposed Fee Change is an Equitable Allocation of Fees and Credits

The Exchange believes its proposal equitably allocates its fees among its market participants.

First, the Exchange is not proposing to adjust the amount of the Step Up Tier 4 credits, which will remain at the current level for all ETP Holders. Rather, the proposal would continue to encourage ETP Holders to send orders that add liquidity to the Exchange, thereby contributing to robust levels of liquidity, which benefits all market participants. The Exchange believes that, for the reasons discussed above, lowering the requirements would make it easier for liquidity providers to qualify for the Step Up Tier 4 credit, thereby encouraging submission of additional liquidity to the Exchange. The proposed change will thereby encourage the submission of additional liquidity to a national securities exchange, thus promoting price discovery and transparency and enhancing order execution opportunities for ETP Holders from the substantial amounts of liquidity present on the Exchange. All ETP Holders would benefit from the greater amounts of liquidity that will be present on the Exchange, which would provide greater execution opportunities.

As noted above, no ETP Holder currently qualifies for the Step Up Tier 4 pricing tier. Without having a view of ETP Holders' activity on other markets and off-exchange venues, the Exchange has no way of knowing whether this proposed rule change would result in any ETP Holders qualifying for this tier. However, the Exchange believes the proposed lower volume requirements would provide an incentive for ETP Holders to continue to submit liquidity-providing order flow, which would promote price discovery and increase execution opportunities for all ETP Holders. The proposed change will thereby encourage the submission of additional liquidity to a national securities exchange, thus promoting price discovery and transparency and enhancing order execution opportunities for ETP Holders from the substantial amounts of liquidity present on the Exchange, which would benefit all market participants on the Exchange.

Finally, the Exchange believes that the proposed Tape B Step Up Tier is equitable because the magnitude of the additional credit is not unreasonably

[24] *See id.*

[25] *See e.g.,* Cboe BZX U.S. Equities Exchange (''BZX'') Fee Schedule, Footnote 1, Add Volume Tiers which provide enhanced rebates between $0.0025 and $0.0032 per share for displayed orders where BZX members meet certain volume thresholds.

[26] *See e.g.,* Fee Schedule, Step Up Tier, Step Up Tier 2, Step Up Tier 3 and Step Up Tier 4, which provide enhanced rebates between $0.0025 and $0.0033 per share in Tape A Securities, between $0.0022 and $0.0034 per share in Tape B Securities, and between $0.0025 and $0.0033 per share in Tape C Securities for orders that provide displayed liquidity where ETP Holders meet certain volume thresholds.

high relative to credits paid by other exchanges for orders that provide additional step up liquidity.[27] The Exchange believes the proposed rule change would improve market quality for all market participants on the Exchange and, as a consequence, attract more liquidity to the Exchange, thereby improving market-wide quality and price discovery.

Since the proposed Tape B Step Up Tier would be new, no ETP Holder currently qualifies for it. The Exchange believes that at least seven ETP Holders could qualify for the proposed higher credit, but without a view of ETP Holder activity on other exchanges and off-exchange venues, the Exchange has no way of knowing whether this proposed rule change would result in any ETP Holder qualifying for the tier. The Exchange believes the proposed higher credit is reasonable as it would provide an additional incentive for ETP Holders to direct their order flow to the Exchange and provide meaningful added levels of liquidity in order to qualify for the higher credit, thereby contributing to depth and market quality on the Exchange.

The Exchange believes the proposed rule change would improve market quality for all market participants on the Exchange and, as a consequence, attract more liquidity to the Exchange thereby improving market-wide quality. The proposal neither targets nor will it have a disparate impact on any particular category of market participant. ETP Holders that currently qualify for credits associated with Step Up pricing tiers on the Exchange will continue to receive credits when they provide liquidity to the Exchange. The Exchange believes that recalibrating the requirements for providing liquidity will continue to attract order flow and liquidity to the Exchange for the benefit of investors generally.

Since no ETP Holder presently qualifies for the credits associated with Step Up Tier 4, the proposal will not adversely impact their existing pricing or their ability to qualify for other credits provided by the Exchange. With the proposed new Tape B Step Up Tier, all ETP Holders would be eligible to qualify for the higher credit if they increase their Adding ADV over their own baseline of order flow. The Exchange believes that offering a higher step up credit for providing liquidity if the step up requirements for Tape B securities are met, will continue to attract order flow and liquidity to the Exchange, thereby providing additional price improvement opportunities on the Exchange and benefiting investors generally. As to those market participants that do not presently qualify for the adding liquidity credits, the proposal will not adversely impact their existing pricing or their ability to qualify for other credits provided by the Exchange.

The Proposed Fee Change Is Not Unfairly Discriminatory

The Exchange believes that the proposal is not unfairly discriminatory. In the prevailing competitive environment, ETP Holders are free to disfavor the Exchange's pricing if they believe that alternatives offer them better value.

The proposal to lower the volume requirement under Step Up Tier 4 neither targets or will it have a disparate impact on any particular category of market participant. The proposal does not permit unfair discrimination because the lower threshold would be applied to all similarly situated ETP Holders, who would all be eligible for the same credit on an equal basis. Accordingly, no ETP Holder already operating on the Exchange would be disadvantaged by this allocation of fees.

The Exchange believes it is not unfairly discriminatory to adopt lower volume requirements for ETP Holders to qualify for the Step Up Tier 4 pricing tier as the proposed change would apply on an equal basis to all ETP Holders that add liquidity by meeting the lower volume requirements. Further, the Exchange believes the proposed lower volume requirements would incentivize ETP Holders to execute more of their liquidity-providers orders on the Exchange to qualify for the increased credits payable under Step Up Tier 4. The Exchange also believes that the proposed change is not unfairly discriminatory because it is reasonably related to the value of the Exchange's market quality associated with higher volume. The proposed lower volume requirements would apply equally to all ETP Holders as each would be required to execute providing volume in Tapes A, B and C Securities during the billing month that is at least 0.55% of US CADV over its providing ADV in September 2019, taken as a percentage of US CADV, regardless of whether an ETP Holder currently meets the requirement of another pricing tier.

The Exchange believes it is not unfairly discriminatory to provide a higher per share step up credit, as the proposed credit would be provided on an equal basis to all ETP Holders that add liquidity by meeting the new proposed Tape B Step Up Tier's requirements. For the same reason, the Exchange believes it is not unfairly discriminatory to provide an additional incremental credit to ETP Holders that satisfy the Tape B Step Up Tier requirements and add liquidity in Tape B Securities. Further, the Exchange believes the proposed Tape B Step Up Tier credit would incentivize ETP Holders that meet the current tiered requirements to send more orders to the Exchange to qualify for higher credits. The Exchange also believes that the proposed change is not unfairly discriminatory because it is reasonably related to the value to the Exchange's market quality associated with higher volume.

Finally, the submission of orders to the Exchange is optional for ETP Holders in that they could choose whether to submit orders to the Exchange and, if they do, the extent of its activity in this regard. The Exchange believes that it is subject to significant competitive forces, as described below in the Exchange's statement regarding the burden on competition.

For the foregoing reasons, the Exchange believes that the proposal is consistent with the Act.

B. Self-Regulatory Organization's Statement on Burden on Competition

In accordance with Section 6(b)(8) of the Act,[28] the Exchange believes that the proposed rule change would not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. Instead, as discussed above, the Exchange believes that the proposed changes would encourage the submission of additional liquidity to a public exchange, thereby promoting market depth, price discovery and transparency and enhancing order execution opportunities for ETP Holders. As a result, the Exchange believes that the proposed change furthers the Commission's goal in adopting Regulation NMS of fostering integrated competition among orders, which promotes ''more efficient pricing of individual stocks for all types of orders, large and small.'' [29]

Intramarket Competition. The proposed change is designed to attract additional order flow to the Exchange. The Exchange believes that the proposed lower volume requirements would continue to incentivize market participants to direct providing displayed order flow to the Exchange. Greater liquidity benefits all market

[27] *See* note 25, *supra.*

[28] 15 U.S.C. 78f(b)(8).

[29] *See* Securities Exchange Act Release No. 51808, 70 FR 37495, 37498–99 (June 29, 2005) (S7–10–04) (Final Rule).

participants on the Exchange by providing more trading opportunities and encourages ETP Holders, to send orders, thereby contributing to robust levels of liquidity, which benefits all market participants. The proposed volume requirements would be applicable to all similarly-situated market participants, and, as such, the proposed change would not impose a disparate burden on competition among market participants on the Exchange.

Intermarket Competition. The Exchange operates in a highly competitive market in which market 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. As noted, the Exchange's market share of intraday trading (*i.e.,* excluding auctions) was 8.2% in August 2019. In such an environment, the Exchange must continually adjust its fees and rebates to remain competitive with other exchanges and with off-exchange venues. Because competitors are free to modify their own fees and credits in response, and because market participants may readily adjust their order routing practices, the Exchange does not believe its proposed fee change can impose any burden on intermarket competition.

The Exchange believes that the proposed change could promote competition between the Exchange and other execution venues, including those that currently offer similar order types and comparable transaction pricing, by encouraging additional orders to be sent to the Exchange for execution.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change is effective upon filing pursuant to Section 19(b)(3)(A) [30] of the Act and subparagraph (f)(2) of Rule 19b–4 [31] thereunder, because it establishes a due, fee, or other charge imposed by the Exchange.

At any time within 60 days of the filing of such 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 shall institute proceedings under Section 19(b)(2)(B) [32] of the Act 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 (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NYSEArca–2019–70 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–NYSEArca-2019–70. 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 (*http://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 offices of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSEArca–2019–70, and should be submitted on or before November 7, 2019.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[33]

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2019–22700 Filed 10–16–19; 8:45 am]

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[30] 15 U.S.C. 78s(b)(3)(A).

[31] 17 CFR 240.19b-4(f)(2).

[32] 15 U.S.C. 78s(b)(2)(B).

[33] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–87286; File No. SR–CboeBZX–2019–076]

Self-Regulatory Organizations; Cboe BZX Exchange, Inc.; Notice of Filing of a Proposed Rule Change, as Modified by Amendment No. 1, To List and Trade Shares of the Clearbridge Small Cap Value ETF Under Currently Proposed Rule 14.11(k)

October 10, 2019.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on September 26, 2019, Cboe BZX Exchange, Inc. (''Exchange'' or ''BZX'') filed with the Securities and Exchange Commission (''Commission'') a proposed rule change, and on October 9, 2019, the Exchange filed Amendment No. 1 to the proposed rule change, which amended and replaced the proposed rule change in its entirety. The proposed rule change, as modified by Amendment No. 1, is 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, as modified by Amendment No. 1, from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes a rule change to list and trade shares of the Clearbridge Small Cap Value ETF under currently proposed Rule 14.11(k).

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,

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

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

This Amendment No. 1 to SR–CboeBZX–2019–076 amends and replaces in its entirety the proposal as originally submitted on September 26, 2019. The Exchange submits this Amendment No. 1 in order to clarify certain points and add additional details to the proposal.

The Exchange has submitted a proposal and two subsequent amendments to add new Rule 14.11(k) for the purpose of permitting the listing and trading of Managed Portfolio Shares, which are securities issued by an actively managed open-end management investment company.[3] Proposed Rule 14.11(k)(2)(A) would require the Exchange to file separate proposals under Section 19(b) of the Act before listing and trading any series of Managed Portfolio Shares on the Exchange. As such, the Exchange is submitting this proposal in order to list and trade shares of the Clearbridge Small Cap Value Fund (the ''Fund'') under proposed Rule 14.11(k).

Description of the Fund and the Trust

The shares of the Fund (the ''Shares'') will be issued by Precidian ETF Trust II (the ''Trust''), a statutory trust organized under the laws of the State of Delaware and registered with the Commission as an open-end management investment company.[4] The investment adviser to the Trust will be Precidian Funds LLC (the ''Adviser''). The Sub-Adviser to the Fund will be ClearBridge Investments, LLC (the ''Sub-Adviser'' or ''ClearBridge''). Legg Mason Investor Services, LLC (the ''Distributor'') will serve as the distributor of the Fund's Shares. All statements and representations made in this filing regarding the description of the portfolio or reference assets, limitations on portfolio holdings or reference assets, dissemination and availability of the Verified Intraday Indicative Value (''VIIV''),[5] reference assets, and intraday indicative values, and the applicability of Exchange rules shall constitute continued listing requirements for listing the Shares on the Exchange, as provided under proposed Rule 14.11(a).

Proposed Rule 14.11(k)(2)(D) provides that if the investment adviser to the Investment Company issuing Managed Portfolio Shares is registered as a broker-dealer or is affiliated with a broker-dealer, such investment adviser will erect and maintain a ''fire wall'' between the investment adviser and personnel of the broker-dealer or broker-dealer affiliate, as applicable, with respect to access to information concerning the composition and/or changes to such Investment Company portfolio and/or Creation Basket.[6] Any person related to the investment adviser or Investment Company who makes decisions pertaining to the Investment Company's portfolio composition or has access to information regarding the Investment Company's portfolio composition, Creation Basket, or changes thereto, must be subject to procedures designed to prevent the use and dissemination of material nonpublic information regarding the applicable Investment Company portfolio or Creation Basket.[7] Proposed Rule 14.11(k)(2)(D) is similar to Rule 14.11(c)(5)(A)(i), related to Index Fund Shares, except that proposed Rule 14.11(k)(2)(D) relates to the establishment of a ''fire wall'' between the investment adviser and the broker-dealer as applicable to an Investment Company's portfolio and Creation Basket, not an underlying benchmark index, as is the case with index-based funds. Proposed Rule 14.11(k)(2)(D) is also similar to Rule 14.11(i)(7), related

[3] As proposed, the term ''Managed Portfolio Share'' means a security that (a) represents an interest in an investment company registered under the Investment Company Act of 1940 (''Investment Company'') organized as an open-end management investment company, that invests in a portfolio of securities selected by the Investment Company's investment adviser consistent with the Investment Company's investment objectives and policies; (b) is issued in a Creation Unit, or multiples thereof, in return for a designated portfolio of instruments (and/or an amount of cash) with a value equal to the next determined net asset value and delivered to the Authorized Participant (as defined in the Investment Company's Form N–1A filed with the SEC) through a Confidential Account; (c) when aggregated into a Redemption Unit, or multiples thereof, may be redeemed for a designated portfolio of instruments (and/or an amount of cash) with a value equal to the next determined net asset value delivered to the Confidential Account for the benefit of the Authorized Participant; and (d) the portfolio holdings for which are disclosed within at least 60 days following the end of every calendar quarter. *See* Securities Exchange Act Release No. 86157 (June 19, 2019), 84 FR 29892 (June 25, 2019) and 87062 (September 23, 2019) (SR–CboeBZX–2019–047) (the ''Proposal'').

[4] The Trust is registered under the 1940 Act. The Trust plans to file a registration statement on Form N–1A relating to the Fund (the ''Registration Statement''). An order granting exemptive relief to the Trust was issued on May 20, 2019 (File No. 812–14405) (the ''Exemptive Order''). Investments made by the Fund will comply with the conditions set forth in the Exemptive Order. The description of the operation of the Trust and the Fund herein is based, in part, on the Exemptive Order. The Exemptive Order specifically notes that ''granting the requested exemptions is appropriate in and consistent with the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act. It is further found that the terms of the proposed transactions, including the consideration to be paid or received, are reasonable and fair and do not involve overreaching on the part of any person concerned, and that the proposed transactions are consistent with the policy of each registered investment company concerned and with the general purposes of the Act.'' *See* Investment Company Act Release Nos. 33440 and 33477.

[5] Proposed Rule 14.11(k)(3)(B) defines the term VIIV as the indicative value of a Managed Portfolio Share based on all of the holdings of a series of Managed Portfolio Shares as of the close of business on the prior business day and, for corporate actions, based on the applicable holdings as of the opening of business on the current business day, priced and disseminated in one second intervals during Regular Trading Hours by the Reporting Authority.

[6] Proposed Rule 14.11(k)(3)(E) defines the term ''Creation Basket'' as on any given business day the names and quantities of the specified instruments that are required for an AP Representative to deposit in-kind on behalf of an Authorized Participant in exchange for a Creation Unit and the names and quantities of the specified instruments that will be transferred in-kind to an AP Representative on behalf of an Authorized Participant in exchange for a Redemption Unit, which will be identical and will be transmitted to each AP Representative before the commencement of trading.

[7] An investment adviser to an open-end fund is required to be registered under the Investment Advisers Act of 1940 (the ''Advisers Act''). As a result, the Adviser, the Sub-Adviser, and their respective related personnel will be subject to the provisions of Rule 204A–1 under the Advisers Act relating to codes of ethics. This Rule requires investment advisers to adopt a code of ethics that reflects the fiduciary nature of the relationship to clients as well as compliance with other applicable securities laws. Accordingly, procedures designed to prevent the communication and misuse of non-public information by an investment adviser must be consistent with Rule 204A–1 under the Advisers Act. In addition, Rule 206(4)–7 under the Advisers Act makes it unlawful for an investment adviser to provide investment advice to clients unless such investment adviser has (i) adopted and implemented written policies and procedures reasonably designed to prevent violations, by the investment adviser and its supervised persons, of the Advisers Act and the Commission rules adopted thereunder; (ii) implemented, at a minimum, an annual review regarding the adequacy of the policies and procedures established pursuant to subparagraph (i) above and the effectiveness of their implementation; and (iii) designated an individual (who is a supervised person) responsible for administering the policies and procedures adopted under subparagraph (i) above.

to Managed Fund Shares, except that proposed Rule 14.11(k)(2)(D) relates to the establishment of a ''fire wall'' between the investment adviser and the broker-dealer as applicable to an Investment Company's portfolio and Creation Basket, and not just the underlying portfolio, as is the case with Managed Fund Shares. The Adviser is not registered as a broker-dealer or affiliated with a broker-dealer. The Sub-Adviser is not registered as a broker-dealer, but is affiliated with a broker-dealer and has implemented and will maintain a ''fire wall'' with respect to such broker-dealer regarding access to information concerning the composition and/or changes to the Fund's portfolio and Creation Basket.

In the event (a) the Adviser or Sub-Adviser becomes registered as a broker-dealer or becomes newly affiliated with a broker-dealer, or (b) any new adviser or sub-adviser is a registered broker-dealer or becomes affiliated with a broker-dealer, it will implement and maintain a fire wall with respect to its relevant personnel or its broker-dealer affiliate regarding access to information concerning the composition and/or changes to the portfolio and the Creation Basket, and will be subject to procedures designed to prevent the use and dissemination of material non-public information regarding such portfolio or Creation Basket.

Further, proposed Rule 14.11(k)(2)(E) requires that any person or entity, including an AP Representative, custodian, pricing verification agent, reporting authority, distributor, or administrator, who has access to information regarding the Investment Company's portfolio composition, the Creation Basket, or changes thereto, must be subject to procedures designed to prevent the use and dissemination of material nonpublic information regarding the applicable Investment Company portfolio or Creation Basket. Moreover, if any such person or entity is registered as a broker-dealer or affiliated with a broker-dealer, such person or entity will erect and maintain a ''fire wall'' between the person or entity and the broker-dealer with respect to access to information concerning the composition and/or changes to such Investment Company portfolio or Creation Basket.

The portfolio for the Fund will consist primarily of U.S. exchange-listed equity securities and shares issued by other U.S. exchange-listed ETFs. All exchange-listed equity securities in which the Fund will invest will be listed and traded on U.S. national securities exchanges.

Description of the Fund

Clearbridge Small Cap Value ETF

The Fund seeks long-term capital growth. Under Normal Market Conditions[8] the Fund will invest at least 80% of its net assets, plus borrowings for investment purposes, in U.S. exchange-listed common stocks and other equity securities of small capitalization U.S. companies or in other U.S. exchange-listed investments with similar economic characteristics, including only the following U.S. exchange-listed securities: Common stocks, preferred securities, securities of other investment companies and of real estate investment companies (''REITs''), and warrants and rights. The portfolio managers use quantitative parameters to select a universe of smaller capitalized companies that fit the Fund's general investment criteria. In selecting individual securities from within this range, the portfolio managers look for ''value'' attributes, such as low stock price relative to earnings, book value and cash flow and high return on invested capital. The portfolio managers also use quantitative methods to identify catalysts and trends that might influence the Fund's industry or sector focus, or the portfolio managers' individual security selection.

In addition, the Fund may also invest up to 20% of its net assets, plus borrowings for investment purposes, in common stocks, preferred securities, and warrants and rights of U.S. exchange-listed companies with larger market capitalizations, U.S. ETFs,[9] U.S. exchange-listed ADRs, U.S. exchange-listed equity futures contracts, and U.S. exchange-listed equity index futures contracts. The Fund may also hold cash without limitation.

The Exchange notes that the Fund's holdings will meet the generic listing standards applicable to series of Managed Fund Shares under Rule 14.11(i)(4)(C). While such standards do not apply directly to series of Managed Portfolio Shares, the Exchange believes that the overarching policy issues related to liquidity, market cap, diversity, and concentration of portfolio holdings that Rule 14.11(i)(4)(C) is intended to address are equally applicable to series of Managed Portfolio Shares.

Investment Restrictions

The Fund may hold up to an aggregate amount of 15% of its net assets in illiquid assets.[10] Illiquid securities and other illiquid assets include those subject to contractual or other restrictions on resale and other instruments or assets that lack readily available markets as determined in accordance with Commission staff guidance.[11] The Fund will monitor its portfolio liquidity on an ongoing basis to determine whether, in light of current circumstances, an adequate level of liquidity is being maintained, and will consider taking appropriate steps in order to maintain adequate liquidity. In any event, the Fund will not purchase any securities that are illiquid investments at the time of purchase.

According to the Registration Statement, the Fund will seek to qualify for treatment as a Regulated Investment Company (''RIC'') under the Internal Revenue Code.[12]

The Shares of the Fund will conform to the initial and continued listing criteria under proposed Rule 14.11(k). The Fund's holdings will be limited to and consistent with what is permissible under the Exemptive Order and described herein.

The Fund's investments will be consistent with its investment objective

[8] Proposed Rule 14.11(k)(3)(I) defines the term ''Normal Market Conditions'' as including, but not limited to, the absence of trading halts in the applicable financial markets generally; operational issues (*e.g.,* systems failure) causing dissemination of inaccurate market information; or force majeure type events such as natural or manmade disaster, act of God, armed conflict, act of terrorism, riot or labor disruption or any similar intervening circumstance.

[9] For purposes of describing the holdings of the Fund, ETFs include Portfolio Depository Receipts (as described in Rule 14.11(b)); Index Fund Shares (as described in Rule 14.11(c)); and Managed Fund Shares (as described in Rule 14.11(i)). The ETFs in which the Fund may invest all will be listed and traded on U.S. national securities exchanges. While the Fund may invest in inverse ETFs, the Fund will not invest in leveraged (*e.g.,* 2X, –2X, 3X or –3X) ETFs.

[10] *See* Rule 22e–4(b)(1)(iv), which prohibits a fund from acquiring any illiquid investment if, immediately after the acquisition, the fund would have invested more than 15% of its net assets in illiquid investments that are assets. *See* Investment Company Act Release No. 32315 (Oct. 13, 2016), 81 FR 82142 (Nov. 18, 2016) (adopting Rule 22e–4 under the 1940 Act). Prior to the adoption of Rule 22e–4 in 2016, the Commission had long-standing guidelines that required open-end funds to hold no more than 15% of their net assets in illiquid securities and other illiquid assets. *See* Investment Company Act Release No. 28193 (March 11, 2008), 73 FR 14618 (March 18, 2008), FN 34. *See also* Investment Company Act Release Nos. 5847 (October 21, 1969), 35 FR 19989 (December 31, 1970) (Statement Regarding ''Restricted Securities''); and 18612 (March 12, 1992), 57 FR 9828 (March 20, 1992) (Revisions of Guidelines to Form N–1A).

[11] A fund's portfolio security is illiquid if it cannot be disposed of in the ordinary course of business within seven days at approximately the value ascribed to it by the fund. *See* Investment Company Act Release Nos. 14983 (March 12, 1986), 51 FR 9773 (March 21, 1986) (adopting amendments to Rule 2a–7 under the 1940 Act); and 17452 (April 23, 1990), 55 FR 17933 (April 30, 1990) (adopting Rule 144A under the Securities Act of 1933).

[12] 26 U.S.C. 851.

and will not be used to enhance leverage. While the Fund may invest in inverse ETFs, the Fund will not invest in leveraged (*e.g.,* 2X, –2X, 3X or –3X) ETFs.

Creations and Redemptions of Shares

Creations and redemptions of the Shares will occur as described in the Proposal. More specifically, in connection with the creation and redemption of Creation Units [13] and Redemption Units,[14] the delivery or receipt of any portfolio securities in-kind will be required to be effected through a separate confidential brokerage account (a ''Confidential Account'').[15] Authorized Participants (as defined in the Fund's Registration Statement, ''AP'') will sign an agreement with an AP Representative [16] establishing the Confidential Account for the benefit of the AP. AP Representatives will be broker-dealers. An AP must be a Depository Trust Company (''DTC'') Participant that has executed a ''Participant Agreement'' with the Distributor with respect to the creation and redemption of Creation Units and Redemption Units and formed a Confidential Account for its benefit in accordance with the terms of the Participant Agreement. For purposes of creations or redemptions, all transactions will be effected through the respective AP's Confidential Account, for the benefit of the AP without disclosing the identity of such securities to the AP.

Each AP Representative will be given, before the commencement of trading each Business Day (defined below), the Creation Basket for that day. This information will permit an AP that has established a Confidential Account with an AP Representative, to instruct the AP Representative to buy and sell positions in the portfolio securities to permit creation and redemption of Creation Units and Redemption Units. Shares of the Fund will be issued and redeemed in Creation Units and Redemption Units of 5,000 or more Shares. The Fund will offer and redeem Creation Units and Redemption Units on a continuous basis at the net asset value (the ''NAV'') per share next determined after receipt of an order in proper form. The NAV per share of the Fund will be determined as of the close of regular trading on the Exchange on each day that the Exchange is open (a ''Business Day''). The Fund will sell and redeem Creation Units and Redemption Units only on Business Days. The Adviser anticipates that the initial price of a share will range from $20 to $60, and that the price of a Creation Unit will be at least $100,000.

To keep costs low and permit the Fund to be as fully invested as possible, Shares will be purchased and redeemed in Creation Units and Redemption Units and generally on an in-kind basis. Accordingly, except where the purchase or redemption will include cash under the circumstances described in the Registration Statement, APs will be required to purchase Creation Units by making an in-kind deposit of specified instruments (''Deposit Instruments''), and APs redeeming their Shares will receive an in-kind transfer of specified instruments (''Redemption Instruments'') through the AP Representative in their Confidential Account.[17]

Placement of Purchase Orders

The Fund will issue Shares through the Distributor on a continuous basis at NAV. The Exchange represents that the issuance of Shares will operate in a manner similar to that of other ETFs. The Fund will issue Shares only at the NAV per share next determined after an order in proper form is received.

In the case of a creation, the AP would enter an irrevocable creation order with the Fund and direct the AP Representative to purchase the Creation Basket. The AP Representative would then purchase the necessary securities in the Confidential Account. In purchasing the necessary securities, the AP Representative will use methods, such as breaking the transaction into multiple transactions and transacting in multiple marketplaces, to avoid revealing the composition of the Creation Basket. Once the Creation Basket has been acquired in the Confidential Account, the AP Representative would contribute the Creation Basket in-kind to the Fund.

The Distributor will furnish acknowledgements to those placing such orders that the orders have been accepted, but the Distributor may reject any order which is not submitted in proper form, as described in the Fund's prospectus or Statement of Additional Information (''SAI''). The NAV of the Fund is expected to be determined once each Business Day at a time determined by the Trust's Board of Trustees (''Board''), currently anticipated to be as of the close of the regular trading session on the Exchange (ordinarily 4:00 p.m. E.T.) (the ''Valuation Time''). The Fund will establish a cut-off time (''Order Cut-Off Time'') for purchase orders in proper form. Such Order Cut-Off Time will be provided in the Registration Statement. To initiate a purchase of Shares, an AP must submit to the Distributor an irrevocable order to purchase such Shares after the most recent prior Valuation Time. All orders to purchase Creation Units must be received by the Distributor no later than the Order Cut-Off Time in each case on the date such order is placed (''Transmittal Date'') for the AP to receive the NAV per share determined on the Transmittal Date.[18]

Purchases of Shares will be settled in-kind and/or cash for an amount equal to the applicable NAV per share purchased plus applicable ''Transaction Fees,'' as discussed below. While the Fund will generally receive securities in-kind, the Adviser may determine from time to time that it is not in the Fund's best interests to receive securities in-kind, but rather to receive cash.

Authorized Participant Redemption

The Shares may be redeemed to the Fund in Redemption Unit size or multiples thereof as described below. Redemption orders of Redemption Units must be placed by an AP (''AP Redemption Order''). The Fund will

[13] Proposed Rule 14.11(k)(3)(F) defines the term ''Creation Unit'' as a specified minimum number of Managed Portfolio Shares issued by an Investment Company at the request of an Authorized Participant in return for a designated portfolio of instruments and/or cash.

[14] Proposed Rule 14.11(k)(3)(G) defines the term ''Redemption Unit'' as a specified minimum number of Managed Portfolio Shares that may be redeemed to an Investment Company at the request of an Authorized Participant in return for a portfolio of instruments and/or cash.

[15] Proposed Rule 14.11(k)(3)(D) defines the term ''Confidential Account'' as an account owned by an Authorized Participant and held with an AP Representative on behalf of the Authorized Participant. The account will be established and governed by contractual agreement between the AP Representative and the Authorized Participant solely for the purposes of creation and redemption, while keeping confidential the Creation Basket constituents of each series of Managed Portfolio Shares, including from the Authorized Participant. The books and records of the Confidential Account will be maintained by the AP Representative on behalf of the Authorized Participant.

[16] Proposed Rule 14.11(k)(3)(C) defines the term ''AP Representative'' as an unaffiliated broker-dealer with which an Authorized Participant has signed an agreement to establish a Confidential Account for the benefit of such Authorized Participant that will deliver or receive all consideration to or from the Investment Company in a creation or redemption. An AP Representative will be restricted from disclosing the Creation Basket. Each AP shall enter into its own separate Confidential Account agreement (''Confidential Account Agreement'') with an AP Representative.

[17] The Fund must comply with the federal securities laws in accepting Deposit Instruments and satisfying redemptions with Redemption Instruments, including that the Deposit Instruments and Redemption Instruments are sold in transactions that would be exempt from registration under the 1933 Act.

[18] To the extent that the Fund allows creations or redemptions to be conducted in cash, such transactions will be effected in the same manner for all APs.

establish in its Registration Statement an Order Cut-Off Time for redemption orders of Redemption Units in proper form. Redemption Units of the Fund will be redeemable at their NAV per share next determined after receipt of a request for redemption by the Trust in the manner specified below before the Order Cut-Off Time. To initiate an AP Redemption Order, an AP must submit to the Distributor an irrevocable order to redeem such Redemption Unit after the most recent prior Valuation Time, but not later than the Order Cut-Off Time.

In the case of a redemption, the AP would enter into an irrevocable redemption order, and then immediately instruct the AP Representative to sell the Creation Basket that it will receive in the redemption. As with the purchase of securities, the AP Representative will use methods, such as breaking the transaction into multiple transactions and transacting in multiple marketplaces, to avoid revealing the composition of the Creation Basket.

Consistent with the provisions of Section 22(e) of the 1940 Act and Rule 22e–2 thereunder, the right to redeem will not be suspended, nor payment upon redemption delayed, except for: (1) Any period during which the Exchange is closed other than customary weekend and holiday closings, (2) any period during which trading on the Exchange is restricted, (3) any period during which an emergency exists as a result of which disposal by the Fund of securities owned by it is not reasonably practicable or it is not reasonably practicable for the Fund to determine its NAV, and (4) for such other periods as the Commission may by order permit for the protection of shareholders.

Redemptions will occur primarily in-kind, although redemption payments may also be made partly or wholly in cash.[19] The Participant Agreement signed by each AP will require establishment of a Confidential Account to receive distributions of securities in-kind upon redemption. Each AP will be required to open a Confidential Account with an AP Representative in order to facilitate orderly processing of redemptions. While the Fund will generally distribute securities in-kind, the Adviser may determine from time to time that it is not in the Fund's best interests to distribute securities in-kind, but rather to sell securities and/or distribute cash. For example, the Adviser may distribute cash to facilitate orderly portfolio management in connection with rebalancing or transitioning a portfolio in line with its investment objective, or if there is substantially more creation than redemption activity during the period immediately preceding a redemption request, or as necessary or appropriate in accordance with applicable laws and regulations.[20]

Net Asset Value

The NAV per share of the Fund will be computed by dividing the value of the net assets of the Fund (*i.e.,* the value of its total assets less total liabilities) by the total number of Shares of the Fund outstanding, rounded to the nearest cent. Expenses and fees, including, without limitation, the management, administration and distribution fees, will be accrued daily and taken into account for purposes of determining NAV. Interest and investment income on the Trust's assets accrue daily and will be included in the Fund's total assets. The NAV per share for the Fund will be calculated by the Fund's administrator and determined as of the close of the regular trading session on the Exchange (ordinarily 4:00 p.m., E.T.) on each day that the Exchange is open.

Shares of U.S. exchange-listed equity securities, including common stocks, preferred securities, securities of other investment companies and of REITs, and warrants and rights, as well as ETFs, exchange-listed ADRs, and U.S. exchange-listed futures will be valued at market value, which will generally be determined using the last reported official closing or last trading price on the exchange or market on which the securities are primarily traded at the time of valuation.

Availability of Information

The Fund's website (*www.PrecidianFunds.com*), which will be publicly available prior to the listing and trading of Shares, will include a form of the prospectus for the Fund that may be downloaded. The Fund's website will include additional quantitative information updated on a daily basis, including, for the Fund, (1) the prior Business Day's NAV, market closing price or mid-point of the bid/ask spread at the time of calculation of such NAV (the ''Bid/Ask Price''),[21] and a calculation of the premium and discount of the market closing price or Bid/Ask Price against the NAV, and (2) data in chart format displaying the frequency distribution of discounts and premiums of the daily Bid/Ask Price against the NAV, within appropriate ranges, for each of the four previous calendar quarters. The website and information will be publicly available at no charge.

The Trust's SAI and the Fund's shareholder reports will be available free upon request from the Trust. These documents and forms may be viewed on-screen or downloaded from the Commission's website at *www.sec.gov.*

Information regarding market price and trading volume of the Shares will be continually available on a real-time basis throughout the day on brokers' computer screens and other electronic services. Quotation and last sale information for the Shares will be available via the Consolidated Tape Association (''CTA'') high-speed line. In addition, the VIIV, as defined in proposed Rule 14.11(k)(3)(B) and as described further below, will be widely disseminated by the Reporting Authority [22] and/or one or more major market data vendors in one-second intervals during Regular Trading Hours.

Dissemination of the VIIV

With respect to trading of the Shares, the ability of market participants to buy and sell Shares at prices near the VIIV is dependent upon their assessment that the VIIV is a reliable, indicative real-time value for the Fund's underlying holdings. Market participants are expected to accept the VIIV as a reliable, indicative real-time value because (1) the VIIV will be calculated and disseminated based on the Fund's actual portfolio holdings, (2) the securities in which the Fund plans to invest are generally highly liquid and actively traded and therefore generally have accurate real time pricing available, and (3) market participants will have a daily opportunity to evaluate whether the VIIV at or near the close of trading is indeed predictive of the actual NAV. The VIIV for the Fund will be

[19] The value of any positions not susceptible to in-kind settlement may be paid in cash.

[20] To the extent that the Fund allows creations or redemptions to be conducted in cash, such transactions will be effected in the same manner for all APs.

[21] The Bid/Ask Price of the Fund will be determined using the mid-point between the current NBB and NBO as of the time of calculation of the Fund's NAV. The records relating to Bid/Ask Prices will be retained by the Fund and its service providers.

[22] Proposed Rule 14.11(k)(3)(H) defines the term ''Reporting Authority'' in respect of a particular series of Managed Portfolio Shares means the Exchange, the exchange that lists a particular series of Managed Portfolio Shares (if the Exchange is trading such series pursuant to unlisted trading privileges), an institution, or a reporting service designated by the Investment Company as the official source for calculating and reporting information relating to such series, including, the net asset value, the Verified Intraday Indicative Value, or other information relating to the issuance, redemption or trading of Managed Portfolio Shares. A series of Managed Portfolio Shares may have more than one Reporting Authority, each having different functions.

disseminated by the Reporting Authority and/or one or more major market data vendors in one-second intervals during Regular Trading Hours. If the Adviser determines that a portfolio security does not have a readily available market quotation, that fact will be disclosed as soon as practicable on the Fund's website, including the identity and weighting of that security in the Fund's portfolio, and the impact of that security on VIIV calculation, including the price for that security being used for the calculation of that day's VIIV.

Trading Halts

With respect to trading halts, the Exchange may consider all relevant factors in exercising its discretion to halt or suspend trading in the Shares of the Fund. The Exchange will halt trading in the Shares under the conditions specified in BZX Rule 11.18. Trading may be halted because of market conditions or for reasons that, in the view of the Exchange, make trading in the Shares inadvisable, including whether unusual conditions or circumstances detrimental to the maintenance of a fair and orderly market are present. Trading in the Shares also will be subject to proposed Rule 14.11(k)(4)(B)(iii)(a) and (b) in the Proposal, which set forth circumstances under which trading in the Shares of the Fund will be halted.

Specifically, Proposed Rule 14.11(k)(4)(B)(iii)(a) provides that, upon notification to the Exchange by the Investment Company or its agent of the existence of any condition or set of conditions specified in any currently applicable exemptive order or no-action relief granted by the Commission or Commission staff that would require the Investment Company's investment adviser to request that the Exchange halt trading in the Managed Portfolio Shares, the Exchange shall halt trading in the Managed Portfolio Shares as soon as practicable. Such halt in trading shall continue until the Investment Company or its agent notifies the Exchange that the condition or conditions necessary for the resumption of trading have been met.[23] The Adviser has represented to the Exchange that it will provide the Exchange with prompt notification upon the existence of any such condition or set of conditions.

Proposed Rule 14.11(k)(4)(B)(iii)(b) provides that, if the Exchange becomes aware that: (i) The Fund's VIIV is not being calculated or disseminated in one second intervals, as required; (ii) the Fund's NAV is not disseminated to all market participants at the same time; (iii) the Fund's holdings are not made available on at least a quarterly basis as required under the 1940 Act; or (iv) such holdings are not made available to all market participants at the same time, it will halt trading in such series until such time as the VIIV, the NAV, or the holdings are available to all market participants as required.

Trading Rules

The Exchange deems the Shares to be equity securities, thus rendering trading in the Shares subject to the Exchange's existing rules governing the trading of equity securities. Shares will trade on the Exchange only during Regular Trading Hours as provided in proposed Rule 14.11(k)(2)(B). As provided in BZX Rule 11.11(a), the minimum price variation for quoting and entry of orders in securities traded on the Exchange is $0.01, with the exception of securities that are priced less than $1.00, for which the minimum price variation for order entry is $0.0001.

The Shares will conform to the initial and continued listing criteria under Rule 14.11(k) as well as all terms in the Exemptive Order. The Exchange represents that, for initial and/or continued listing, the Fund will be in compliance with Rule 10A–3 under the Act.[24] A minimum of 100,000 Shares of the Fund will be outstanding at the commencement of trading on the Exchange. The Exchange will obtain a representation from the issuer of the Shares of the Fund that the NAV per share of the Fund will be calculated daily and will be made available to all market participants at the same time.

Surveillance

The Exchange believes that its surveillance procedures are adequate to properly monitor the trading of the Shares on the Exchange during all trading sessions and to deter and detect violations of Exchange rules and the applicable federal securities laws. Trading of the Shares through the Exchange will be subject to the Exchange's surveillance procedures for derivative products, including Managed Portfolio Shares. As part of these surveillance procedures and consistent with proposed Rule 14.11(k)(2)(C), the Adviser will upon request make available to the Exchange and/or FINRA, on behalf of the Exchange, the daily portfolio holdings of the Fund. The issuer has represented to the Exchange that it will advise the Exchange of any failure by the Fund to comply with the continued listing requirements, and, pursuant to its obligations under Section 19(g)(1) of the Exchange Act, the Exchange will surveil for compliance with the continued listing requirements. If the Fund is not in compliance with the applicable listing requirements, the Exchange will commence delisting procedures under Exchange Rule 14.12.

The Exchange or FINRA, on behalf of the Exchange, or both, will communicate as needed regarding trading in the Shares, underlying equity securities and U.S. exchange-listed futures with other markets and other entities that are members of the Intermarket Surveillance Group (''ISG''), and the Exchange or FINRA, on behalf of the Exchange, or both, may obtain trading information regarding trading such securities from such markets and other entities. In addition, the Exchange may obtain information regarding trading in the Shares, underlying equity securities and U.S. exchange-listed futures from markets and other entities that are members of ISG or with which the Exchange has in place a comprehensive surveillance sharing agreement.[25]

In addition, the Exchange also has a general policy prohibiting the distribution of material, non-public information by its employees.

Information Circular

Prior to the commencement of trading, the Exchange will inform its members in an Information Circular (''Circular'') of the special characteristics and risks associated with trading the Shares. Specifically, the Circular will discuss the following: (1) The procedures for purchases and redemptions of Shares; (2) BZX Rule 3.7, which imposes suitability obligations on Exchange members with respect to recommending transactions in the Shares to customers; (3) how information regarding the VIIV is disseminated; (4) the requirement that members deliver a prospectus to investors purchasing newly issued Shares prior to or concurrently with the

[23] As provided in the Exemptive Order, such conditions would exist where either: (i) The intraday indicative values calculated by the pricing verification agent(s) differ by more than 25 basis points for 60 seconds in connection with pricing of the Verified Intraday Indicative Value; or (ii) holdings representing 10% or more of the Fund's portfolio have become subject to a trading halt or otherwise do not have readily available market quotations. The Exchange shall halt trading in the Shares as soon as practicable after receipt of notification of the existence of such conditions. Such halt in trading shall continue until the Adviser or its agent notifies the Exchange that these conditions no longer exist.

[24] *See* 17 CFR 240.10A–3.

[25] For a list of the current members of ISG, *see www.isgportal.org.*

confirmation of a transaction; (5) trading information; and (6) that the portfolio holdings will be disclosed within at least 60 days following the end of every calendar quarter.

In addition, the Circular will reference that the Fund is subject to various fees and expenses described in the Registration Statement. The Circular will discuss any exemptive, no-action, and interpretive relief granted by the Commission from any rules under the Act. The Circular will also disclose that the NAV for the Shares will be calculated after 4:00 p.m., E.T. each trading day.

2. Statutory Basis

The Exchange believes that this proposal is consistent with Section 6(b) of the Act [26] in general and Section 6(b)(5) of the Act [27] in particular in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, 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.

The Exchange believes that, to the extent that the Proposal and, thus proposed Rule 14.11(k), is approved by the Commission, this proposed rule change is designed to prevent fraudulent and manipulative acts and practices in that the Fund would meet each of the rules relating to listing and trading of Managed Portfolio Shares and, to the extent that the Fund is not in compliance with such rules, the Exchange would either prevent the Fund from listing and trading if it hadn't started trading on the Exchange or would commence delisting procedures under Exchange Rule 14.12. More specifically, the Exchange will consider the suspension of trading in, and will commence delisting proceedings under Rule 14.12 for, the Fund under any of the following circumstances: (a) If, following the initial twelve-month period after commencement of trading on the Exchange of the Fund, there are fewer than 50 beneficial holders of the Fund; (b) if the value of the VIIV is no longer calculated or available to all market participants at the same time; (c) if the holdings of a series of the Fund are not made available on a quarterly basis as required under the 1940 Act or are not made available to all market participants at the same time; (d) if the Investment Company issuing the Fund has failed to file any filings required by the Commission or if the Exchange is aware that the Investment Company is not in compliance with the conditions of any exemptive order or no-action relief granted by the Commission to the Investment Company with respect to the Fund; (e) if any of the continued listing requirements set forth in Rule 14.11(k) are not continuously maintained; (f) if any of the applicable Continued Listing Representations for the issue of Managed Fund Shares are not continuously met; or (g) if such other event shall occur or condition exists which, in the opinion of the Exchange, makes further dealings on the Exchange inadvisable.

The Adviser is not registered as a broker-dealer or affiliated with a broker-dealer. The Sub-Adviser is not registered as a broker-dealer, but is affiliated with a broker-dealer and has implemented and will maintain a ''fire wall'' with respect to such broker-dealer regarding access to information concerning the composition and/or changes to the Fund's portfolio and Creation Basket.

In the event (a) the Adviser or Sub-Adviser becomes registered as a broker-dealer or becomes newly affiliated with a broker-dealer, or (b) any new adviser or sub-adviser is a registered broker-dealer or becomes affiliated with a broker-dealer, it will implement and maintain a fire wall with respect to its relevant personnel or its broker-dealer affiliate regarding access to information concerning the composition and/or changes to the portfolio and Creation Basket, and will be subject to procedures designed to prevent the use and dissemination of material non-public information regarding such portfolio or Creation Basket.

Further, proposed Rule 14.11(k)(2)(E) requires that any person or entity, including an AP Representative, custodian, pricing verification agent, reporting authority, distributor, or administrator, who has access to information regarding the Investment Company's portfolio composition, the Creation Basket, or changes thereto, must be subject to procedures designed to prevent the use and dissemination of material nonpublic information regarding the applicable Investment Company portfolio or Creation Basket. Moreover, if any such person or entity is registered as a broker-dealer or affiliated with a broker-dealer, such person or entity will erect and maintain a ''fire wall'' between the person or entity and the broker-dealer with respect to access to information concerning the composition and/or changes to such Investment Company portfolio or Creation Basket.

The Exchange further believes that the proposed rules are designed to prevent fraudulent and manipulative acts and practices related to the listing and trading of Managed Portfolio Shares because they provide meaningful requirements about both the data that will be made publicly available about the Shares as well as the information that will only be available to certain parties and the controls on such information. Specifically, the Exchange believes that the requirements related to information protection enumerated under proposed Rule 14.11(k)(2)(E) [28] will act as a strong safeguard against misuse and improper dissemination of information related to the Fund's portfolio composition, the Creation Basket, or changes thereto. The requirement that any person or entity implement procedures to prevent the use and dissemination of material nonpublic information regarding the portfolio or Creation Basket will act to prevent any individual or entity from sharing such information externally and the internal ''fire wall'' requirements applicable where an entity is a registered broker-dealer or affiliated with a broker-dealer will act to make sure that no entity will be able to misuse the data for their own purposes. As such, the Exchange believes that this proposal is designed to prevent fraudulent and manipulative acts and practices.

The Exchange further believes that the proposal is designed to prevent fraudulent and manipulative acts and practices related to the listing and trading of Managed Portfolio Shares and to promote just and equitable principles of trade and to protect investors and the public interest in that the Exchange would halt trading under certain circumstances under which trading in the Shares may be inadvisable. Specifically, trading in the Shares will be subject to proposed Rule 14.11(k)(4)(B)(iii)(a), which provides that, upon notification to the Exchange by the Investment Company or its agent

[26] 15 U.S.C. 78f.

[27] 15 U.S.C. 78f(b)(5).

[28] As described above, proposed Rule 14.11(k)(2)(E) provides that any person or entity, including an AP Representative, custodian, pricing verification agent, reporting authority, distributor, or administrator, who has access to information regarding the Investment Company's portfolio composition, the Creation Basket, or changes thereto, must be subject to procedures designed to prevent the use and dissemination of material nonpublic information regarding the applicable Investment Company portfolio or Creation Basket. Moreover, if any such person or entity is registered as a broker-dealer or affiliated with a broker-dealer, such person or entity will erect and maintain a ''fire wall'' between the person or entity and the broker-dealer with respect to access to information concerning the composition and/or changes to such Investment Company portfolio or Creation Basket.

of the existence of any condition or set of conditions specified in any currently applicable exemptive order or no-action relief granted by the Commission or Commission staff that would require the Investment Company's investment adviser to request that the Exchange halt trading in the Managed Portfolio Shares, the Exchange shall halt trading in the Managed Portfolio Shares as soon as practicable. Such halt in trading shall continue until the Investment Company or its agent notifies the Exchange that the condition or conditions necessary for the resumption of trading have been met.[29] The Adviser has represented to the Exchange that it will provide the Exchange with prompt notification upon the existence of any such condition or set of conditions. Trading in the Shares will also be subject to proposed Rule 14.11(k)(4)(B)(iii)(b), which provides that, if the Exchange becomes aware that: (i) The Fund' VIIV is not being calculated or disseminated in one second intervals, as required; (ii) the Fund's NAV is not disseminated to all market participants at the same time; (iii) the Fund's holdings are not made available on at least a quarterly basis as required under the 1940 Act; or (iv) such holdings are not made available to all market participants at the same time, it will halt trading in such series until such time as the VIIV, the NAV, or the holdings are available to all market participants as required.

With respect to the proposed listing and trading of Shares of the Fund, the Exchange believes that the proposed rule change is designed to prevent fraudulent and manipulative acts and practices in that the Shares will be listed and traded on the Exchange pursuant to the initial and continued listing criteria in Rule 14.11(k). The Fund will invest at least 80% of its net assets, plus borrowings for investment purposes, in common stocks and other equity securities of small capitalization U.S. companies or in other U.S. exchange-listed investments with similar economic characteristics, including only the following U.S. exchange-listed securities: Common stocks, preferred securities, securities of other investment companies and of REITs, and warrants and rights. All equity securities in which the Fund will invest will be listed and traded on U.S. national securities exchanges. Price information for the U.S. exchange-listed equity securities held by the Fund will be available through major market data vendors or securities exchanges listing and trading such securities. Price information for any other U.S. exchange-listed instruments held by the Fund will be available through major market data vendors or exchanges listing and trading such instruments. The Fund's investments will be consistent with its investment objective and will not be used to enhance leverage. The Fund will not invest in non-U.S. exchange-listed securities. All futures held by the Fund will be listed on U.S. futures exchanges. The Exchange or FINRA, on behalf of the Exchange, or both, will communicate as needed regarding trading in the Shares, underlying equity securities and U.S. exchange-listed futures with other markets and other entities that are members of the ISG, and the Exchange or FINRA, on behalf of the Exchange, or both, may obtain trading information regarding trading such securities from such markets and other entities. In addition, the Exchange may obtain information regarding trading in the Shares, underlying equity securities, and U.S. exchange-listed futures from markets and other entities that are members of ISG or with which the Exchange has in place a comprehensive surveillance sharing agreement.

With respect to trading of the Shares, the ability of market participants to buy and sell Shares at prices near the VIIV is dependent upon their assessment that the VIIV is a reliable, indicative real-time value for the Fund's underlying holdings. Market participants are expected to accept the VIIV as a reliable, indicative real-time value because (1) the VIIV will be calculated and disseminated based on the Fund's actual portfolio holdings, (2) the securities in which the Fund plans to invest are generally highly liquid and actively traded and therefore generally have accurate real time pricing available, and (3) market participants will have a daily opportunity to evaluate whether the VIIV at or near the close of trading is indeed predictive of the actual NAV.[30]

The proposed rule change is designed to promote just and equitable principles of trade and to protect investors and the public interest in that the Exchange will obtain a representation that the NAV per share of the Fund will be calculated daily and that the NAV will be made available to all market participants at the same time. Investors can also obtain the Fund's SAI, shareholder reports, Form N–CEN, Form N–CSR, and Form N–PORT. The Fund's SAI and shareholder reports will be available free upon request from the applicable fund, and those documents and the Form N–CSR and Form N–PORT may be viewed on-screen or downloaded from the Commission's website. In addition, with respect to the Fund, a large amount of information will be publicly available regarding the Fund and the Shares, thereby promoting market transparency. Quotation and last sale information for the Shares will be available via the CTA high-speed line. Information regarding the VIIV will be widely disseminated every second throughout Regular Trading Hours by the Reporting Authority and/or one or more major market data vendors. The website for the Fund will include a prospectus for the Fund that may be downloaded, and additional data relating to NAV and other applicable quantitative information, updated on a daily basis.

Moreover, prior to the commencement of trading, the Exchange will inform its members in a Circular of the special characteristics and risks associated with trading the Shares. The Exchange will halt trading in the Shares under the conditions specified in BZX Rule 11.18 or for reasons that, in the view of the Exchange, make trading in the Shares inadvisable. Trading in the Shares will be subject to proposed Rule 14.11(k)(4)(B)(iii)(a) and (b), which set forth circumstances under which Shares of the Fund will be halted.

In addition, as noted above, investors will have ready access to the VIIV, and quotation and last sale information for the Shares. The Shares will conform to the initial and continued listing criteria under proposed Rule 14.11(k). The Fund's holdings will be limited to and consistent with what is permissible under the Exemptive Order and described herein. The Fund's investments will be consistent with its investment objective and will not be used to enhance leverage. While the Fund may invest in inverse ETFs, the Fund will not invest in leveraged (*e.g.,* 2X, –2X, 3X or –3X) ETFs.

The proposed rule change is designed to perfect the mechanism of a free and open market and, in general, to protect investors and the public interest in that it will facilitate the listing and trading of an actively-managed exchange-traded

[29] As provided in the Exemptive Order, such conditions would exist where either: (i) The intraday indicative values calculated by the pricing verification agent(s) differ by more than 25 basis points for 60 seconds in connection with pricing of the Verified Intraday Indicative Value; or (ii) holdings representing 10% or more of the Fund's portfolio have become subject to a trading halt or otherwise do not have readily available market quotations. The Exchange shall halt trading in the Shares as soon as practicable after receipt of notification of the existence of such conditions. Such halt in trading shall continue until the Adviser or its agent notifies the Exchange that these conditions no longer exist.

[30] The statements in the Statutory Basis section of this filing relating to pricing efficiency, arbitrage, and activities of market participants, including market makers and APs, are based on statements in the Exemptive Order, representations by Precidian, and review by the Exchange.

product that will enhance competition among market participants, to the benefit of investors and the marketplace. As noted above, the Exchange has in place surveillance procedures relating to trading in the Shares and may obtain information via ISG from other exchanges that are members of ISG or with which the Exchange has entered into a comprehensive surveillance sharing agreement. In addition, as noted above, investors will have ready access to information regarding the VIIV and quotation and last sale information for the Shares.

For the above reasons, the Exchange believes that the proposed rule change is consistent with the requirements of Section 6(b)(5) of the Act.

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 purpose of the Act. The Exchange notes that the proposed rule change, rather will facilitate the listing and trading of actively-managed exchange-traded products that will enhance competition among both market participants and listing venues, to the benefit of investors and the marketplace.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange has neither solicited nor received written comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the Exchange consents, the Commission will:

A. By order approve or disapprove such proposed rule change, or

B. institute proceedings to determine whether the proposed rule change should be 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, as modified by Amendment No. 1, is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–CboeBZX–2019–076 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–2019–076. 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 (*http://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. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–CboeBZX–2019–076 and should be submitted on or before November 7, 2019.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[31]

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2019–22600 Filed 10–16–19; 8:45 am]

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[31] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–87293; File No. SR–CboeEDGX–2019–060]

Self-Regulatory Organizations; Cboe EDGX Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend the Fee Schedule To Institute a Derived Data API Service

October 11, 2019.

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 October 1, 2019, 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.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Cboe EDGX Exchange, Inc. (''EDGX'' or the ''Exchange'') is filing with the Securities and Exchange Commission (the ''Commission'') a proposed rule change to amend the fee schedule to institute a Derived Data API Service. The text of the proposed rule change is attached as Exhibit 5 [sic].

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.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the proposed rule change is to implement a pricing structure that would reduce fees charged to Distributors that distribute Derived Data through an Application Programming Interface (''API'')—*i.e.,* the Derived Data API Service (the ''Program''). The Exchange initially filed to introduce the Program on August 1, 2019 (''Initial Proposal'') based on customer demand, and in order to be able to decrease the cost of Derived Data to Distributors that wish to distribute Derived Data through an API Service.[3] The Initial Proposal was published in the **Federal Register** on August 20, 2019,[4] and the Commission received no commenter letters on the proposal. The Program remained in effect until the fee change was temporarily suspended pursuant to a suspension order (the ''Suspension Order'').[5] The Suspension Order also instituted proceedings to determine whether to approve or disapprove the Initial Proposal.[6]

The Exchange continues to believe that it is in the best interest of its customers and investors to permit the distribution of Derived Data through an API Service at a lower cost, and is therefore filing again to reduce the fees charged to Distributors that offer an API Service. By reducing its pricing, the Exchange hopes to be able to better compete with top of book market data products offered by other national securities exchanges and the securities information processors (''SIPs''). For the reasons expressed both in this filing and the Initial Proposal, the Exchange believes that the Program is pro-competitive, and otherwise consistent with the Exchange Act. In sum, the Exchange remains committed to competing for business by offering both high quality and cost effective data. Continued operation of the Program would ultimately support that goal, and indeed would foster additional competition in the market for U.S. equity market data.

Derived Data

''Derived Data'' is pricing data or other data that (i) is created in whole or in part from Exchange Data, (ii) is not an index or financial product, and (iii) cannot be readily reverse-engineered to recreate Exchange Data or used to create other data that is a reasonable facsimile or substitute for Exchange Data. The Exchange currently offers a Derived Data White Label Service Program that allows Distributors to benefit from discounted fees when distributing Derived Data taken from EDGX Top, which is a proprietary data product that provides top of book quotations and execution information for all equity securities traded on the Exchange.[7] The current program is limited to the distribution of Derived Data to subscribers within a White Label Service which is a type of hosted display solution in which a Distributor hosts, maintains, and controls a website or platform on behalf of a third-party entity.

When the Exchange filed to introduce the White Label Service Program, a number of Distributors contacted the Exchange to inquire about offering a similar program for API Services due to demand for such products from their end clients. The Derived Data API Service would supplement the current Derived Data White Label Service Program by offering discounted fees for Distributors that make Derived Data available through an API, thereby allowing Distributors to benefit from reduced fees when distributing Derived Data to subscribers that establish their own platforms rather than relying on a hosted display solution. In turn, the Exchange believes that the Program would allow Distributors to reach a broader customer base that includes end clients that desire more flexibility and control over how Derived Data is used, furthering both the distribution and cost effectiveness of Exchange market data, and allowing the Exchange to compete for business that may otherwise go to its competitors.

Although White Label Service Platforms are valuable to certain end clients that may not have the technology or resources to build their own applications to display Derived Data, such products offer only an ''off-the-shelf'' solution, as the platform is ultimately designed and controlled by the Distributor. Thus, subsequent to the introduction of the White Label Service Program, Distributors have encouraged the Exchange to offer a Program for API Services that would provide greater flexibility and control to end clients who have already developed applications and tools for servicing their customers. Unlike the White Label Service, where the Distributor is responsible for developing an ''off-the-shelf'' technology platform that is standard and not designed specifically for a particular client, the API Service allows Distributors to use Exchange market data to create financial instruments, such as contracts for difference, that are then offered via API to end clients that can use that information in one or more of their own customized applications based on their specific business needs and the needs of their downstream users. The API Service would therefore offer significant advantages over the White Label Service Program, and would provide another alternative pricing option that Distributors can choose to utilize (or not) in their efforts to obtain high quality and cost effective access to top of book U.S. equities data to create Derived Data.

With the implementation of the API Service Program, the Exchange would continue to offer the current White Label Service Platform, thereby ensuring that Distributors that prefer the design or cost structure of that offering can continue to reap the benefits of that program. Offering additional programs for Derived Data based on customer demand and the ways in which Derived Data is currently being utilized enhances customer choice, and provides alternatives to the market that would otherwise not be available to Distributors and their end clients.

Current Fee Structure

The Exchange currently charges a fee of $1,500 per month for external distribution of EDGX Top. In addition, external distributors of EDGX Top are charged a fee of $4 per month for each Professional User and $0.10 per month for each Non-Professional User. The Exchange also offers special pricing for Derived Data provided through a White Label Service, as mentioned above. This service allows Distributors to make Derived Data available on a platform that is branded with a third-party brand, or co-branded with a third party and a Distributor.[8] The White Label Service Program can be used for a number of different purposes, including the display of information or data, or the

[3] An ''API Service'' is a type of data feed distribution in which a Distributor delivers an API or similar distribution mechanism to a third-party entity for use within one or more platforms. The service allows Distributors to provide Derived Data to a third-party entity for use within one or more downstream platforms that are operated and maintained by the third-party entity. The Distributor maintains control of the entitlements, but does not maintain technical control of the usage or the display.

[4] *See* Securities Exchange Act Release No. 86644 (August 13, 2019), 84 FR 42971 (August 19, 2019) (SR–CboeEDGX–2019–049).

[5] *See* Securities Exchange Act Release No. 87144 (September 27, 2019) (SR–CboeEDGX–2019–049) (**Federal Register** publication pending).

[6] *Id.*

[7] *See* Rule 13.8(c).

[8] The Distributor maintains control of the application's data, entitlements and display.

creation of derivative instruments, primarily contracts for difference,[9] but is unavailable to Distributors that make such information available through an API. Such Distributors are not eligible for discounted Derived Data pricing today, and are instead liable for the fees normally applicable for the distribution of EDGX Top, as listed at the beginning of this paragraph.

Discounted Fees for Derived Data API Service

As proposed, a Distributor that provides a Derived Data API Service for Derived Data taken from EDGX Top would be liable for the following fees instead of the fees normally applicable for the distribution of EDGX Top. Instead of the regular fee for external distribution, Distributors would be charged a tiered External Subscriber Fee based on the number of API Service Platforms (*i.e.,* ''External Subscribers'') that receive Derived Data from the Distributor through a Derived Data API Service.

As proposed, Distributors would continue to be charged a fee of $1,500 per month for each External Subscriber if the Distributor makes Derived Data available to 1–5 External Subscribers. Distributors that make Derived Data available to additional External Subscribers would benefit from discounted pricing based on the number of External Subscribers. Specifically, the external distribution fee would be lowered by 16.67% to $1,250 per month for each External Subscriber if the Distributor makes Derived Data available to 6–20 External Subscribers, and further lowered another 16.67% to $1,000 per month for each External Subscriber if the Distributor makes Derived Data available to 21 or more External Subscribers.

As is the case under the Derived Data White Label Service, the External Subscriber Fee would be non-progressive and based on the number of External Subscribers that receive Derived Data from the Distributor. For example, a Distributor providing Derived Data based on EDGX Top to six External Subscribers that are API Service Platforms would be charged a monthly fee of $7,500 (*i.e.,* 6 External Subscribers × $1,250 each). The Derived Data API Service, however, would allow end clients to, at their discretion, choose to use Derived Data in one or more customized applications (*e.g.,* mobile application, website, terminal) without incurring additional External Subscriber fees. That is, the fees would be charged per API Service, and not based in any way on the number of applications used by the end client to serve their downstream users. By contrast, under the White Label Service, end clients are generally limited to a single platform managed by the Distributor, rather than uncontrolled access to an API, and would be subject to the full External Subscriber fee for access to that single platform without the ability to offer additional platforms for the same fee.

The Exchange would continue to charge a monthly Professional User fee of $4 per month for each Professional User that accesses Derived Data through an API Service. The current Non-Professional User fee of $0.10 per month would be eliminated when participating in the Derived Data API Service, further reducing costs for Distributors that provide access to such data to downstream investors.

Financial Product Distribution Program

With the proposed introduction of the Derived Data API Service, the Exchange would bring together the Derived Data White Label Service and Derived Data API Service under the common heading ''Financial Product Distribution Program.'' The Financial Product Distribution Program would encompass both of these products.

Similar to the Derived Data White Label Service, the Derived Data API Service would be entirely optional, in that it applies only to Distributors that opt to use Derived Data from EDGX Top to create an API Service, as described herein. It does not impact or raise the cost of any other Exchange product, nor does it affect the cost of EDGX Top, except in instances where Derived Data is made available on an API Service. A Distributor that provides a White Label Service or API Service for Derived Data taken from EDGX Top would be liable for the fees associated with the White Label Service or API Service instead of the fees normally applicable for the distribution of EDGX Top. A Distributor that provides a White Label Service or API Service for EDGX Top data that is not Derived Data or distributes Derived Data through a platform other than a White Label Service or API Service would be liable for the fees normally applicable for the distribution of EDGX Top.

Market Background

The market for top of book data is highly competitive as national securities exchanges compete both with each other and with the SIPs to provide efficient, reliable, and low cost data to a wide range of investors and market participants. In fact, Regulation NMS requires all U.S. equities exchanges to provide their best bids and offers, and executed transactions, to the two registered SIPs for dissemination to the public. Top of book data is therefore widely available to investors today at a relatively modest cost. National securities exchanges may also disseminate their own top of book data, but no rule or regulation of the Commission requires market participants to purchase top of book data from an exchange.

In an effort to widen distribution to market participants that use equities market data to compute pricing for certain derivatives instruments, national securities exchanges including the Exchange, its affiliate, Cboe BZX Exchange Inc., and The Nasdaq Stock Market LLC (''Nasdaq'') offer discounted pricing for Derived Data that is created using their top of book products. The Program would therefore compete with similar products offered by other national securities exchanges that offer discounted fees to market participants that purchase Derived Data. Derived Data is largely used to create derivative instruments, such as contracts for difference, rather than to trade equity securities, and is often purchased by market data customers outside of the U.S. where such derivative instruments are more commonly offered. As a result, customers that purchase top of book data to create Derived Data do not need a consolidated quotation, and typically only purchase top of book data to create Derived Data from one source. Customers therefore choose where to obtain top of book data to create Derived Data based on two factors: (1) Data quality, *i.e.,* how much the quoted prices reflect the overall market for particular securities, and (2) the cost of obtaining that data. The Program would allow the Exchange to better compete on the second of these factors by reducing the cost of market data charged to Distributors that offer an API Service.

As explained, the Exchange filed the Initial Proposal to introduce the Program in August in order to provide an attractive pricing option to Distributors that wish to provide Derived Data through an API Service rather than a White Label Service due to the advantages of this form of distribution, including more flexibility and control for end clients. Although that filing was suspended by the Commission, the Exchange believes that the experience of its affiliates in offering a similar Program reflect the competitive nature of the market for the

[9] A contract for difference is an agreement to exchange the difference between the current value of an asset and its future value. If the price increases, the seller pays the buyer the amount of the increase. If the price decreases, the buyer pays the seller the amount of the decrease.

creation and distribution of Derived Data.[10] Specifically, after Cboe BZX Exchange, Inc. (''BZX'') initially reduced the fees charged for API Services under its initial proposal to introduce an API Service, it successfully onboarded one new customer that switched from a competitor product offered by Nasdaq due to the attractive pricing.[11] The Exchange has also been discussing the Program with a handful of additional prospective clients that are interested in offering API Services. Without the proposed pricing discounts, the Exchange believes that prospective customers may not be interested in purchasing top of book data from the Exchange, and would instead continue purchasing such data from other national securities exchanges or the SIPs, potentially at a higher cost than would be available pursuant to the Program. Continued operation of the Program would therefore serve to both reduce fees for customers and to provide alternatives to data and pricing offered by competitors. Ultimately, the Exchange believes that it is critical that it be allowed to compete by offering attractive pricing to customers as increasing the availability of such products ensures continued competition with alternative offerings. Such competition may be constrained when competitors are impeded from offering alternative and cost effective solutions to customers.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the objectives of Section 6 of the Act,[12] in general, and furthers the objectives of Section 6(b)(4),[13] in particular, as it is designed to provide for the equitable allocation of reasonable dues, fees and other charges among its members and other recipients of Exchange data.

The Exchange also believes that the proposed rule change is consistent with Section 11(A) of the Act.[14] Specifically, the proposed rule change supports (i) fair competition among brokers and dealers, among exchange markets, and between exchange markets and markets other than exchange markets, and (ii) the availability to brokers, dealers, and investors of information with respect to quotations for and transactions in securities. In addition, the proposed rule change is consistent with Rule 603 of Regulation NMS,[15] which provides that any national securities exchange that distributes information with respect to quotations for or transactions in an NMS stock do so on terms that are not unreasonably discriminatory.

In adopting Regulation NMS, the Commission granted SROs and broker-dealers increased authority and flexibility to offer new and unique market data to the public. It was believed that this authority would expand the amount of data available to consumers, and also spur innovation and competition for the provision of market data. The Exchange believes that the proposed fee change would further broaden the availability of U.S. equity market data to investors, consistent with the principles of Regulation NMS.

The Exchange operates in a highly competitive environment. Indeed, there are thirteen registered national securities exchanges that trade U.S. equities and offer associated top of book market data products to their customers. The national securities exchanges also compete with the SIPs for market data customers. 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.'' [16] The proposed fee change is a result of the competitive environment, as the Exchange seeks to amend its fees to attract additional subscribers for one of its proprietary top of book data offerings through the introduction of a Derived Data API Service.

The Exchange believes that it is reasonable to introduce reduced fees for the use of Derived Data on API Services as the proposed fee reduction would facilitate cost effective access to market information that is used primarily to create certain derivative instruments rather than to trade U.S. equity securities. The fees that are the subject of this rule filing are constrained by competition, and it is this competition that is driving the proposed fee change. Indeed, the Program is designed to allow the Exchange to compete more effectively for market data distributors that purchase market information to offer Derived Data to investors. The existence of alternatives to the Program ensures that the Exchange cannot set unreasonable or unfairly discriminatory fees, as subscribers are free to elect such alternatives. That is, the Exchange competes with other exchanges that provide similar market data products and pricing programs. Expanding the availability of diverse competitive products actually promotes *additional* competition as it ensures that alternative products from different sources are readily available to Distributors and the broader market. The Exchange therefore believes that introduction of pricing programs such as the Derived Data API Service are not only constrained by competition but also ensure continued competition that acts as a constraint on the pricing of services provided by other national securities exchanges and the SIPs.

Derived Data is primarily purchased for the creation of certain derivative instruments rather than for the trading of U.S. equity securities. As a result, Distributors of Derived Data do not need a consolidated view of the market across multiple exchanges, and generally purchase such data from a single exchange. If a competing exchange were to charge less for a similar product than the Exchange charges under the proposed fee structure, prospective subscribers may choose not subscribe to, or cease subscribing to, the Program. The Exchange believes that lowering the cost of accessing Derived Data may make the Exchange's market information more attractive, and encourage additional Distributors to subscribe to EDGX Top market data instead of competitor products.

Indeed, the Exchange's affiliate, BZX, has already successfully onboarded one new Distributor that has decided to purchase top of book data from that exchange to create Derived Data rather than purchasing top of book data from a competitor exchange, and the Exchange is in discussions with a handful of other Distributors that are interested in procuring market data from the Exchange due to the attractive pricing offered pursuant to the Program. Distributors can discontinue use at any time and for any reason, including due to an assessment of the reasonableness of fees charged. Further, firms have a wide variety of alternative market data products from which to choose, such as

[10] On August 1, 2019 both the Exchange and BZX filed to introduce API Services for Derived Data. The BZX filing was also suspended by the Commission but remained in effect prior to being suspended. *See* Securities Exchange Act Release No. 87125 (September 26, 2019) (SR–CboeBZX–2019–070) (**Federal Register** publication pending).

[11] *See* Cboe Innovation Spotlight, ''Invast Global—An alternative prime broker,'' *available at https://markets.cboe.com/us/equities/market_data_products/spotlight.*

[12] 15 U.S.C. 78f.

[13] 15 U.S.C. 78f(b)(4).

[14] 15 U.S.C. 78k–1.

[15] *See* 17 CFR 242.603.

[16] *See* Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005) (''Regulation NMS Adopting Release'').

similar proprietary data products offered by other national securities exchanges, including those that choose to offer discounted fees for the distribution of Derived Data in an effort to compete for this business.

The proposed rule change would provide an alternate fee structure for providing EDGX Top market data to Distributors that make Derived Data available to External Subscribers via API Services. As proposed, if a Distributor uses an API Service to distribute Derived Data, the Distributor will be charged a fee that is tiered based on the number of External Subscribers that are provided access to that data instead of the higher fee normally charged for external distribution. The Exchange believes that this fee is equitable and not unfairly discriminatory because the Exchange will apply the same fees to any similarly situated Distributors that elect to participate in the Program based on the number of External Subscribers provided access to Derived Data through an API Service, with Distributors providing access to six or more External Subscribers receiving a discount compared to the current pricing applicable for external distribution of EDGX Top.

The Exchange believes that it is equitable and not unfairly discriminatory to begin providing discounted rates to Distributors that provide access to at least six External Subscribers as the discounted rates are designed to incentivize firms to grow the number of External Subscribers that purchase Derived Data from the Exchange. The Exchange understands that Distributors that may provide this sort of API Service typically serve a relatively larger number of External Subscribers, and would therefore be able to meet the proposed threshold by providing Derived Data taken from EDGX Top to those customers. The one current subscriber to the API Service offered on the Exchange's affiliate, BZX, intends to provide Derived Data to significantly more than six External Subscribers.

The Exchange would also continue to charge a small fee for Professional Users but would eliminate Non-Professional User fees for data provided under the Program. The Exchange believes that it is equitable and not unfairly discriminatory to charge a fee for Professional Users but no fee for Non-Professional Users. Non-Professional Users are already subject to a heavily discounted fee for EDGX Top market data relative to Professional Users. Differential fees for Professional and Non-Professional Users are widely used by the Exchange and other exchanges for their proprietary market data as this reduces costs for retail investors and makes market data more broadly available. The Exchange believes that eliminating fees for Non-Professional Users that access Derived Data from Distributors pursuant to the Program is consistent with longstanding precedent indicating that it is consistent with the Act to provide reasonable incentives to retail investors that rely on the public markets for their investment needs.

Further, the proposed fees will only apply to Distributors that elect to participate in the Program by distributing Derived Data through an API Service. EDGX Top market data is distributed and purchased on a voluntary basis, in that neither the Exchange nor market data distributors are required by any rule or regulation to make this data available. Distributors of EDGX Top are not required to participate in the proposed Program, which is merely an alternative option being proposed by the Exchange to potentially lower costs for market data that is Derived Data. As previously explained, the Exchange currently offers discounted fees for Distributors that distribute Derived Data on a White Label Service. Expanding the universe of customers that can benefit from discounted fees for distributing Derived Data would serve to further increase the accessibility of the Exchange's market data products. Although the proposed pricing for the Program differs from the pricing currently in place for the White Label Service Program, the Exchange believes that its pricing reflects the relative benefits provided to Distributors that offer an API Service that allows end clients to offer one or more customized applications to their customers rather than simply offering a single ''off-the-shelf'' solution designed and controlled by the Distributors. Indeed, the Program was developed by the Exchange in response to demand for such a product for Distributors that believe that they would be better able to serve their end clients with an API Service. Distributors that prefer the design or cost structure of the White Label Service Program would continue to be able to subscribe to that offering. Based on customer feedback, however, the Exchange believes that the API Service Program would be valuable to a number of Distributors that have expressed interest specifically in that offering.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change would result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange operates in a highly competitive environment, and its ability to price these data products is constrained by: (i) Competition among exchanges that offer similar data products, and pricing options, to their customers; and (ii) the existence of inexpensive real-time consolidated data disseminated by the SIPs. Top of book data is disseminated by both the SIPs and the thirteen equities exchanges. There are therefore a number of alternative products available to market participants and investors. In this competitive environment potential subscribers are free to choose which competing product to purchase to satisfy their need for market information. Often, the choice comes down to price, as broker-dealers or vendors look to purchase the cheapest top of book data product, or quality, as market participants seek to purchase data that represents significant market liquidity. In order to better compete for this segment of the market, the Exchange is proposing to reduce fees charged to Distributors that distribute Derived Data through an API. The Exchange believes that this would facilitate greater access to such data, ultimately benefiting investors that are provided access to such data.

The proposed fees apply to data derived from EDGX Top, which is subject to competition from both the SIPs and exchanges that offer similar products, including but not limited to those that choose to provide similar pricing options for Derived Data. A number of national securities exchanges, including the Exchange, its affiliated Cboe U.S. equities exchanges, and Nasdaq offer pricing discounts for Derived Data today. These pricing programs reduce the cost of accessing top of book market information that is used, among other things, to create derivative instruments rather than to trade U.S. equity securities. In order to better compete for this segment of the market, the Exchange is proposing to expand the programs that it offers to include a Derived Data API Service, allowing additional market data customers to benefit from discounted pricing. The Exchange does not believe that the proposed price reduction for Derived Data offered through an API would cause any unnecessary or inappropriate burden on intermarket competition as other exchanges and data vendors are free to lower their prices to better compete with the Exchange's offering. The Exchange believes that the proposed rule change is pro-competitive as it seeks to offer pricing incentives to

customers to better position the Exchange as it competes to attract additional market data subscribers.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

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 [17] and paragraph (f) of Rule 19b–4 [18] 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 (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–CboeEDGX–2019–060 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–2019–060. 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 (*http://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. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–CboeEDGX–2019–060 and should be submitted on or before November 7, 2019.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[19]

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2019–22698 Filed 10–16–19; 8:45 am]

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[17] 15 U.S.C. 78s(b)(3)(A).

[18] 17 CFR 240.19b–4(f).

[19] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–87271; File No. SR–BX–2019–035]

Self-Regulatory Organizations; Nasdaq BX, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Transaction Fees at Equity 7, Section 118(a)

October 10, 2019.

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 September 30, 2019, Nasdaq BX, Inc. (''BX'' or ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''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

The Exchange proposes to amend its transaction fees at Equity 7, Section 118(a), as described further below. While these amendments are effective upon filing, the Exchange has designated the proposed amendments to be operative on October 1, 2019.

The text of the proposed rule change is available on the Exchange's website at *http://nasdaqbx.cchwallstreet.com/,* at the principal office of the Exchange, 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 operates on the ''taker-maker'' model, whereby it generally pays credits to members that take liquidity and charges fees to members that provide liquidity. Currently, the Exchange has a schedule, at Equity 7, Section 118(a), which consists of several different credits that it provides for orders in securities priced at $1 or more per share that access liquidity on the Exchange and several different charges that it assesses for orders in such securities that add liquidity on the Exchange.

Over the course of the last few months, the Exchange has experimented with various reformulations of its pricing schedule with the purpose of increasing activity on the Exchange, improving market quality, and increasing market share.[3] The Exchange

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* SR–BX–2019–031(filed September 12, 2019, pending publication); Securities Exchange Act Release No. 34–86120 (June 17, 2019); 84 FR 29270 (June 21, 2019) (SR–BX–2019–026); Securities

Continued

now proposes a further amendment to its pricing schedule to support these efforts.

Specifically, the Exchange proposes to amend one of its charges for displayed orders in securities that add liquidity to the Exchange. Presently, the Exchange charges $0.0012 per share executed for displayed orders in securities in Tape C that add liquidity entered by a member that: (i) Adds liquidity equal to or exceeding 0.17% of total Consolidated Volume; [4] and (ii) adds liquidity equal to or exceeding 0.15% of total Consolidated Volume in securities in Tape C during a month. The Exchange proposes to amend this charge by lowering the threshold level of total Consolidated Volume that a member must achieve in securities in Tape C from 0.15% to 0.12% during a month.

Applicability to and Impact on Participants

By lowering the level of total Consolidated Volume in securities in Tape C that is necessary to qualify for the $0.012 per share executed charge, the Exchange intends to render it easier for a member to qualify for this charge, which represents the lowest transaction fee that the Exchange charges for orders that add liquidity in securities in Tape C. The Exchange believes this change will incentivize members to increase their liquidity adding activity in Tape C, and to thereby improve the overall quality and attractiveness of the Nasdaq BX market.

Exchange members that act as net adders of liquidity to the Exchange in securities in Tape C will stand to benefit most from the proposed change. Other members will benefit indirectly from any improvement in the overall quality of the market that this proposal facilitates. The Exchange notes that its proposal is not otherwise targeted at or expected to be limited in its applicability to a specific segment(s) of market participants nor will it apply differently to different types of market participants.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[5] in general, and furthers the objectives of Sections 6(b)(4) and 6(b)(5) of the Act,[6] in particular, in that it provides for the equitable allocation of reasonable dues, fees and other charges among members and issuers and other persons using any facility, and is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers. The proposal is also consistent with Section 11A of the Act relating to the establishment of the national market system for securities.

The Proposal Is Reasonable

The Exchange's proposed change to its schedule of charges is reasonable in several respects. As a threshold matter, the Exchange is subject to significant competitive forces in the market for equity securities transaction services that constrain its pricing determinations in that market. The fact that this market is competitive has 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'. . . .'' [7]

The Commission and the courts have repeatedly expressed their preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. In Regulation NMS, while adopting a series of steps to improve the current market model, 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.'' [8]

Numerous indicia demonstrate the competitive nature of this market. For example, clear substitutes to the Exchange exist in the market for equity security transaction services. The Exchange is only one of several equity venues to which market participants may direct their order flow, and it represents a small percentage of the overall market. It is also only one of several taker-maker exchanges. Competing equity exchanges offer similar tiered pricing structures to that of the Exchange, including schedules of rebates and fees that apply based upon members achieving certain volume thresholds.[9]

Within this environment, market participants can freely and often do shift their order flow among the Exchange and competing venues in response to changes in their respective pricing schedules.[10] Separately, the Exchange has provided the SEC staff with multiple examples of instances where pricing changes by BX and other exchanges have resulted in shifts in exchange market share. Within the foregoing context, the proposal represents a reasonable attempt by the Exchange to increase its liquidity and market share relative to its competitors.

The Exchange has designed its proposal to ease its qualification requirements for a reduced $0.0012 per share executed charge and to provide increased overall incentives to members to increase their liquidity adding activity on the Exchange in Tape C securities. An increase in liquidity adding activity on the Exchange will, in turn, improve the quality of the Nasdaq BX market and increase its attractiveness to existing and prospective participants. Generally, the proposed amended charge will be comparable to, if not favorable to, those that its competitors provide.[11]

The Exchange notes that those participants that are dissatisfied with the proposed amended charge are free to shift their order flow to competing venues that offer them lower charges or less stringent qualification criteria.

The Proposal Is an Equitable Allocation of Charges

The Exchange believes its proposal will allocate its charges fairly among its

Exchange Act Release No. 34–85912 (May 22, 2019); 84 FR 24834 (May 29, 2019) (SR–BX–2019–013).

[4] As used in Equity 7, Section 118(a), the term ''Consolidated Volume'' means the total consolidated volume reported to all consolidated transaction reporting plans by all exchanges and trade reporting facilities during a month in equity securities, excluding executed orders with a size of less than one round lot.

[5] 15 U.S.C. 78f(b).

[6] 15 U.S.C. 78f(b)(4) and (5).

[7] *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)).

[8] Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005) (''Regulation NMS Adopting Release'').

[9] CBOE EDGA provides a standard charge of $0.0030 per share executed for liquidity adders (or between $0.0022 and $0.0026 if a member qualifies for a volume tier). NYSE National has a standard charge of $0.0028 per share executed for liquidity adders (and a range of charges from $0.0020–$0.0026 if a member qualifies for a volume tier).

[10] The Exchange perceives no regulatory, structural, or cost impediments to market participants shifting order flow away from it. In particular, the Exchange notes that these examples of shifts in liquidity and market share, along with many others, have occurred within the context of market participants' existing duties of Best Execution and obligations under the Order Protection Rule under Regulation NMS.

[11] *See* n.9, *supra.*

market participants. It is equitable for the Exchange to reduce the qualification requirements for its $0.0012 per share executed charge for displayed orders that add liquidity to the Exchange as a means of incentivizing liquidity adding activity. An increase in overall liquidity addition activity on the Exchange will improve the quality of the Nasdaq BX market and increase its attractiveness to existing and prospective participants.

The Proposed Credit Is Not Unfairly Discriminatory

The Exchange believes that the proposal is not unfairly discriminatory. As an initial matter, the Exchange believes that nothing about its volume-based tiered pricing model is inherently unfair; instead, it is a rational pricing model that is well-established and ubiquitous in today's economy among firms in various industries—from co-branded credit cards to grocery stores to cellular telephone data plans—that use it to reward the loyalty of their best customers that provide high levels of business activity and incent other customers to increase the extent of their business activity. It is also a pricing model that the Exchange and its competitors have long employed with the assent of the Commission. It is fair because it incentivizes customer activity that increases liquidity, enhances price discovery, and improves the overall quality of the equity markets.

The Exchange intends for the proposal to attract more liquidity to the market, improving market wide quality and price discovery. Although net adders of liquidity in Tape C will benefit most from the proposal, this result is fair insofar as increased activity in securities in Tape C will help to improve market quality and the attractiveness of the Nasdaq BX market to all existing and prospective participants. Moreover, any participant that does not find the qualifying criteria for the amended charge to be sufficiently is attractive is free to shift its order flow to a competing venue.

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 not necessary or appropriate in furtherance of the purposes of the Act.

Intramarket Competition

The Exchange does not believe that its proposal will place any category of Exchange participant at a competitive disadvantage. As noted above, all members of the Exchange will benefit from any increase in market activity that the proposal effectuates. Members may grow or modify their businesses so that they can receive the $0.0012 per share executed charge. Moreover, members are free to trade on other venues to the extent they believe that the fees charged are too high or the qualification criteria are not attractive. As one can observe by looking at any market share chart, price competition between exchanges is fierce, with liquidity and market share moving freely between exchanges in reaction to fee and credit changes. The Exchange notes that the tier structure is consistent with broker-dealer fee practices as well as the other industries, as described above.

Intermarket Competition

The Exchange believes that its proposed modification to its schedule of charges will not impose a burden on competition because the Exchange's execution services are completely voluntary and subject to extensive competition both from the other 12 live exchanges and from off-exchange venues, which include 32 alternative trading systems. The Exchange notes that it operates in a highly competitive market in which market participants can readily favor competing venues if they deem fee levels at a particular venue to be excessive, or rebate opportunities available at other venues to be more favorable. In such an environment, the Exchange must continually adjust its fees to remain competitive with other exchanges and with alternative trading systems that have been exempted from compliance with the statutory standards applicable to exchanges. Because competitors are free to modify their own fees in response, and because market participants may readily adjust their order routing practices, the Exchange believes that the degree to which fee changes in this market may impose any burden on competition is extremely limited.

The proposed amended schedule of charges is reflective of this competition because, as a threshold issue, the Exchange is a relatively small market so its ability to burden intermarket competition is limited. In this regard, even the largest U.S. equities exchange by volume only has 17–18% market share, which in most markets could hardly be categorized as having enough market power to burden competition. Moreover, as noted above, price competition between exchanges is fierce, with liquidity and market share moving freely between exchanges in reaction to fee and credit changes. This is in addition to free flow of order flow to and among off-exchange venues which comprised more than 37% of industry volume for the month of July 2019.

The Exchange intends for the proposed change to increase member incentives to engage in the addition of Tape C liquidity on the Exchange. This change is procompetitive and reflective of the Exchange's efforts to make it an attractive and vibrant venue to market participants.

In sum, if the change proposed herein is unattractive to market participants, it is likely that the Exchange will lose market share as a result. Accordingly, the Exchange does not believe that the proposed change will impair the ability of members or competing order execution venues to maintain their competitive standing in the financial markets.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

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)(ii) of the Act.[12]

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: (i) Necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule 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 (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–BX–2019–035 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange

[12] 15 U.S.C. 78s(b)(3)(A)(ii).

Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–BX–2019–035. 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 (*http://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. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–BX–2019–035 and should be submitted on or before November 7, 2019.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[13]

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2019–22589 Filed 10–16–19; 8:45 am]

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[13] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–87295; File No. SR–CboeEDGX–2019–059]

Self-Regulatory Organizations; Cboe EDGX Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Introduce a Small Retail Broker Distribution Program

October 11, 2019.

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 October 1, 2019, 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.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Cboe EDGX Exchange, Inc. (''EDGX'' or the ''Exchange'') is filing with the Securities and Exchange Commission (the ''Commission'') a proposed rule change to introduce a Small Retail Broker Distribution Program. The text of the proposed changes to the fee schedule are enclosed as Exhibit 5. [sic]

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.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the proposed rule change is to introduce a pricing program that would allow small retail brokers that purchase top of book market data from the Exchange to benefit from discounted fees for access to such market data. The Small Retail Broker Distribution Program (the ''Program'') would reduce the distribution and consolidation fees paid by small broker-dealers that operate a retail business. In turn, the Program may increase retail investor access to real-time U.S. equity quote and trade information, and allow the Exchange to better compete for this business with competitors that offer similar optional products. The Exchange initially filed to introduce the Program on August 1, 2019 (''Initial Proposal'') to further ensure that retail investors served by smaller firms have cost effective access to its market data products, and as part of its ongoing efforts to improve the retail investor experience in the public markets. The Initial Proposal was published in the **Federal Register** on August 20, 2019,[3] and the Commission received no commenter letters on the proposal. The Program remained in effect until the fee change was temporarily suspended pursuant to a suspension order (the ''Suspension Order'').[4] The Suspension Order also instituted proceedings to determine whether to approve or disapprove the Initial Proposal.[5]

Current Fees

Today, the Exchange offers two top of book data feeds that provide real-time U.S. equity quote and trade information to investors. First, the Exchange offers the EDGX Top Feed, which is an uncompressed data feed that offers top of book quotations and execution information based on equity orders entered into the System. The fee for external distribution of EDGX Top data is $1,500 per month, and external distributors are also liable for a fee of $4 per month for each Professional User, and $0.10 per month for each Non-Professional User.

Second, the Exchange offers the Cboe One Summary Feed, which offers similar information based on equity

[3] *See* Securities Exchange Act Release No. 86678 (August 14, 2019), 84 FR 43246 (August 20, 2019) (SR–CboeEDGX–2019–048).

[4] *See* Securities Exchange Act Release No. 87172 (September 30, 2019) (SR–CboeEDGX–2019–048) (**Federal Register** publication pending).

[5] *Id.*

orders submitted to the Exchange and its affiliated equities exchanges—*i.e.,* Cboe EDGA Exchange, Inc., Cboe BZX Exchange, Inc., and Cboe BYX Exchange, Inc. Specifically, the Cboe One Summary Feed is a data feed that contains the aggregate best bid and offer of all displayed orders for securities traded on the Exchange and its affiliated exchanges. The Cboe One Summary Feed also contains the individual last sale information for the Exchange and each of its affiliated exchanges, and consolidated volume for all listed equity securities. The fee for external distribution of the Cboe One Summary Feed is $5,000 per month, and external distributors are also liable for a Data Consolidation Fee of $1,000 per month, and User fees equal to $10 per month for each Professional User, and $0.25 per month for each Non-Professional User.[6]

Small Retail Broker Eligibility Requirements

The Exchange proposes to introduce a Program that would reduce costs for small retail brokers that provide top of book data to their clients. In order to be approved for the Small Retail Broker Distribution Program, Distributors would have to provide either the EDGX Top Feed or Cboe One Summary Feed (''EDGX Equities Exchange Data'') to a limited number of clients with which the firm has established a brokerage relationship, and would have to provide such data primarily to Non-Professional Data Users. Specifically, distributors would have to attest that they meet the following criteria: (1) Distributor is a broker-dealer distributing EDGX Equities Exchange Data to Non-Professional Data Users with whom the broker-dealer has a brokerage relationship; (2) More than 50% of the Distributor's total Data User population must consist of Non-Professional Data Users, inclusive of those not receiving EDGX Equities Exchange Data; and (3) Distributor distributes EDGX Equities Exchange Data to no more than 5,000 Non-Professional Data Users.[7]

These proposed requirements for participating in the Program are designed to ensure that the benefits provided by the Program inure to the benefit of small retail brokers that provide EDGX Equities Exchange Data to a limited number of subscribers. As explained later in this filing, distributors that provide EDGX Exchange Data to a larger number of subscribers can benefit from the current pricing structure through scale, due to subscriber fees that are significantly lower than those charged by the Exchange's competitors, and an Enterprise license that caps the total fees to be paid by firms that distribute market data to a sizeable customer base. The Exchange believes that offering similarly attractive pricing to small retail brokers, including regional firms both inside and outside of the U.S. that may not have the same established client base as the larger retail brokers, would make the Exchange's data a more competitive alternative for those firms, and would help ensure that such information is widely available to a larger number of retail investors globally. The Program would also be available to retail brokers more generally, regardless of size, that wish to trial the Exchange's top of book products with a limited number of subscribers before potentially expanding distribution to additional clients, potentially further increasing the accessibility of the Exchange's market data to retail investors. The Program would be exclusive to the Exchange's top of book offerings as retail investors typically do not need or use depth of book data to facilitate their equity investments, and their brokers typically do purchase such market data on their behalf.

Discounted Fees

Distributors that participate in the Program would be liable for lower distribution fees for access to the EDGX Top Feed, and lower distribution and consolidation fees for access to the Cboe One Summary Data Feed.[8] First, the distribution fee charged for EDGX Top would be lowered by 50% from the current $1,500 per month to $750 per month for distributors that meet the requirements of the Program. Second, the distribution fee charged to these distributors for the Cboe One Summary Feed would be lowered by 30% from the current $5,000 per month to $3,500 per month. Finally, the Data Consolidation Fee charged for the Cboe One Summary Feed would be lowered by 65% from the current $1,000 per month to $350 per month. User fees for any Professional or Non-Professional Users that access EDGX Top or Cboe One Summary Feed data from a distributor that participates in the Program would remain at their current levels as the current subscriber charges are already among the most competitive in the industry.[9]

The Exchange believes that these fees, which represent a significant cost savings for small retail brokers, would help ensure that retail investors continue to have fair and efficient access to U.S. equity market data. While retail investors normally pay a fixed commission when buying or selling equities, and do not typically pay separate fees for market data, the Exchange believes that the proposed reduction in fees would make the Exchange's data more competitive with other available alternatives, and may encourage retail brokers to make such data more readily available to their clients. In sum, the Exchange believes that the proposed fee reductions may facilitate more cost effective access to top of book data that is purchased on a voluntary basis by retail brokers and provided to their retail investor clients.

Market Background

The market for top of book data is highly competitive as national securities exchanges compete both with each other and with the securities information processors (''SIPs'') to provide efficient, reliable, and low cost data to a wide range of investors and market participants. In fact, Regulation NMS requires all U.S. equities exchanges to provide their best bids and offers, and executed transactions, to the two registered SIPs for dissemination to the public. Top of book data is therefore widely available to investors today at a relatively modest cost. National securities exchanges may also disseminate their own top of book data, but no rule or regulation of the Commission requires market participants to purchase top of book data from an exchange.[10] The EDGX Top

[6] The Exchange also offers an Enterprise license for the EDGX Top and Cboe One Summary Feeds. An Enterprise license permits distribution to an unlimited number of Professional and Non-Professional Users, keeping costs down for firms that provide access to a large number of subscribers. An Enterprise license is $15,000 per month for the EDGX Top Feed, and $50,000 per month for the Cboe One Summary Feed.

[7] Distributors would have to meet these requirements for whichever product they would like to distribute pursuant to the Program. For example, a distributor that distributes Cboe One Summary Feed data pursuant to the Program, would be limited to distributing the Cboe One Summary Feed to no more than 5,000 Non-Professional Data Users.

[8] New external distributors of the EDGX Top Feed or Cboe One Summary Feed are not currently charged external distributor fees for their first month of service. This would continue to be the case for external distributors that participate in the Program.

[9] By comparison, The Nasdaq Stock Market LLC (''Nasdaq'') charges a subscriber fee for Nasdaq Basic that adds up to $26 per month for Professional Subscribers and $1 per month for Non-Professional Subscribers (Tapes A, B, and C). *See* Nasdaq Equity Rules, Equity 7, Pricing Schedule, Section 147(b)(1).

[10] By contrast, Rule 603(c) of Regulation NMS (the ''Vendor Display Rule'') effectively requires that SIP data or some other consolidated display be utilized

Continued

Feed and Cboe One Summary Feed therefore compete with the SIP and with similar products offered by other national securities exchanges that offer their own competing top of book products. In fact, there are ten competing top of book products offered by other national securities exchanges today, not counting products offered by the Exchange's affiliates.[11]

The purpose of the proposed rule change is to further increase the competitiveness of the Exchange's top of book market data products compared to competitor offerings that may currently be cheaper for firms with a limited subscriber base that do not yet have the scale to take advantage of the lower subscriber fees offered by the Exchange. In turn, the Exchange believes that this change may benefit market participants and investors by spurring additional competition and increasing the accessibility of the Exchange's top of book data.

As explained, the Exchange filed the Initial Proposal to introduce the Program in August in order to provide an attractive pricing option for small retail brokers. Although that filing was ultimately suspended by the Commission, the Exchange believes that its experience in offering the Program while it was in effect reflect the competitive nature of the market for the creation and distribution of top of book data. Specifically, after the Exchange initially reduced the fees charged to small retail brokers under the Initial Proposal, it successfully onboarded one new customer due to the attractive pricing, and is currently in the process of onboarding another customer.[12] These customers are now able to offer high quality and cost effective data to their retail investor clients. The Exchange has also been discussing the Program with a handful of additional prospective clients that are interested in providing top of book data to retail investors. Without the proposed pricing discounts, the Exchange believes that those customers and prospective customers may not be interested in purchasing top of book data from the Exchange, and would instead purchase such data from other national securities exchanges or the SIPs, potentially at a higher cost than would be available pursuant to the Program. The Program has therefore already been successful in increasing competition for such market data, and continued operation of the Program would serve to both reduce fees for such customers and to provide alternatives to data and pricing offered by competitors. Ultimately, the Exchange believes that it is critical that it be allowed to compete by offering attractive pricing to customers as increasing the availability of such products ensures continued competition with alternative offerings. Such competition may be constrained when competitors are impeded from offering alternative and cost effective solutions to customers.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the objectives of Section 6 of the Act,[13] in general, and furthers the objectives of Section 6(b)(4),[14] in particular, as it is designed to provide for the equitable allocation of reasonable dues, fees and other charges among its members and other recipients of Exchange data.

The Exchange also believes that the proposed rule change is consistent with Section 11(A) of the Act.[15] Specifically, the proposed rule change supports (i) fair competition among brokers and dealers, among exchange markets, and between exchange markets and markets other than exchange markets, and (ii) the availability to brokers, dealers, and investors of information with respect to quotations for and transactions in securities. In addition, the proposed rule change is consistent with Rule 603 of Regulation NMS,[16] which provides that any national securities exchange that distributes information with respect to quotations for or transactions in an NMS stock do so on terms that are not unreasonably discriminatory.

In adopting Regulation NMS, the Commission granted SROs and broker-dealers increased authority and flexibility to offer new and unique market data to the public. It was believed that this authority would expand the amount of data available to consumers, and also spur innovation and competition for the provision of market data. The Exchange believes that the proposed fee change would further broaden the availability of U.S. equity market data to investors, and in particular retail investors, consistent with the principles of Regulation NMS.

The Exchange operates in a highly competitive environment. Indeed, there are thirteen registered national securities exchanges that trade U.S. equities and offer associated top of book market data products to their customers. The national securities exchanges also compete with the SIPs for market data customers. 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.'' [17] The proposed fee change is a result of the competitive environment, as the Exchange seeks to amend its fees to attract additional subscribers for its proprietary top of book data offerings.

The proposed fee change would reduce fees charged to small retail brokers that provide access to two top of book data products: The EDGX Top Feed and the Cboe One Summary Feed. The EDGX Top Feed provides top of book quotations and transactions executed on the Exchange, and provides a valuable window into the market for securities traded on a market that accounts for about 5% of U.S. equity market volume today.[18] The Cboe One Summary Feed is a competitively-priced alternative to top of book data disseminated by SIPs, or similar data disseminated by other national securities exchanges.[19] It provides subscribers with consolidated top of book quotes and trades from four Cboe U.S. equities markets, which together account for about 17% of consolidated U.S. equities trading volume.[20] Together, these products are purchased by a wide variety of market participants and vendors, including data platforms, websites, fintech firms, buy-side investors, retail brokers, regional banks, and securities firms inside and outside of the U.S. that desire low cost, high quality, real-time U.S. equity market data. By providing lower cost access to U.S. equity market data, the EDGX Top and Cboe One Summary Feeds benefit a

in any context in which a trading or order-routing decision can be implemented.

[11] Competing top of book products include, Nasdaq Basic, BX Basic, PSX Basic, NYSE BQT, NYSE BBO/Trades, NYSE Arca BBO/Trades, NYSE American BBO/Trades, NYSE Chicago BBO/Trades, and IEX TOPS.

[12] *See e.g.,* Cboe Innovation Spotlight, ''dough—The commission-free online broker with premium content and insights,'' *available at https://markets.cboe.com/us/equities/market_data_products/spotlight/.*

[13] 15 U.S.C. 78f.

[14] 15 U.S.C. 78f(b)(4).

[15] 15 U.S.C. 78k–1.

[16] *See* 17 CFR 242.603.

[17] *See* Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005) (''Regulation NMS Adopting Release'').

[18] *See https://markets.cboe.com/us/equities/market_share/.*

[19] *See e.g.,* supra note 9 (discussing Nasdaq Basic).

[20] *Id.*

wide range of investors that participate in the national market system. Reducing fees for broker-dealers that represent retail investors and that may have more limited resources than some of their larger competitors would further increase access to such data and facilitate a competitive market for U.S. equity securities, consistent with the goals of the Act.

While the Exchange is not required to make any data, including top of book data, available through its proprietary market data platform, the Exchange believes that making such data available increases investor choice, and contributes to a fair and competitive market. Specifically, making such data publicly available through proprietary data feeds allows investors to choose alternative, potentially less costly, market data based on their business needs. While some market participants that desire a consolidated display choose the SIP for their top of book data needs, and in some cases are effectively required to do so under the Vendor Display Rule, others may prefer to purchase data directly from one or more national securities exchanges. For example, a buy-side investor may choose to purchase the Cboe One Summary Feed, or a similar product from another exchange, in order to perform investment analysis. The Cboe One Summary Feed represents quotes from four highly liquid equities markets. As a result, the Cboe One Summary Feed is within 1% of the national best bid and offer approximately 98% of the time,[21] and therefore serves as a valuable reference for investors that do not require a consolidated display that contains quotations for all U.S. equities exchanges. Making alternative products available to market participants ultimately ensures increased competition in the marketplace, and constrains the ability of exchanges to charge supracompetitive fees. In the event that a market participant views one exchanges top of book data fees as more or less attractive than the competition they can and frequently do switch between competing products. In fact, the competiveness of the market for such top of book data products is one of the primary factors animating this proposed rule change, which is designed to allow the Exchange to further compete for this business.

Indeed, the Exchange has already successfully onboarded one new Distributor that has decided to purchase Cboe One Summary Data from the Exchange rather than purchasing top of book data from a competitor exchange, and is in the process of onboarding another new Distributor. In addition, the Exchange is in discussions with a handful of other Distributors that are interested in procuring market data from the Exchange due to the attractive pricing offered pursuant to the Program. Distributors can discontinue use at any time and for any reason, including due to an assessment of the reasonableness of fees charged. Further, firms have a wide variety of alternative market data products from which to choose, such as similar proprietary data products offered by other national securities exchanges. Making the Exchange's top of book data available at a lower cost, ultimately serves the interests of retail investors that rely on the public markets. The Exchange understands that the Commission is interested in ensuring that retail investors are appropriately served in the U.S. equities market. The Exchange agrees that it is important to ensure that our markets continue to serve the needs of ordinary investors, and the Program is consistent with this goal.

The Exchange believes that the proposed fees are reasonable as they represent a significant cost reduction for smaller, primarily regional, retail brokers that provide top of book data from EDGX and its affiliated equities exchanges to their retail investor clients. The market for top of book data is intensely competitive due to the availability of substitutable products that can be purchased either from other national securities exchanges, or from registered SIPs that make such top of book data publicly available to investors at a modest cost. The proposed fee reduction is being made to make the Exchange's fees more competitive with such offerings for this segment of market participants, thereby increasing the availability of the Exchange's data products, and expanding the options available to firms making data purchasing decisions based on their business needs. The Exchange believes that this is consistent with the principles enshrined in Regulation NMS to ''promote the wide availability of market data and to allocate revenues to SROs that produce the most useful data for investors.'' [22]

Today, the Exchange's top of book market data products are among the most competitively priced in the industry due to modest subscriber fees, and a lower Enterprise cap, both of which keep fees at a relatively modest level for larger firms that provide market data to a sizeable number of Professional or Non-Professional Users. Distributors with a smaller user base, however, may choose to use competitor products that have a lower distribution fee and higher subscriber fees. The Program would help the Exchange compete for this segment of the market, and may broaden the reach of the Exchange's data products by providing an additional low cost alternative to competitor products for small retail brokers. While such firms may already utilize similar market data products from other sources, the Exchange believes that offering its own data to small retail brokers at lower distribution and data consolidation costs has the potential to increase choice for market participants, and ultimately increase the data available to retail investors when coupled with the Exchange's lower subscriber fees.

The Exchange also believes that the proposed fees are equitable and not unfairly discriminatory as the proposed fee structure is designed to decrease the price and increase the availability of U.S. equities market data to retail investors. The Program is designed to reduce the cost of top of book market data for broker-dealers that provide such data to Non-Professional Data User clients that make up the majority of the distributor's total subscriber population. While there is no ''exact science'' to choosing one eligibility threshold compared to another, the Exchange believes that having more Non-Professional Data Users than Professional Data User across a firm's entire business, *i.e.,* not limited exclusively to Data Users that are provided access to the Exchange's data products, is indicative of a broker-dealer that is primarily and actively engaged in the business of serving retail investors. This understanding is confirmed by the current customers that participate in or are soon to participate in the Program, each of which are focused on providing trading services to ordinary investors. As such, the Program would be broadly available to a wide range of retail brokers that either purchase the Cboe One Summary Feed today, or that may choose to switch from competing products due to the potential cost savings. In addition to the subscribers that are participating and are soon to participate in the Program, dozens of distributors that currently purchase top of book data from one of the four Cboe U.S. equities exchanges, and many more prospective customers, could benefit from the Program. Each of these current or prospective retail broker customers would receive the same benefits in

[21] *See https://markets.cboe.com/us/equities/market_data_services/cboe_one/.*

[22] *See* Regulation NMS Adopting Release, supra note 17, at 37503.

terms of reduced distribution and consolidation fees based on the product that they purchase from the Exchange.

The Commission has long stressed the need to ensure that the equities markets are structured in a way that meets the needs of ordinary investors. For example, the Commission's strategic plan for fiscal years 2018–2022 touts ''focus on the long-term interests of our Main Street investors'' as the Commission's number one strategic goal.[23] The Program would be consistent with the Commission's stated goal of improving the retail investor experience in the public markets. Furthermore, national securities exchanges commonly charge reduced fees and offer market structure benefits to retail investors, and the Commission has consistently held that such incentives are consistent with the Act. The Exchange believes that the Program is consistent with longstanding precedent indicating that it is consistent with the Act to provide reasonable incentives to retail investors that rely on the public markets for their investment needs.

In addition, while the Program would be effectively limited to smaller firms that distribute data to no more than 5,000 Non-Professional Data Users, the Exchange does not believe that this limitation makes the fees inequitable, unfairly discriminatory, or otherwise contrary to the purposes of the Act. Large broker-dealers and/or vendors that distribute the Exchange's data products to a sizeable number of investors benefit from the current fee structure, which includes lower subscriber fees and Enterprise licenses. Due to lower subscriber fees, distributors that provide EDGX Equities Exchange Data to more than 5,000 Non-Professional Data Users already enjoy cost savings compared to competitor products. The Program would therefore ensure that small retail brokers that distribute top of book data to their retail investor customers could also benefit from reduced pricing, and would aid in increasing the competitiveness of the Exchange's data products for this key segment of the market.

The table below illustrates the impact of the proposed pricing on firms that qualify for the Program, both compared to the Exchange's current pricing, and compared to the fees charged for a competitor product, *i.e.,* Nasdaq Basic. As shown, Cboe One Summary Feed Data provided pursuant to the Program would be cheaper than Nasdaq Basic for firms with more than 1,200 Non-Professional Users, and the benefits of the pricing structure would continue to scale up to firms with 5,000 Non-Professional Users. Further, EDGX Top Data, which is already subject to a lower distribution fee than Nasdaq Basic, would become even more cost effective. After 5,000 Non-Professional Users the firm would no longer be eligible for the Small Retail Broker Distribution Program but would already enjoy significant cost savings compared to Nasdaq Basic under the current pricing structure. The Exchange therefore believes that the Program would allow the Exchange to better compete with competitors for smaller firms that currently pay a lower fee under, for example, the Nasdaq Basic pricing model, while also ensuring that larger firms continue to receive attractive pricing that is already cheaper than top of book data offered by the main competitor product. The Exchange believes this supplemental information further validates its assessment that the proposed fee reduction is reasonable, equitable, and not unfairly discriminatory. Without the proposed fee reduction, small retail brokers that would otherwise qualify for the reduced fees proposed would be subject to either higher fees for accessing Exchange top of book data, or may switch to competitor offerings that are also less cost effective, but at current fees levels, cheaper than the current Cboe One Summary fee.

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[23] *See* U.S. Securities and Exchange Commission, Strategic Plan, Fiscal Years 2018–2022, available at *https://www.sec.gov/files/SEC_Strategic_Plan_FY18-FY22_FINAL_0.pdf.*

	1,200			Nasdaq Basic	Difference vs. Nasdaq Basic
Product	Non-Professional User Qty	Standard Model Total Fee	SRBP Total Fee	Total Fee	Total Fee
Cboe One Summary	1,200	$ 6,000.00	$ 3,850.00	$3,850	0.00
EDGX Top	1,200	$ 1,500.00	$ 750.00	$3,850	3100.00

	3,350			Nasdaq Basic	Difference vs. Nasdaq Basic
Product	Non-Professional User Qty	Standard Model Total Fee	SRBP Total Fee	Total Fee	Total Fee
Cboe One Summary	3,350	$ 6,000.00	$ 3,850.00	$6,000	2150.00
EDGX Top	3,350	$ 1,500.00	$ 750.00	$6,000	5250.00

	7,500			Nasdaq Basic	Difference vs. Nasdaq Basic
Product	Non-Professional User Qty	Standard Model Total Fee	SRBP Total Fee	Total Fee	Total Fee
Cboe One Summary	7,500	$ 6,000.00	$ 3,850.00	$10,150	4150.00
EDGX Top	7,500	$ 1,500.00	$ 750.00	$10,150	9400.00

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B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change would result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange operates in a highly competitive environment, and its ability to price these data products is constrained by: (i) Competition among exchanges that offer similar data products to their customers; and (ii) the existence of inexpensive real-time consolidated data disseminated by the SIPs. Top of book data is disseminated by both the SIPs and the thirteen equities exchanges. There are therefore a number of alternative products available to market participants and investors. In this competitive environment potential subscribers are free to choose which competing product to purchase to satisfy their need for market information. Often, the choice comes down to price, as broker-dealers or vendors look to purchase the cheapest top of book data product, or quality, as market participants seek to purchase data that represents significant market liquidity. In order to better compete for this segment of the market, the Exchange is proposing to reduce the cost of top of book data provided by small retail brokers to their retail investor clients. The Exchange believes that this would facilitate greater access to such data, ultimately benefiting the retail investors that are provided access to such market data.

The Exchange does not believe that this price reduction would cause any unnecessary or inappropriate burden on intermarket competition as other exchanges and data vendors are free to lower their prices to better compete with the Exchange's offering. Indeed, as explained in the basis section of this proposed rule change, the Exchange's decision to lower its distribution and consolidation fees for small retail brokers is itself a competitive response to different fee structures available on competing markets. The Exchange therefore believes that the proposed rule change is pro-competitive as it seeks to offer pricing incentives to customers to better position the Exchange as it competes to attract additional market data subscribers. The Exchange also believes that the proposed reduction in fees for small retail brokers would not cause any unnecessary or inappropriate burden on intramarket competition. Although the proposed fee discount would be largely limited to small retail broker subscribers, larger broker-dealers and vendors can already purchase top of book data from the Exchange at prices that represent a significant cost savings

when compared to competitor products that combine higher subscriber fees with lower fees for distribution. In light of the benefits already provided to this group of subscribers, the Exchange believes that additional discounts to small retail brokers would increase rather than decrease competition among broker-dealers that participate on the Exchange. Furthermore, as discussed earlier in this proposed rule change, the Exchange believes that offering pricing benefits to brokers that represent retail investors facilitates the Commission's mission of protecting ordinary investors, and is therefore consistent with the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

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 [24] and paragraph (f) of Rule 19b–4 [25] 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 (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–CboeEDGX–2019–059 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–2019–059. 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 (*http://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. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR-CboeEDGX–2019–059 and should be submitted on or before November 7, 2019.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[26]

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2019–22702 Filed 10–16–19; 8:45 am]

BILLING CODE 8011–01–P

[24] 15 U.S.C. 78s(b)(3)(A).

[25] 17 CFR 240.19b–4(f).

[26] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

Submission for OMB Review; Comment Request

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736

Extension:

Rules 13n–4(b)(9), (b)(10) and (d), SEC File No. 270–793, OMB Control No. 3235–0738

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1995 (''PRA'') (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (''Commission'') has submitted to the Office of Management and Budget (''OMB'') a request for approval of extension of the previously approved collection of information provided for in rules 13n–4(b)(9), (b)(10) and (d) under the Securities Exchange Act of 1934 (15 U.S.C. 78a *et seq.*).

Rules 13n–4(b)(9), (b)(10) and (d) implement Exchange Act sections 13(n)(5)(G) and (H), which conditionally require security-based swap data repositories (SDRs) registered with the SEC to make security-based swap data available to certain regulators and other authorities. The rules in part would condition this access to data on the regulators and other authorities entering into memoranda of understanding or other arrangements with the Commission to address the confidentiality of the data made available. The rules further would require SDRs to create and maintain records regarding such data access. In addition, certain regulators or other authorities that are not otherwise designated by statute or rule may submit applications to the Commission requesting that they be deemed eligible to access the relevant security-based swap data.

Implementation of the statutory data access provisions—including the confidentiality condition and the Commission's authority to designate entities to access such information—will facilitate regulatory oversight of the security-based swap market and its participants, including oversight of systemic and other risks associated with the market. Implementation also will promote compliance with applicable laws and regulations, including but not limited to compliance with the antifraud provisions of the federal securities laws.

Commission Staff estimates that the total annual burden associated with Rules 13n–4(b)(9), (b)(10) and (d) is 35,700 hours and $400,000, calculated as follows:

Commission staff estimates a total of 30 regulators or other authorities will enter into confidentiality arrangements with the Commission to obtain access to security-based swap data pursuant to these provisions. On average, each of those recipients of data is expected to expend 500 hours in connection with negotiating these MOUs or other arrangements, for a one-time aggregate burden of 15,000 hours, with no associated ongoing burdens. This

equates to 5,000 hours per year when annualized over three years.

Commission staff estimates that a total of 21 regulators or other authorities (that otherwise are not identified by statute or the rules as being eligible for access) may request that the Commission determine that they be able to access such security-based swap data. On average, each of those entities is expected to expend 40 hours in connection with such requests, for a one-time aggregate burden of 840 hours, with no associated ongoing burdens. This equates to 280 hours per year when annualized over three years.

Commission staff also estimates that a total of 10 SDRs may be expected to incur systems-related costs associated with setting up access to security-based swap data for regulators and other authorities. On average, each of those entities is expected to expend 7,800 hours in connection with providing such connectivity, for a one-time aggregate burden of 78,000 hours, with no associated no ongoing burdens associated with this requirement. This equates to 26,000 hours when annualized over three years.

In addition, Commission staff estimates that a total of 10 SDRs may incur costs associated with notifying the Commission when the SDR receives the first request for security-based swap data from a particular entity. On average, each of those SDRs is expected to expend 150 hours in connection with this notice requirement (based on each SDR providing 300 notices, at half-hour per notice), for a one-time aggregate burden of 1,500 hours, with no associated ongoing burdens. This equates to 500 hours per year when annualized over three years.

Commission staff estimates that a total of 10 SDRs may incur costs associated with the requirement that they maintain records of all information related to initial and subsequent requests for data access. On average, compliance with this provision is expected to require 360 hours initially and 280 hours annually per SDR, for a total burden of 3,600 hours initially and 2,800 hours annually across ten SDRs. This equates to 4,000 hours per year when annualized over three years. Commission staff further estimates that those SDRs each will require $40,000 annually in connection with that requirement, for a total cost of $400,000 annually across ten SDRs.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information under the PRA unless it displays a currently valid OMB control number.

The public may view background documentation for this information collection at the following website: *www.reginfo.gov.* Comments should be directed to: (i) Desk Officer for the Securities and Exchange Commission, Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10102, New Executive Office Building, Washington, DC 20503, or by sending an email to: *Lindsay.M.Abate@omb.eop.gov;* and (ii) Charles Riddle, Acting Director/Chief Information Officer, Securities and Exchange Commission, c/o Candace Kenner, 100 F Street NE, Washington, DC 20549, or by sending an email to: *PRA_Mailbox@sec.gov.* Comments must be submitted to OMB within 30 days of this notice.

Dated: October 10, 2019.

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2019–22579 Filed 10–16–19; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–87270; File No. SR–BX–2019–033]

Self-Regulatory Organizations; Nasdaq BX, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend BX Rules at Chapter VI, Section 6

October 10, 2019.

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 October 8, 2019, Nasdaq BX, Inc. (''BX'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II, 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

The Exchange proposes to amend BX Rules at Chapter VI, Section 6, ''Acceptance of Quotes and Orders,'' Chapter VI, Section 7, ''Entry and Display Orders,'' Chapter VI, Section 10, ''Book Processing,'' Chapter VI, Section 21, ''Order and Quote Protocols,'' Chapter VII, Section 5, ''Obligations of Market Makers,'' and Chapter VII, Section 12, ''Order Exposure Requirements.'' The Exchange proposes to relocate certain current rules to new Rules Chapter VI, Section 22, titled ''Kill Switch'' and 23, titled ''Detection of Loss of Communication.''

The text of the proposed rule change is available on the Exchange's website at *http://nasdaqbx.cchwallstreet.com/,* at the principal office of the Exchange, 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 Chapter VI, Section 6, ''Acceptance of Quotes and Orders,'' Chapter VI, Section 7, ''Entry and Display Orders,'' Chapter VI, Section 10, ''Book Processing,'' Chapter VI, Section 21, ''Order and Quote Protocols,'' Chapter VII, Section 5, ''Obligations of Market Makers,'' and Chapter VII, Section 12, ''Order Exposure Requirements.'' The Exchange proposes to relocate certain current rules to new Rules Chapter VI, Section 22, titled ''Kill Switch'' and 23, titled ''Detection of Loss of Communication.'' Each rule change will be discussed in greater detail below.

Chapter VI, Section 6, Acceptance of Quotes and Orders

Currently, Chapter VI, Section 6 is titled ''Acceptance of Quotes and Orders.'' The Exchange proposes to retitle Chapter VI, Section 6 as ''Entry and Display of Quotes.'' The Exchange proposes to add an (a) before the first paragraph. The Exchange is removing references to orders in this Rule because it also proposes to adopt a new Chapter VI, Section 7, titled ''Entry and Display of Orders'' to describe requirements for order entry.

The Exchange proposes to add a new section (b) to Chapter VI, Section 6 to describe the current requirements and

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

conditions for submitting quotes. These requirements reflect the current System operation today. The Exchange proposes to memorialize the various requirements for the submission of quotes into the System for greater transparency. The Exchange proposes to provide at proposed Chapter VI, Section 6(b), ''Quotes are subject to the following requirements and conditions:''. The Exchange proposes to add at Chapter VI, Section 6(b)(1) that ''Market Makers may generate and submit option quotations.'' Current Chapter VII, Section 6 makes clear that Market Makers may submit quotes,[3] however the Exchange proposes to create a list of rules related to quote submission within this rule for ease of reference. The Exchange proposes to provide at proposed Chapter VI, Section 6(b)(2) that ''The System shall time-stamp a quote which shall determine the time ranking of the quote for purposes of processing the quote.'' The Exchange notes that all quotes today are time-stamped for purposes of processing quotes. Proposed Rule Chapter VI, Section 6(b)(3) states that ''Market Makers may enter bids and/or offers in the form of a two-sided quote. Only one quote may be submitted at a time for an option series.'' The Exchange believes that this information will provide Market Makers with information on submitting a quote. The Exchange notes that bid or offer may be a ''0,'' however a price is required to be entered for both the bid and offer to be entered into the System. Further, the Exchange proposes at Chapter VI, Section 6(b)(4) to provide clarity for entering quotes and proposes to specify, ''The System accepts quotes beginning at a time specified by the Exchange and communicated on the Exchange's website.'' [4] The Exchange believes that this information will bring greater transparency to the Rulebook with respect to limitations for submitting quotations into the System.

The Exchange proposes a provision regarding firm quote within proposed Rule Chapter VI, Section 6(b)(5):

Firm Quote. When quotes in options on another market or markets are subject to relief from the firm quote requirement set forth in the SEC Quote Rule, orders and quotes will receive an automatic execution at or better than the NBBO based on the best bid or offer in markets whose quotes are not subject to such relief. Such determination may be made by way of notification from another market that its quotes are not firm or are unreliable; administrative message from the Option Price Reporting Authority (''OPRA''); quotes received from another market designated as ''not firm'' using the appropriate indicator; and/or telephonic or electronic inquiry to, and verification from, another market that its quotes are not firm. The Exchange shall maintain a record of each instance in which another exchange's quotes are excluded from the Exchange's calculation of NBBO, and shall notify such other exchange that its quotes have been so excluded. Where quotes in options on another market or markets previously subject to relief from the firm quote requirement set forth in the Quote Rule are no longer subject to such relief, such quotations will be included in the calculation of NBBO for such options. Such determination may be made by way of notification from another market that its quotes are firm; administrative message from OPRA; and/or telephonic or electronic inquiry to, and verification from, another market that its quotes are firm.

BX Chapter VI, Section 6(b)(5) describes Firm Quote for purposes of quote submission. The Exchange proposes to memorialize within its Rules the requirement for the dissemination of quotations pursuant to Reg NMS.[5] The Exchange is proposing to add the above rule text to provide context as to this restriction for submitting quotes. The Exchange proposes to make clear the manner in which quote relief will occur. Specifically, this proposed rule text indicates the manner in which a determination for quote relief is made. Further, the rule notes the Exchange shall maintain a record of each instance in which another exchange's quotes are excluded from the Exchange's calculation of NBBO, and shall notify such other exchange that its quotes have been so excluded. Also, when relief is no longer available, such quotations will be included in the calculation of NBBO for such options. The Exchange notes how the determination is made that relief is no longer available. The proposed rule text adds greater context to the manner in which Firm Quote relief is applied. This rule text represents the current practice.

Similarly, the Exchange proposes to provide the following proposed new Chapter VI, Section 6(b)(6):

Trade-Through Compliance and Locked or Crossed Markets. A quote will not be executed at a price that trades through another market or displayed at a price that would lock or cross another market. If, at the time of entry, a quote would cause a locked or crossed market violation or would cause a trade-through, violation, it will be re-priced to the current national best offer (for bids) or the current national best bid (for offers) and displayed at one minimum price variance above (for offers) or below (for bids) the national best price.

Today, quotations may not be executed against prices that trade-through an away market as provided for in the Options Order Protection and Locked/Crossed Market Plan which is also described within Chapter XII, Options Order Protection and Locked and Crossed Market Rules. Also, quotations may not lock or cross an away market. The repricing is provided for today within BX Chapter VI, Section 7(b)(3)(C).[6] By stating this limitation in the rule, Market Makers will have greater clarity as to this limitation. Further, the Exchange is making clear that a quote that would cause a locked or crossed market violation or would cause a trade-through violation will be re-priced. The Exchange would display the quote at one minimum price variation (''MPV'') above (for offers) or below (for bids) the national best price. Repricing quotes is consistent with the Act because the Exchange is not permitted to lock or cross an away market's quote or order. The Exchange reprices the quotes one MPV inferior to cause the displayed price to reflect the available market on BX.

Finally, the Exchange proposes at Chapter VI, Section 6(b)(7) to provide, ''Quotes submitted to the System are subject to the following: Minimum increments provided for in Chapter VI, Section 5 and risk protections provided for in Chapter VI, Section 18.'' The Exchange is noting herein the manner in which a quote may be rejected by the System to provide market participants with expectations as to the interplay among the various BX Rules. Specifically, if the Market Maker does not submit a quotation compliant with Chapter VI, Section 5, the quote will not be accepted by the System because market participants are required to abide by Chapter VI, Section 5 which describes the increments with which options series are to be quoted. Chapter VI, Section 18 provides a list of all protections applicable to quotes that may be rejected. The Exchange believes that this rule will provide Options Participants with requirements and

[3] Chapter VII, Section 6(b) provides, ''A Market Maker that enters a bid (offer) in a series of an option in which he is registered on BX Options must enter an offer (bid).''

[4] The system settings page is located: *http://www.nasdaqtrader.com/content/technicalsupport/BXOptions_SystemSettings.pdf.*

[5] 17 CFR 242.602.

[6] An order that is designated by a member as non-routable will be re-priced in order to comply with applicable Trade-Through and Locked and Crossed Markets restrictions.

conditions for submitting quotations and provide transparency as to limitations that cause a quote to be rejected.

The Exchange proposes to provide at Chapter VI, Section 6(c), ''Quotes will be displayed in the System as described in Chapter VI, Section 19.'' Chapter VI, Section 19, titled ''Data Fees and Trade Information'' provides for the available feeds that Options Participants may access on the Exchange. This list represents the available data feeds and the content of those data feeds which are offered today by BX.

The amendments to BX Chapter VI, Section 6 create a list of all the requirements and conditions for submitting quotes on BX within one rule is consistent with the Act because it will provide greater transparency to market participants of the applicable requirements. Further, this proposal will make the current rule clear and understandable for market participants thereby protecting investors and the general public. The Exchange notes that while some of these requirements appear in other rules, for ease of reference the requirements are located within a single rule with this proposal. The proposal reflects the Exchange's current practice with respect to quoting requirements. This proposal will conform this Rule to other Nasdaq affiliated markets filing similar rules.[7] The Exchange's proposal is intended to provide greater information with respect to Firm Quote within new BX Chapter VI, Section 6(b)(5) and regarding trade-through and locked and crossed markets Section 6(b)(6). The addition of this rule text is consistent with the Act because the Exchange is adding detail regarding the method in which quotes which are firm or locked and crossed will be handled in the System. The notifications for Firm Quote are made clear with the proposed rule text. The Exchange believes that it is consistent with the Act to specify when quotes are firm and the handling of such quotes by the System for the protection of investors and the general public. The clarity is designed to promote just and equitable principles of trade by notifying all participants engaged in market making of potential outcomes. Today, quotations may not be executed against at prices that trade-through an away market. Also, quotations may not lock or cross an away market. The repricing of quotations is consistent with the Act because repricing prevents the Exchange from disseminating a price which locks or crosses another market. BX is required to avoid displaying a quotation that would lock or cross a quotation of another market center at the time it is displayed. Preventing inferior prices from displaying perfects the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest.

The Exchange proposes to delete the rule text at Chapter VI, Section 6(a)(1) and (2), which states:

(a) General—A System order is an order that is entered into the System for display and/or execution as appropriate. Such orders are executable against marketable contra-side orders in the System.

(1) All System Orders shall indicate whether they are a call or put and buy or sell and a price, if any. Systems Orders can be designated as Immediate or Cancel (''IOC''), Good-till-Cancelled (''GTC''), Day (''DAY'') or WAIT. Any of the foregoing may also be designated as a Directed Order.

(2) A System order may also be designated as a Limit Order, a Minimum Quantity Order, a Market Order, or an All-or-None Order. Any of the foregoing may also be designated as a Directed Order.

The Exchange notes that all order types listed in Chapter VI, Section 1(e) may be entered on BX. All order types are executable against marketable contra-side orders in the System. The System will not permit an order to execute that is not marketable. BX has described in this proposal that it would not trade-through an away market. All Time in Force designations noted in Chapter VI, Section 1(g) are available to market participants entering orders on BX. The Exchange believes that the information provided in Chapter VI, Section 6(a)(1) and (2) is also covered within Chapter VI, Section 1 and therefore proposes to delete this rule text.

The Exchange proposes to relocate Chapter VI, Section 6(a)(3), relating to zero-bid, and 6(b), relating to routing, into Chapter VI, Section 10(5) and (6). The Exchange believes that this information should be described within the rule describing allocation. Chapter VI, Section 6(c), which is reserved, is being deleted. The Exchange proposes to relocate Chapter VI, Section 6(d), related to the BX Options Kill Switch, to new Chapter VI, Section 22. The Exchange proposes to relocate Chapter VI, Section 6(e), related to Detection of Loss of Communication, to new Chapter VI, Section 23. The Exchange believes that these two topics should be in separate rules for ease of locating those rules.

The Exchange is not proposing to amend the Kill Switch or Detection of Loss of Communication rules; this rule change is non-substantive. The Exchange proposes to update internal cross-references.

Chapter VI, Section 7, Entry and Display Orders

The Exchange proposes to amend Chapter VI, Section 7 titled ''Entry and Display Orders.'' The Exchange proposes to retitle this rule, ''Entry and Display of Orders.'' Similar to Chapter VI, Section 6 for quotes, the Exchange proposes this new rule to describe the current requirements and conditions for entering orders. The Exchange notes that the requirements provided for within this rule represent the current practice. The purpose of Chapter VI, Section 7 is to memorialize this information within a single rule.

The Exchange proposes to amend Chapter VI, Section 7(a) to remove the title, ''Entry of Orders- ''. The Exchange proposes to memorialize the manner in which orders may be submitted to the System to add more detail to its rules. The Exchange proposes to amend Chapter VI, Section 7(a)(1) to remove and unnecessary ''a'' and also to remove the sentence which provides, ''Each order shall indicate the amount of Reserve Size (if applicable).'' No order type on BX has a Reserve Size.[8] BX no longer has any order types with non-displayed interest; previously, BX offered Discretionary Orders and Reserve Orders on BX, but both have been eliminated. The Exchange proposes to adopt a new Chapter VI, Section 7(a)(2) which provides, ''The System accepts orders beginning at a time specified by the Exchange and communicated on the Exchange's website.'' [9] The Exchange proposes to renumber current Chapter VI, Section 7(a)(2) as (a)(3). The Exchange proposes to renumber current Chapter VI, Section 7(a)(3) as (a)(4) and amend the rule which provides, ''Orders can be entered into the System (or previously entered orders cancelled) from the time prior to market open specified by the Exchange on its website until market close'' to ''Orders submitted to the System are subject to minimum increments

[7] Nasdaq Phlx, Nasdaq ISE, LLC, Nasdaq GEMX, LLC and Nasdaq MRX, LLC have similar rules. *See* Securities Exchange Act Release Nos. 86286 (July 2, 2019), 84 FR 32794 (July 9, 2019) (SR–Phlx–2019–25); 86947 (September 12, 2019), 84 FR 49165 (September 18, 2019) (SR–ISE–2019–23); 87180 (October 1, 2019), 84 FR 53497 (October 7, 2019) (SR–GEMX–2019–13) and 87182 (October 1, 2019), 84 FR 53534 (October 7, 2019) (SR–MRX–2019–20).

[8] *See* Securities Exchange Act Release No. 65873 (December 2, 2011), 76 FR 76786 (December 8, 2011) (SR–NASDAQ–2011–164).

[9] *See* note 4 above.

provided for in Chapter VI, Section 5, risk protections within Chapter VI, Section 18 and the restrictions of order types within Chapter VI, Section 21(b). Orders may execute at multiple prices.'' The Exchange is proposing to conform order entry rules across its Nasdaq Affiliated markets, where applicable. The Exchange proposed the time during which the System accepts orders within Chapter VI, Section 7(a)(2) and therefore this rule text is not necessary as the proposed rule describes time for accepting orders elsewhere. All orders must adhere to other rule requirements such as minimum increments, risk protection rules and order types. Similar to the rule text for quotes, orders are currently subject to the minimum increment requirements in Chapter VI, Section 5, the risk protections for orders which are listed within current Chapter VI, Section 18 as well as the restrictions of order types within Chapter VI, Section 21(b). This rule provides a list of other requirements which may impact the execution of an order. Finally, orders may execute at multiple prices. This rule provides a list of other requirements which may impact the execution of an order.

The Exchange proposes to add new rule at Chapter VI, Section 7(a)(5) which states, ''Nullification by Mutual Agreement. Trades may be nullified if all parties participating in the trade agree to the nullification. In such case, one party must notify the Exchange and the Exchange promptly will disseminate the nullification to OPRA. It is considered conduct inconsistent with just and equitable principles of trade for a party to use the mutual adjustment process to circumvent any applicable Exchange rule, the Act or any of the rules and regulations thereunder.'' The rule text of new Chapter VI, Section 7(a)(5) is similar to Nasdaq ISE, LLC (''ISE''), Nasdaq GEMX, LLC (''GEMX'') and Nasdaq MRX, LLC (''MRX'') Options 3, Section 4(b). Trades may be nullified today by agreement of the parties. The Exchange believes that it is consistent with the Act to permit parties to agree to a nullification provided the nullification does not violate other exchange rules. The Exchange notes that parties may not agree to a mutual agreement for purposes that would cause another rule to be violated. The Exchange believes that it is consistent with the Act and protection of investors and general public to make clear the expected behavior with respect to nullifications.

The Exchange proposes to adopt new rule text at Chapter VI, Section 7(b) is similar to rule text at to ISE, GEMX and MRX Options 3, Section 15(a). This proposed rule provides,

NBBO Price Protection. Orders, other than Intermarket Sweep Orders (as defined in Rule Chapter XII, Section 1(9)) will not be automatically executed by the System at prices inferior to the NBBO (as defined in Chapter XII, Section 1(11)). There is no NBBO price protection with respect to any other market whose quotations are Non-Firm (as defined in Chapter XII, Section 1(12)).

The Exchange believes that although BX Rules [10] make clear that orders may not execute at prices inferior to the NBBO, this rule text will provide that limitation in this proposed list of limitations for ease of reference. The Exchange notes that this NBBO Protection applies to orders and therefore is being discussed within proposed Chapter VI, Section 7 which applies to all Options Participants. In contrast, Chapter VI, Section 6, which applies to quotes entered by Market Makers, describes the Firm Quote protections and the interplay of NBBO with respect to quotes. Trade-Through is described in both Chapter VI, Section 6 and 7.

The Exchange proposes to state at Chapter VI, Section 7(c), ''The System automatically executes eligible orders using the Exchange's displayed best bid and offer (''BBO'').'' This rule seeks to define the Exchange's best bid and offer as the ''BBO.'' On BX, eligible orders will execute at the best price available, the BBO. The Exchange believes that this information will provide Options Participants with additional information as some markets have non-displayed order types and BX has no non-displayed order types.

The Exchange proposes to relocate BX Chapter VI, Section 7(b)(3)(C) to Chapter VI, Section 7(d).

The Exchange proposes to add a sentence at Chapter VI, Section 7(e) which provides, ''Orders will be displayed in the System as described in Chapter VI, Section 19.'' Chapter VI, Section 19 contains information on data feeds and the information that is provided. This provision is similar to Chapter VI, Section 6(c).

The Exchange proposes to delete current Chapter VI, Section 7(b)(1)–(3) which provides,

(1) System Book Feed—displayed orders resident in the System available for execution will be displayed via the System Book Feed.

(2) Best Priced Order Display—For each System Security, the aggregate size of all Orders at the best price to buy and sell resident in the System will be transmitted for display to the appropriate network processor.

(3) Exceptions—The following exceptions shall apply to the display parameters set forth in paragraphs (1) and (2) above:

The display of orders as well as the text relating to System Book Feed are being deleted because data feeds are described in other rules.[11] The Exchange believes this information is unnecessary as the data feeds are specific as to the content of the displayed information. The Exchange is also proposing to remove the rule text related to Best Priced Order Display as this information is described within Chapter XII, Options Order Protection and Locked and Crossed Markets. Specifically, BX Chapter XII, Section 1(18) which describes a Protected Bid and Offer and the manner in which they are disseminated to the OPRA Plan. The Exchange proposes to delete Chapter VI, Section 7(b)(3) as well as subsections (A), which is currently reserved. Current BX Chapter VI, Section 7(b)(3) notes exceptions to the display parameters. As noted (A) is reserved and as mentioned herein (B) and (C) are relocated within Section 7.

The Exchange's proposal to adopt a new Chapter VI, Section 7, ''Entry and Display of Orders'' and describe the current requirements and conditions for entering orders, similar to proposed changes to Chapter VI, Section 6 for quotes is consistent with the Act because it will provide transparency as to manner in which orders may be submitted to the System. The Exchange's new rule reflects the current requirements for submitting orders into the System. Similar to proposed Chapter VI, Section 6, the Exchange proposes to memorialize requirements and limitations within one rule for ease of reference.

Chapter VI, Section 10, Book Processing

As noted above, the Exchange is relocating rule text from current Chapter VI, Section 6(a)(3) and 6(b) to Chapter VI, Section 10(5) and (6). The Exchange also proposes to renumber current Chapter VI, Section 10(5) as ''(7)''.

Chapter VI, Section 21, Order and Quote Protocols

The Exchange proposes to amend Chapter VI, Section 21(a)(i)(B) to add the following sentence to Specialized

[10] Intermarket Sweep Orders (as defined in Rule Chapter XII, Section 1(9)) will not be automatically executed by the System at prices inferior to the NBBO (as defined in Chapter XII, Section 1(11)).

[11] *See* BX Chapter VI, Section 19, ''Data Feeds and Trade Information.''

Quote Feed (''SQF''), ''Market Makers may only enter interest into SQF in their assigned options series.'' The Exchange notes that today Market Makers may utilize SQF to quote only in their assigned options series.[12] This proposed rule text is consistent with the Act because it will add greater clarity to the current rule for the protection of investors and the public interest.

Chapter VII, Section 5, Obligations of Market Makers

The Exchange proposes to add a new Chapter VII, Section 5(d) to describe the manner in which Market Makers may enter orders on BX. There is no rule currently describing order entry by Market Makers. The Exchange proposes to memorialize the current practice by providing ''Market Makers may enter all order types defined in Chapter VI, Section 1(e) in the options classes to which they are appointed and non-appointed.'' This rule will provide Market Makers with information as to the types of orders that may entered on BX.

Chapter VII, Section 12, Order Exposure Requirements

The Exchange proposes to amend current Chapter VII, Section 12, titled ''Order Exposure Requirements.'' The Exchange proposes to amend the title to ''Limitations on Order Entry'' to conform the rule to other Nasdaq affiliate market rules.[13]

The Exchange proposes to amend Chapter VII, Section 12(a) to add the title ''Limitations on Principal Transactions.'' This change is not substantive. The Exchange proposes to amend Chapter VII, Section 12(b) to re-number it as (1) and replace the words ''Section 12'' with ''This Rule.'' The Exchange proposes to add a new Chapter VII, Section 12(b) similar to Phlx Rule 1097(a). The rule text would provide,

Limit Orders. Options Participants shall not enter Public Customer limit orders into the System in the same options series, for the account or accounts of the same or related beneficial owners, in such a manner that the beneficial owner(s) effectively is operating as a market maker by holding itself out as willing to buy and sell such options contract on a regular or continuous basis. In determining whether a beneficial owner effectively is operating as a market maker, the Exchange will consider, among other things: the simultaneous or near-simultaneous entry of limit orders to buy and sell the same options contract and the entry of multiple limit orders at different prices in the same options series.

This Rule prohibits Public Customers from entering limit orders into the Order Book in the same option series in a manner where the public customer is effectively operating as a market maker by holding itself out as willing to buy and sell such options contract on a regular or continuous basis. This rule would limit the ability of Options Participants that are not Market Makers to compete on preferential terms, including Public Customers who are provided with certain benefits, such as priority of bids and offers. Restrictions on the entry of Professional or broker-dealer orders are not imposed because the same priority does not exist. As noted herein, Market Makers are required to register with the Exchange.[14] Market Makers are afforded preferential pricing.[15] The Exchange believes that Public Customers that desire to make markets on BX should register with the Exchange. The Exchange's proposal to adopt this new rule text within Chapter VII, Section 12(b) will bring greater clarity to current limitations that exist when entering orders. Section 12 is consistent with the Act and will promote just and equitable principles of trade and remove impediments to and perfect the mechanism of a free and open market and a national market system because it will continue to make clear the requirement to expose orders as well as present more specific limitations on order entry which would violate BX Rules. Providing members with more information as to the type of behavior that is violative with respect to order exposure will prevent inadvertent violations of Exchange rules and ensure that orders are subject to appropriate price discovery.

The Exchange proposes to amend Chapter VII, Section 12(c) by adding a new titled ''Limitations on Solicitation Orders.'' The Exchange also proposes to amend the rule text to more closely align with ISE, GEMX and MRX Rules at Options 3, Section 22. The amendments to the rule text is not substantive and simply reiterates the same exception for BX PRISM that is currently contained within Chapter VII, Section 12(a) for completeness.

The Exchange proposes to amend Chapter VII, Section 12(d) to add rule text that specifically notes that ''for purposes of violating Chapter VII, Section 12'' at the end of the rule text. This phrase will make clear that the violation is specific to this rule.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[16] in general, and furthers the objectives of Section 6(b)(5) of the Act,[17] in particular, in that it is designed to promote just and equitable principles of trade, 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 as provided for within the purpose section.

Chapter VI, Section 6, Acceptance of Quotes and Orders

The Exchange's proposal to add a new section (b) to Chapter VI, Section 6 to describe the current requirements and conditions for submitting quotes is consistent with the Act. The Exchange proposes within Chapter VI, Section 6 to create a list of all the requirements and conditions for submitting quotes on BX within one rule is consistent with the Act because it will provide greater transparency to market participants of the applicable requirements. The Exchange's proposal is intended to provide greater information with respect to Firm Quote within new Section 6(b)(5) and regarding trade-through and locked and crossed markets Section 6(b)(6).

The additional rule text is consistent with the Act because it adds detail regarding the method in which orders which are firm or locked and crossed will be handled in the System. The notifications for Firm Quote are made clear with the proposed rule text. The Exchange believes that it is consistent with the Act to specify when quotes are firm and the handling of such quotes by the System for the protection of investors and the general public. The clarity is designed to promote just and equitable principles of trade by notifying all participants engaged in market making of potential outcomes. Today, quotations may not be executed against at prices that trade-through an away market. Also, quotations may not lock or cross an away market. The repricing of quotations is consistent with the Act because repricing prevents the Exchange from disseminating a price which locks or crosses another market. BX is required to avoid displaying a quotation that would lock or cross a quotation of another market center at the time it is displayed. Preventing inferior prices from displaying perfects

[12] *See* BX Chapter VII, Section 2.

[13] *See* note 7 above.

[14] *See* BX Chapter VII, Section 2.

[15] *See* BX's Pricing Schedule at Options 7.

[16] 15 U.S.C. 78f(b).

[17] 15 U.S.C. 78f(b)(5).

the mechanism of a free and open market and a national market system, and, in general protects investors and the public interest.

BX is memorializing its current practice by reflecting the various requirements and limitations for quote entry in one rule for ease of reference and clarity. The Exchange proposes to conform this rule to similar rules across other Nasdaq affiliated exchanges.[18] Making clear the manner in which Market Makers may generate and submit option quotations will provide these market participants with clear guidance within the rules. Chapter VII, Section 6(b)(1) makes clear that Market Makers may submit quotes.[19] Further, Chapter VI, Section 21 describes the SQF interface.[20] BX proposes to clarify that only one quote may be submitted at a time for a series. The Exchange believes that memorializing these restrictions will bring greater clarity to the Exchange's rules.

The relocations of both the Kill Switch and Detection of Loss of Communication rules is consistent with the Act because these relocations will bring greater transparency to these protection rules because they will be easier to search by the title within the Rulebook. The relocation of the zero-bid and routing information to Chapter VI, Section 10(5) and (6) is intended to locate that information with rules describing allocation.

The Exchange's proposal to eliminate rule text within current Chapter VI, Section 6(a)(1) and (2) is consistent with the Act because these rules describe order types in general. The order types are described today within Chapter VI, Section 1(e). All order types are executable against marketable contra-side orders in the System. All Time in Force designations noted in Chapter VI, Section 1(g) are available to market participants entering orders on BX. The Exchange believes that the information provided in Chapter VI, Section 6(a)(1) and (2) is covered within Chapter VI, Section 1. The Exchange believes that eliminating this rule is consistent with the Act because the rule text does not add any new information.

Chapter VI, Section 7, Entry and Display Orders

Similar to Chapter VI, Section 6, which describes requirements for quotes, the Exchange proposes to adopt a new Chapter VI, Section 7, ''Entry and Display of Orders'' and describe the current requirements and conditions for entering orders. The Exchange notes that the requirements provided for within this rule represent the current practice. The purpose of Chapter VI, Section 7 is to memorialize this information within a single rule to provide a list of other requirements which may impact the execution of an order. Trades may be nullified today by agreement of the parties. The Exchange believes that it is consistent with the Act to permit parties to agree to a nullification provided the nullification does not violate other exchange rules. The Exchange notes that parties may not agree to a mutual agreement for purposes that would cause another rule to be violated. The Exchange believes that it is consistent with the Act and protection of investors and general public to make clear the expected behavior with respect to nullifications.

Today, orders may not be executed at a price that trades through an away market. Also, orders may not lock or cross an away market. Routable orders must comply with Trade-Through and Locked and Crossed Markets restrictions. The repricing of orders is consistent with the Act because repricing prevents the Exchange from disseminating a price which locks or crosses another market. BX is required avoiding displaying an order that would lock or cross a quotation of another market center at the time it is displayed. Preventing inferior prices from displaying perfects the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest. The Exchange's proposal to adopt a new Chapter VI, Section 7, ''Entry and Display of Orders'' and describe the current requirements and conditions for entering orders, similar to proposed changes to Chapter VI, Section 6 for quotes is consistent with the Act because it will provide transparency as to manner in which orders may be submitted to the System. The Exchange's new rule reflects the current requirements for submitting orders into the System. Similar to proposed Chapter VI, Section 6, the Exchange proposes to memorialize requirements and limitations within one rule for ease of reference.

The Exchange's proposal to adopt a new Chapter VI, Section 7 will conform proposed Rule to other Nasdaq affiliated markets filing similar rules.[21] The Exchange's proposal to add rule text to describe potential violations of this rule will bring greater clarity to current limitations that exist when entering orders. Proposed Chapter VI, Section 7 is consistent with the Act because it provides one rule for ease of reference which lists the current limitations and some additional limitations. The Exchange believes the proposed rule will promote just and equitable principles of trade and remove impediments to and perfect the mechanism of a free and open market and a national market system because it will continue to make clear the requirement to expose orders as well as present more specific limitations on order entry which would violate BX Rules. Providing members with more information as to the type of behavior that is violative with respect to order exposure will prevent inadvertent violations of Exchange rules and ensure that orders are subject to appropriate price discovery.

Chapter VI, Section 21, Order and Quote Protocols

The Exchange's proposal to amend Chapter VI, Section 21(a)(i)(B) to make clear that Market Makers may only enter interest into SQF in their assigned options series is consistent with the Act. Chapter VII, Section 2, Market Maker Registration, describes the manner in which Market Makers are appointed in options series. This sentence simply provides that SQF may only be utilized for quoting in assigned options series.

Chapter VII, Section 5, Obligations of Market Makers

Memorializing information related to order entry for Market Makers within Chapter VII, Section 5 will bring greater clarity to the Rulebook. Today, Market Makers may enter all order types defined in Chapter VI, Section 1(e).

Chapter VII, Section 12, Order Exposure Requirements

The Exchange's proposal to amend Chapter VII, Section 12 to provide a specific rule for entering Public Customer is consistent with the Act. Providing market participants with clear guidelines will protect investors and the public interest by providing additional notice of violative behavior when

[18] *See* note 7 above.

[19] Chapter VII, Section 2 describes the manner in which Market Makers must register and Section 6(c) provides for firm quote.

[20] Chapter VI, Section 21(a)(i)(B) provides, ''Specialized Quote Feed'' or ''SQF'' is an interface that allows Market Makers to connect, send, and receive messages related to quotes, Immediate-or-Cancel Orders, and auction responses into and from the Exchange. Features include the following: (1) Options symbol directory messages (e.g., underlying instruments); (2) system event messages (*e.g.,* start of trading hours messages and start of opening); (3) trading action messages (*e.g.,* halts and resumes); (4) execution messages; (5) quote messages; (6) Immediate-or-Cancel Order messages; (7) risk protection triggers and purge notifications; (8) opening imbalance messages; (9) auction notifications; and (10) auction responses. The SQF Purge Interface only receives and notifies of purge request from the Market Maker.

[21] *See* note 7 above.

entering orders. The proposed rule text is similar to current Nasdaq Phlx LLC Rules.[22] The Exchange believes that this proposed language will provide more transparency as to the types of transactions that are not permitted today on BX. With respect to limit orders, the Exchange seeks to limit the ability of non-market makers to effectively make markets on the Exchange using automated systems that place and cancel orders in a manner that is similar to quoting. With respect to principal transactions, the Exchange is making clear that a BX Options Participant may not take both sides of a trade (the agency side and also act as principal) on an execution without order exposure to provide the agency order the opportunity for price improvement. This rule is intended to ensure that customers receive fair executions. This rule is consistent with the Act in that it promotes just and equitable principles of trade and protects investors and the public interest. The Exchange's proposal to describe exposure of agency orders mirrors language already contained with Chapter VI, Section 12. The Exchange also notes that current Chapter III, Section 4(d) would apply to the types of violations noted with respect to new Chapter VII, Section 12 provisions.

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. The Exchange notes that other options markets have similar rules with respect to order and quote entry and the requirements to expose orders. The implementation of such rules may vary across options markets. Despite the variation in implementation, the Exchange does not believe this proposal creates an undue burden on inter-market competition because the requirements for order exposure are consistent with respect to all markets as well as the ability to submit quotes and orders on all options markets.'

Chapter VI, Section 6, Acceptance of Quotes and Orders

The Exchange's proposal to describe the current requirements and conditions for submitting quotes does not impose an undue burden on competition and all Market Makers are subject to these requirements today. The Exchange is memorializing its current practice by reflecting the various requirements and limitations for quote entry in one rule for ease of reference and clarity. The Exchange is also proposing to conform this rule to similar rules across other Nasdaq affiliated exchanges.

Chapter VI, Section 7, Entry and Display Orders

The Exchange's proposal to amend Chapter VI, Section 7, ''Entry and Display Orders'' to describe the current requirements and conditions for entering orders, similar to proposed changes to Chapter VI, Section 6 for quotes does not create an undue burden on competition because it will apply uniformly to all market participants. The Exchange is memorializing its current practice by reflecting the various requirements and limitations for order entry in one rule for ease of reference and clarity. The Exchange is also proposing to conform this rule to similar rules across other Nasdaq affiliated exchanges. Making clear the manner in which Options Participants may generate and submit option orders will provide these market participants with clear guidance within the rules.

Chapter VI, Section 21, Order and Quote Protocols

The Exchange proposes to amend Chapter VI, Section 21(a)(i)(B) to make clear that Market Makers may only enter interest into SQF in their assigned options series does not impose an undue burden on competition, rather it makes clear that SQF may only be utilized for quoting in assigned options series. This rule is applicable to all Market Makers.

Chapter VII, Section 5, Obligations of Market Makers

Memorializing information related to order entry for Market Makers within Chapter VII, Section 5 does not impose an undue burden on competition. Today, Market Makers may enter all order types defined in Chapter VI, Section 1(e).

Chapter VII, Section 12, Order Exposure Requirements

The Exchange's proposal to amend Chapter VII, Section 12 to provide specific rules for limitations on entering limit orders, principal transactions and agency orders does not impose an undue burden on competition because these rules provide additional specificity as to the manner in which orders may be entered on BX. The Exchange believes that this proposed language will provide more transparency as to the types of transactions that are not permitted today on BX and would violate BX Chapter III, Section 4(f). These rules will apply uniformly to all BX Options Participants.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A)(iii) of the Act[23] and subparagraph (f)(6) of Rule 19b–4 thereunder.[24]

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 shall institute proceedings to determine whether the proposed rule 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 (*http://www.sec.gov/rules/sro.shtml);* or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–BX–2019–033 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.

[22] *See* Nasdaq Phlx LLC Rule 1097.

[23] 15 U.S.C. 78s(b)(3)(A)(iii).

[24] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

All submissions should refer to File Number SR–BX–2019–033. 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 (*http://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. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–BX–2019–033 and should be submitted on or before November 7, 2019.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[25]

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2019–22588 Filed 10–16–19; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–87294; File No. SR–CboeEDGA–2019–015]

Self-Regulatory Organizations; Cboe EDGA Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Introduce a Small Retail Broker Distribution Program

October 11, 2019.

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 October 1, 2019, Cboe EDGA Exchange, Inc. (''Exchange'' or ''EDGA'') 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 EDGA Exchange, Inc. (''EDGA'' or the ''Exchange'') is filing with the Securities and Exchange Commission (the ''Commission'') a proposed rule change to introduce a Small Retail Broker Distribution Program. The text of the proposed changes to the fee schedule are enclosed as Exhibit 5. [sic]

The text of the proposed rule change is also available on the Exchange's website (*http://markets.cboe.com/us/equities/regulation/rule_filings/edga/*), 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 purpose of the proposed rule change is to introduce a pricing program that would allow small retail brokers that purchase top of book market data from the Exchange to benefit from discounted fees for access to such market data. The Small Retail Broker Distribution Program (the ''Program'') would reduce the distribution and consolidation fees paid by small broker-dealers that operate a retail business. In turn, the Program may increase retail investor access to real-time U.S. equity quote and trade information, and allow the Exchange to better compete for this business with competitors that offer similar optional products. The Exchange initially filed to introduce the Program on August 1, 2019 (''Initial Proposal'') to further ensure that retail investors served by smaller firms have cost effective access to its market data products, and as part of its ongoing efforts to improve the retail investor experience in the public markets. The Initial Proposal was published in the **Federal Register** on August 20, 2019,[3] and the Commission received no commenter letters on the proposal. The Program remained in effect until the fee change was temporarily suspended pursuant to a suspension order (the ''Suspension Order'').[4] The Suspension Order also instituted proceedings to determine whether to approve or disapprove the Initial Proposal.[5]

Current Fees

The Cboe One Summary Feed is a top of book data feed that provides real-time U.S. equity quote and trade information to investors based on equity orders submitted to the Exchange and its affiliated equities exchanges—*i.e.,* Cboe EDGX Exchange, Inc., Cboe BZX Exchange, Inc., and Cboe BYX Exchange, Inc. Specifically, the Cboe One Summary Feed is a data feed that contains the aggregate best bid and offer of all displayed orders for securities traded on the Exchange and its affiliated exchanges. The Cboe One Summary Feed also contains the individual last sale information for the Exchange and each of its affiliated exchanges, and consolidated volume for all listed equity securities. The fee for external distribution of the Cboe One Summary Feed is $5,000 per month, and external distributors are also liable for a Data Consolidation Fee of $1,000 per month, and User fees equal to $10 per month for each Professional User, and $0.25 per month for each Non-Professional User.[6]

[25] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 86676 (August 14, 2019), 84 FR 43218 (August 20, 2019) (SR–CboeEDGA–2019–013).

[4] *See* Securities Exchange Act Release No. 87165 (September 30, 2019) (SR–CboeEDGA–2019–013) (**Federal Register** publication pending).

[5] *Id.*

[6] The Exchange also offers an Enterprise license for the Cboe One Summary Feed at a cost of $50,000 per month. An Enterprise license permits distribution to an unlimited number of Professional and Non-Professional Users, keeping costs down for firms that provide access to a large number of subscribers.

Small Retail Broker Eligibility Requirements

The Exchange proposes to introduce a Program that would reduce costs for small retail brokers that provide top of book data to their clients. In order to be approved for the Small Retail Broker Distribution Program, Distributors would have to provide Cboe One Summary Feed Data to a limited number of clients with which the firm has established a brokerage relationship, and would have to provide such data primarily to Non-Professional Data Users. Specifically, distributors would have to attest that they meet the following criteria: (1) Distributor is a broker-dealer distributing Cboe One Summary Feed Data to Non-Professional Data Users with whom the broker-dealer has a brokerage relationship; (2) More than 50% of the Distributor's total Data User population must consist of Non-Professional Data Users, inclusive of those not receiving Cboe One Summary Feed Data; and (3) Distributor distributes Cboe One Summary Feed Data to no more than 5,000 Non-Professional Data Users.

These proposed requirements for participating in the Program are designed to ensure that the benefits provided by the Program inure to the benefit of small retail brokers that provide Cboe One Summary Feed Data to a limited number of subscribers. As explained later in this filing, distributors that provide EDGA Exchange Data to a larger number of subscribers can benefit from the current pricing structure through scale, due to subscriber fees that are significantly lower than those charged by the Exchange's competitors, and an Enterprise license that caps the total fees to be paid by firms that distribute market data to a sizeable customer base. The Exchange believes that offering similarly attractive pricing to small retail brokers, including regional firms both inside and outside of the U.S. that may not have the same established client base as the larger retail brokers, would make the Exchange's data a more competitive alternative for those firms, and would help ensure that such information is widely available to a larger number of retail investors globally. The Program would also be available to retail brokers more generally, regardless of size, that wish to trial the Cboe One Summary Feed with a limited number of subscribers before potentially expanding distribution to additional clients, potentially further increasing the accessibility of the Exchange's market data to retail investors. The Program would be exclusive to the Cboe One Summary Feed, which is a top of book offering, as retail investors typically do not need or use depth of book data to facilitate their equity investments, and their brokers typically do purchase such market data on their behalf.

Discounted Fees

Distributors that participate in the Program would be liable for lower distribution and consolidation fees for access to the Cboe One Summary Data Feed.[7] The distribution fee charged for the Cboe One Summary Feed would be lowered by 30% from the current $5,000 per month to $3,500 per month for distributors that meet the requirements of the Program. In addition, the Data Consolidation Fee charged for the Cboe One Summary Feed would be lowered by 65% from the current $1,000 per month to $350 per month. User fees for any Professional or Non-Professional Users that access Cboe One Summary Feed data from a distributor that participates in the Program would remain at their current levels as the current subscriber charges are already among the most competitive in the industry.[8]

The Exchange believes that these fees, which represent a significant cost savings for small retail brokers, would help ensure that retail investors continue to have fair and efficient access to U.S. equity market data. While retail investors normally pay a fixed commission when buying or selling equities, and do not typically pay separate fees for market data, the Exchange believes that the proposed reduction in fees would make the Exchange's data more competitive with other available alternatives, and may encourage retail brokers to make such data more readily available to their clients. In sum, the Exchange believes that the proposed fee reductions may facilitate more cost effective access to top of book data that is purchased on a voluntary basis by retail brokers and provided to their retail investor clients.

Market Background

The market for top of book data is highly competitive as national securities exchanges compete both with each other and with the securities information processors (''SIPs'') to provide efficient, reliable, and low cost data to a wide range of investors and market participants. In fact, Regulation NMS requires all U.S. equities exchanges to provide their best bids and offers, and executed transactions, to the two registered SIPs for dissemination to the public. Top of book data is therefore widely available to investors today at a relatively modest cost. National securities exchanges may also disseminate their own top of book data, but no rule or regulation of the Commission requires market participants to purchase top of book data from an exchange.[9] The Cboe One Summary Feed therefore competes with the SIP and with similar products offered by other national securities exchanges that offer their own competing top of book products. In fact, there are ten competing top of book products offered by other national securities exchanges today, not counting products offered by the Exchange's affiliates.[10]

The purpose of the proposed rule change is to further increase the competitiveness of the Exchange's top of book market data products compared to competitor offerings that may currently be cheaper for firms with a limited subscriber base that do not yet have the scale to take advantage of the lower subscriber fees offered by the Exchange. In turn, the Exchange believes that this change may benefit market participants and investors by spurring additional competition and increasing the accessibility of the Exchange's top of book data.

As explained, the Exchange filed the Initial Proposal to introduce the Program in August in order to provide an attractive pricing option for small retail brokers. Although that filing was ultimately suspended by the Commission, the Exchange believes that its experience in offering the Program while it was in effect reflect the competitive nature of the market for the creation and distribution of top of book data. Specifically, after the Exchange initially reduced the fees charged to small retail brokers under the Initial Proposal, it successfully onboarded one new customer due to the attractive

[7] New external distributors of the Cboe One Summary Feed are not currently charged external distributor fees for their first month of service. This would continue to be the case for external distributors that participate in the Program.

[8] By comparison, The Nasdaq Stock Market LLC (''Nasdaq'') charges a subscriber fee for Nasdaq Basic that adds up to $26 per month for Professional Subscribers and $1 per month for Non-Professional Subscribers (Tapes A, B, and C). *See* Nasdaq Equity Rules, Equity 7, Pricing Schedule, Section 147(b)(1).

[9] By contrast, Rule 603(c) of Regulation NMS (the ''Vendor Display Rule'') effectively requires that SIP data or some other consolidated display be utilized in any context in which a trading or order-routing decision can be implemented.

[10] Competing top of book products include, Nasdaq Basic, BX Basic, PSX Basic, NYSE BQT, NYSE BBO/Trades, NYSE Arca BBO/Trades, NYSE American BBO/Trades, NYSE Chicago BBO/Trades, and IEX TOPS.

pricing, and is currently in the process of onboarding another customer.[11] These customers are now able to offer high quality and cost effective data to their retail investor clients. The Exchange has also been discussing the Program with a handful of additional prospective clients that are interested in providing top of book data to retail investors. Without the proposed pricing discounts, the Exchange believes that those customers and prospective customers may not be interested in purchasing top of book data from the Exchange, and would instead purchase such data from other national securities exchanges or the SIPs, potentially at a higher cost than would be available pursuant to the Program. The Program has therefore already been successful in increasing competition for such market data, and continued operation of the Program would serve to both reduce fees for such customers and to provide alternatives to data and pricing offered by competitors. Ultimately, the Exchange believes that it is critical that it be allowed to compete by offering attractive pricing to customers as increasing the availability of such products ensures continued competition with alternative offerings. Such competition may be constrained when competitors are impeded from offering alternative and cost effective solutions to customers.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the objectives of Section 6 of the Act,[12] in general, and furthers the objectives of Section 6(b)(4),[13] in particular, as it is designed to provide for the equitable allocation of reasonable dues, fees and other charges among its members and other recipients of Exchange data.

The Exchange also believes that the proposed rule change is consistent with Section 11(A) of the Act.[14] Specifically, the proposed rule change supports (i) fair competition among brokers and dealers, among exchange markets, and between exchange markets and markets other than exchange markets, and (ii) the availability to brokers, dealers, and investors of information with respect to quotations for and transactions in securities. In addition, the proposed rule change is consistent with Rule 603 of Regulation NMS,[15] which provides that any national securities exchange that distributes information with respect to quotations for or transactions in an NMS stock do so on terms that are not unreasonably discriminatory.

In adopting Regulation NMS, the Commission granted SROs and broker-dealers increased authority and flexibility to offer new and unique market data to the public. It was believed that this authority would expand the amount of data available to consumers, and also spur innovation and competition for the provision of market data. The Exchange believes that the proposed fee change would further broaden the availability of U.S. equity market data to investors, and in particular retail investors, consistent with the principles of Regulation NMS.

The Exchange operates in a highly competitive environment. Indeed, there are thirteen registered national securities exchanges that trade U.S. equities and offer associated top of book market data products to their customers. The national securities exchanges also compete with the SIPs for market data customers. 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.'' [16] The proposed fee change is a result of the competitive environment, as the Exchange seeks to amend its fees to attract additional subscribers for its proprietary top of book data offerings.

The proposed fee change would reduce fees charged to small retail brokers that provide access to the Cboe One Summary Feed. The Cboe One Summary Feed is a competitively-priced alternative to top of book data disseminated by SIPs, or similar data disseminated by other national securities exchanges.[17] It provides subscribers with consolidated top of book quotes and trades from four Cboe U.S. equities markets, which together account for about 17% of consolidated U.S. equities trading volume.[18] The Cboe One Summary Feed is purchased by a wide variety of market participants and vendors, including data platforms, websites, fintech firms, buy-side investors, retail brokers, regional banks, and securities firms inside and outside of the U.S. that desire low cost, high quality, real-time U.S. equity market data. By providing lower cost access to U.S. equity market data, the Cboe One Summary Feed benefits a wide range of investors that participate in the national market system. Reducing fees for broker-dealers that represent retail investors and that may have more limited resources than some of their larger competitors would further increase access to such data and facilitate a competitive market for U.S. equity securities, consistent with the goals of the Act.

While the Exchange is not required to make any data, including top of book data, available through its proprietary market data platform, the Exchange believes that making such data available increases investor choice, and contributes to a fair and competitive market. Specifically, making such data publicly available through proprietary data feeds allows investors to choose alternative, potentially less costly, market data based on their business needs. While some market participants that desire a consolidated display choose the SIP for their top of book data needs, and in some cases are effectively required to do so under the Vendor Display Rule, others may prefer to purchase data directly from one or more national securities exchanges. For example, a buy-side investor may choose to purchase the Cboe One Summary Feed, or a similar product from another exchange, in order to perform investment analysis. The Cboe One Summary Feed represents quotes from four highly liquid equities markets. As a result, the Cboe One Summary Feed is within 1% of the national best bid and offer approximately 98% of the time,[19] and therefore serves as a valuable reference for investors that do not require a consolidated display that contains quotations for all U.S. equities exchanges. Making alternative products available to market participants ultimately ensures increased competition in the marketplace, and constrains the ability of exchanges to charge supracompetitive fees. In the event that a market participant views one exchanges top of book data fees as more or less attractive than the

[11] *See e.g.,* Cboe Innovation Spotlight, ''dough—The commission-free online broker with premium content and insights,'' *available at https://markets.cboe.com/us/equities/market_data_products/spotlight/.*

[12] 15 U.S.C. 78f.

[13] 15 U.S.C. 78f(b)(4).

[14] 15 U.S.C. 78k–1.

[15] *See* 17 CFR 242.603.

[16] *See* Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005) (''Regulation NMS Adopting Release'').

[17] *See e.g.,* supra note 5 (discussing Nasdaq Basic).

[18] *Id.*

[19] *See https://markets.cboe.com/us/equities/market_data_services/cboe_one/.*

competition they can and frequently do switch between competing products. In fact, the competiveness of the market for such top of book data products is one of the primary factors animating this proposed rule change, which is designed to allow the Exchange to further compete for this business.

Indeed, the Exchange has already successfully onboarded one new Distributor that has decided to purchase Cboe One Summary Data from the Exchange rather than purchasing top of book data from a competitor exchange, and is in the process of onboarding another new Distributor. In addition, the Exchange is in discussions with a handful of other Distributors that are interested in procuring market data from the Exchange due to the attractive pricing offered pursuant to the Program. Distributors can discontinue use at any time and for any reason, including due to an assessment of the reasonableness of fees charged. Further, firms have a wide variety of alternative market data products from which to choose, such as similar proprietary data products offered by other national securities exchanges. Making the Exchange's top of book data available at a lower cost, ultimately serves the interests of retail investors that rely on the public markets. The Exchange understands that the Commission is interested in ensuring that retail investors are appropriately served in the U.S. equities market. The Exchange agrees that it is important to ensure that our markets continue to serve the needs of ordinary investors, and the Program is consistent with this goal.

The Exchange believes that the proposed fees are reasonable as they represent a significant cost reduction for smaller, primarily regional, retail brokers that provide top of book data from EDGA and its affiliated equities exchanges to their retail investor clients. The market for top of book data is intensely competitive due to the availability of substitutable products that can be purchased either from other national securities exchanges, or from registered SIPs that make such top of book data publicly available to investors at a modest cost. The proposed fee reduction is being made to make the Exchange's fees more competitive with such offerings for this segment of market participants, thereby increasing the availability of the Exchange's data products, and expanding the options available to firms making data purchasing decisions based on their business needs. The Exchange believes that this is consistent with the principles enshrined in Regulation NMS to ''promote the wide availability of market data and to allocate revenues to SROs that produce the most useful data for investors.'' [20]

Today, the Cboe One Summary Feed is among the most competitively priced top of book offerings in the industry due to modest subscriber fees, and a lower Enterprise cap, both of which keep fees at a relatively modest level for larger firms that provide market data to a sizeable number of Professional or Non-Professional Users. Distributors with a smaller user base, however, may choose to use competitor products that have a lower distribution fee and higher subscriber fees. The Program would help the Exchange compete for this segment of the market, and may broaden the reach of the Exchange's data products by providing an additional low cost alternative to competitor products for small retail brokers. While such firms may already utilize similar market data products from other sources, the Exchange believes that offering its own data to small retail brokers at lower distribution and data consolidation costs has the potential to increase choice for market participants, and ultimately increase the data available to retail investors when coupled with the Exchange's lower subscriber fees.

The Exchange also believes that the proposed fees are equitable and not unfairly discriminatory as the proposed fee structure is designed to decrease the price and increase the availability of U.S. equities market data to retail investors. The Program is designed to reduce the cost of top of book market data for broker-dealers that provide such data to Non-Professional Data User clients that make up the majority of the distributor's total subscriber population. While there is no ''exact science'' to choosing one eligibility threshold compared to another, the Exchange believes that having more Non-Professional Data Users than Professional Data User across a firm's entire business, *i.e.,* not limited exclusively to Data Users that are provided access to the Exchange's data products, is indicative of a broker-dealer that is primarily and actively engaged in the business of serving retail investors. This understanding is confirmed by the current customers that participate in or are soon to participate in the Program, each of which are focused on providing trading services to ordinary investors. As such, the Program would be broadly available to a wide range of retail brokers that either purchase the Cboe One Summary Feed today, or that may choose to switch from competing products due to the potential cost savings. In addition to the subscribers that are participating and are soon to participate in the Program, dozens of distributors that currently purchase top of book data from one of the four Cboe U.S. equities exchanges, and many more prospective customers, could benefit from the Program. Each of these current or prospective retail broker customers would receive the same benefits in terms of reduced distribution and consolidation fees based on the product that they purchase from the Exchange.

The Commission has long stressed the need to ensure that the equities markets are structured in a way that meets the needs of ordinary investors. For example, the Commission's strategic plan for fiscal years 2018–2022 touts ''focus on the long-term interests of our Main Street investors'' as the Commission's number one strategic goal.[21] The Program would be consistent with the Commission's stated goal of improving the retail investor experience in the public markets. Furthermore, national securities exchanges commonly charge reduced fees and offer market structure benefits to retail investors, and the Commission has consistently held that such incentives are consistent with the Act. The Exchange believes that the Program is consistent with longstanding precedent indicating that it is consistent with the Act to provide reasonable incentives to retail investors that rely on the public markets for their investment needs.

In addition, while the Program would be effectively limited to smaller firms that distribute data to no more than 5,000 Non-Professional Data Users, the Exchange does not believe that this limitation makes the fees inequitable, unfairly discriminatory, or otherwise contrary to the purposes of the Act. Large broker-dealers and/or vendors that distribute the Exchange's data products to a sizeable number of investors benefit from the current fee structure, which includes lower subscriber fees and Enterprise licenses. Due to lower subscriber fees, distributors that provide Cboe One Summary Feed Data to more than 5,000 Non-Professional Data Users already enjoy cost savings compared to competitor products. The Program would therefore ensure that small retail brokers that distribute top of book data to their retail investor customers could also benefit from reduced pricing, and would aid in increasing the

[20] *See* Regulation NMS Adopting Release, supra note 12, at 37503.

[21] *See* U.S. Securities and Exchange Commission, Strategic Plan, Fiscal Years 2018–2022, available at *https://www.sec.gov/files/SEC_Strategic_Plan_FY18–FY22_FINAL_0.pdf.*

competitiveness of the Exchange's data products for this key segment of the market.

The table below illustrates the impact of the proposed pricing on firms that qualify for the Program, both compared to the Exchange's current pricing, and compared to the fees charged for a competitor product, *i.e.,* Nasdaq Basic. As shown, Cboe One Summary Feed Data provided pursuant to the Program would be cheaper than Nasdaq Basic for firms with more than 1,200 Non-Professional Users, and the benefits of the pricing structure would continue to scale up to firms with 5,000 Non-Professional Users. After 5,000 Non-Professional Users the firm would no longer be eligible for the Small Retail Broker Distribution Program but would already enjoy significant cost savings compared to Nasdaq Basic under the current pricing structure. The Exchange therefore believes that the Program would allow the Exchange to better compete with competitors for smaller firms that currently pay a lower fee under, for example, the Nasdaq Basic pricing model, while also ensuring that larger firms continue to receive attractive pricing that is already cheaper than top of book data offered by the main competitor product. The Exchange believes this supplemental information further validates its assessment that the proposed fee reduction is reasonable, equitable, and not unfairly discriminatory. Without the proposed fee reduction, small retail brokers that would otherwise qualify for the reduced fees proposed would be subject to either higher fees for accessing Exchange top of book data, or may switch to competitor offerings that are also less cost effective, but at current fees levels, cheaper than the current Cboe One Summary fee.

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	1,200			**Nasdaq Basic**	**Difference vs. Nasdaq Basic**
Product	Non-Professional User Qty	Standard Model Total Fee	SRBP Total Fee	Total Fee	Total Fee
Cboe One Summary	1,200	$6,000.00	$3,850.00	$3,850	0.00
EDGA Top	1,200	$30.00	$30.00	$3,850	3820.00

	3,350			**Nasdaq Basic**	**Difference vs. Nasdaq Basic**
Product	Non-Professional User Qty	Standard Model Total Fee	SRBP Total Fee	Total Fee	Total Fee
Cboe One Summary	3,350	$6,000.00	$3,850.00	$6,000	2150.00
EDGA Top	3,350	$83.75	$83.75	$6,000	5916.25

	7,500			**Nasdaq Basic**	**Difference vs. Nasdaq Basic**
Product	Non-Professional User Qty	Standard Model Total Fee	SRBP Total Fee	Total Fee	Total Fee
Cboe One Summary	7,500	$6,000.00	$3,850.00	$10,150	4150.00
EDGA Top	7,500	$187.50	$187.50	$10,150	9962.50

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B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change would result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange operates in a highly competitive environment, and its ability to price these data products is constrained by: (i) Competition among exchanges that offer similar data products to their customers; and (ii) the existence of inexpensive real-time

consolidated data disseminated by the SIPs. Top of book data is disseminated by both the SIPs and the thirteen equities exchanges. There are therefore a number of alternative products available to market participants and investors. In this competitive environment potential subscribers are free to choose which competing product to purchase to satisfy their need for market information. Often, the choice comes down to price, as broker-dealers or vendors look to purchase the cheapest top of book data product, or quality, as market participants seek to purchase data that represents significant market liquidity. In order to better compete for this segment of the market, the Exchange is proposing to reduce the cost of top of book data provided by small retail brokers to their retail investor clients. The Exchange believes that this would facilitate greater access to such data, ultimately benefiting the retail investors that are provided access to such market data.

The Exchange does not believe that this price reduction would cause any unnecessary or inappropriate burden on intermarket competition as other exchanges and data vendors are free to lower their prices to better compete with the Exchange's offering. Indeed, as explained in the basis section of this proposed rule change, the Exchange's decision to lower its distribution and consolidation fees for small retail brokers is itself a competitive response to different fee structures available on competing markets. The Exchange therefore believes that the proposed rule change is pro-competitive as it seeks to offer pricing incentives to customers to better position the Exchange as it competes to attract additional market data subscribers. The Exchange also believes that the proposed reduction in fees for small retail brokers would not cause any unnecessary or inappropriate burden on intramarket competition. Although the proposed fee discount would be largely limited to small retail broker subscribers, larger broker-dealers and vendors can already purchase top of book data from the Exchange at prices that represent a significant cost savings when compared to competitor products that combine higher subscriber fees with lower fees for distribution. In light of the benefits already provided to this group of subscribers, the Exchange believes that additional discounts to small retail brokers would increase rather than decrease competition among broker-dealers that participate on the Exchange. Furthermore, as discussed earlier in this proposed rule change, the Exchange believes that offering pricing benefits to brokers that represent retail investors facilitates the Commission's mission of protecting ordinary investors, and is therefore consistent with the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

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 [22] and paragraph (f) of Rule 19b–4 [23] 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 (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–CboeEDGA–2019–015 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–CboeEDGA–2019–015. 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 (*http://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. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–CboeEDGA–2019–015 and should be submitted on or before November 7, 2019.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[24]

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2019–22697 Filed 10–16–19; 8:45 am]

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[22] 15 U.S.C. 78s(b)(3)(A).

[23] 17 CFR 240.19b–4(f).

[24] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–87291; File No. SR–CBOE–2019–049]

Self-Regulatory Organizations; Cboe Exchange, Inc.; Notice of Designation of a Longer Period for Commission Action on a Proposed Rule Change, as Modified by Amendment No. 1, To Make Permanent Certain Options Market Rules That Are Linked to the Equity Market Plan To Address Extraordinary Market Volatility

October 11, 2019.

On August 21, 2019, Cboe Exchange, Inc. (''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 make permanent certain options market rules that are linked to the equity

[1] 15 U.S.C.78s(b)(1).

[2] 17 CFR 240.19b–4.

market Plan to Address Extraordinary Market Volatility. The proposed rule change was published for comment in the **Federal Register** on August 29, 2019.[3] On October 10, 2019, the Exchange filed Amendment No. 1 to the proposed rule change.[4] The Commission has received no comment letters on the proposed rule change.

Section 19(b)(2) of the Act[5] 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 October 13, 2019.

The Commission is extending the 45-day time period for Commission action on the proposed rule change. 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, as modified by Amendment No. 1. Accordingly, pursuant to Section 19(b)(2) of the Act,[6] the Commission designates October 18, 2019, 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–CBOE–2019–049), as modified by Amendment No. 1.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[7]

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2019–22701 Filed 10–16–19; 8:45 am]

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[3] *See* Securities Exchange Act Release No. 86744 (August 23, 2019), 84 FR 45565.

[4] In Amendment No. 1, the Exchange revised the proposed rule text to reflect rule numbering and organizational changes enacted by separate proposed rule changes that became effective while the instant proposal was pending before the Commission.

[5] 15 U.S.C. 78s(b)(2).

[6] *Id.*

[7] 17 CFR 200.30–3(a)(31).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–87276; File No. SR–NASDAQ–2019–084]

Self-Regulatory Organizations; The Nasdaq Stock Market LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend The Nasdaq Options Market LLC (“NOM”) Pricing Schedule at Options 7, Section 2

October 10, 2019.

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 September 27, 2019, The Nasdaq Stock Market LLC (‘‘Nasdaq’’ or ‘‘Exchange’’) 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

The Exchange proposes to amend The Nasdaq Options Market LLC (‘‘NOM’’) Pricing Schedule at Options 7, Section 2, titled ‘‘Nasdaq Options Market—Fees and Rebates.’’

The text of the proposed rule change is available on the Exchange’s website at *http://nasdaq.cchwallstreet.com/,* at the principal office of the Exchange, 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.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

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 NOM’s Pricing Schedule at Options 7, Section 2, titled ‘‘Nasdaq Options Market—Fees and Rebates.’’ Specifically, the Exchange proposes to amend the Tier 5 NOM Market Maker Rebate to Add Liquidity in Penny Pilot Options.

Description of Proposed NOM Market Maker Pricing

The purpose of the proposed rule change is to incentivize Market Makers to add liquidity on the Exchange. Today, NOM offers Market Maker Rebates to Add Liquidity in Penny Pilot Options. There are currently 6 tiers of Rebates to Add Liquidity.[3] This proposal seeks to amend Tier 5 of the NOM Market Maker Rebates to Add Liquidity in Penny Pilot Options, which currently pays a $0.40 per contract rebate to a Participant that adds NOM Market Maker liquidity in Penny Pilot Options and/or Non-Penny Pilot Options of above 0.30% of total industry customer equity and ETF option ADV contracts per day in a month and qualifies for the Tier 6 Customer and/or Professional Rebate to Add Liquidity in Penny Pilot Options.

The Exchange proposes to increase the Tier 5 Market Maker Rebate to Add Liquidity in Penny Pilot Options from $0.40 to $0.44 per contract. Further, the Exchange proposes to amend the first requirements to obtain a Tier 5 Market Maker Rebate to Add Liquidity. The Exchange proposes to amend the current rule text to require a Participant to add NOM Market Maker liquidity in Penny Pilot Options and/or Non-Penny Pilot Options of above 0.40% of total industry customer equity and ETF option ADV contracts per day in a month This amendment increases the amount of total industry customer equity and ETF options ADV contracts per day in a month from 0.30% to 0.40%. In addition to the aforementioned requirement, Tier 5 additionally currently requires, as a second requirement, that a Participant qualify for the Tier 6[4] Customer and/or

[3] *See* NOM Pricing Schedule at Options 7, Section 2(1).

[4] Tier 6 of the Customer and/or Professional Rebate to Add Liquidity in Penny Pilot Options requires that, ‘‘Participant adds Customer, Professional, Firm, Non-NOM Market Maker and/or Broker-Dealer liquidity in Penny Pilot Options and/or Non-Penny Pilot Options above 0.80% or more of total industry customer equity and ETF option

Professional Rebate to Add Liquidity in Penny Pilot Options. The Exchange proposes to remove this requirement to qualify for the Tier 6 Customer and/or Professional Rebate to Add Liquidity in Penny Pilot Options and instead require, as the second part of the overall Tier 5 requirements, that a Participant transact in all securities through one or more of its Nasdaq Market Center MPIDs that represent 0.40% or more of Consolidated Volume (''CV'') [5] which adds liquidity in the same month on The Nasdaq Stock Market.[6] This particular requirement is intended to incentivize Participants to transact a greater volume on The Nasdaq Stock Market in order to qualify for the Tier 5 rebate on NOM. As proposed, the Tier 5 Market Maker Rebate to Add Liquidity in Penny Pilot Options requirement would provide.

Participant adds NOM Market Maker liquidity in Penny Pilot Options and/or Non-Penny Pilot Options of above 0.40% of total industry customer equity and ETF option ADV contracts per day in a month and transacts in all securities through one or more of its Nasdaq Market Center MPIDs that represent 0.40% or more of Consolidated Volume (''CV'') which adds liquidity in the same month on The Nasdaq Stock Market.

Both the requirement to add 0.40% of total industry customer equity and ETF option ADV contracts per day in a month and the requirement to transact in all securities through one or more of its Nasdaq Market Center MPIDs that represent 0.40% or more of Consolidated Volume (''CV''), as specified, are necessary to achieve the proposed increased rebate of $0.44 per contract. This proposal would provide participants with additional opportunities to earn an increased Tier 5 NOM Market Maker rebate, and will encourage Participants to send order flow to both the options and equity markets to receive the rebate. This proposal is designed as a means to improve market quality by providing Participants with an incentive to increase their provision of liquidity on the Exchange's equity and options markets.

The Exchange also proposes to add a new note to Options 7, Section 2 of the Pricing Schedule which provides that NOM Participants that qualify for the Tier 5 NOM Market Maker Rebate to Add Liquidity in Penny Pilot Options and add NOM Market Maker liquidity in Penny Pilot Options and/or Non-Penny Pilot Options of above 0.50% of total industry customer equity and ETF option ADV contracts per day in a month, will receive a $0.46 per contract rebate to add liquidity in Penny Pilot Options as Market Maker in lieu of the Tier 5 rebate. The Exchange notes that in comparison to proposed Tier 5 qualifications, which require 0.40% of total industry customer equity and ETF option ADV contracts per day in a month and pays a proposed $0.44 per contract rebate, this incentive would pay an increased rebate of $0.46 per contract for 0.50% of total industry customer equity and ETF option ADV contracts per day in a month, in lieu of the Tier 5 rebate. The Exchange believes that this incentive will attract additional liquidity to NOM to the benefit of all market participants who may interact with that order flow.

Applicability to and Impact on Participants [7]

The Exchange believes that increasing the NOM Market Maker Tier 5 Rebate to Add Liquidity in Penny Pilot Options from $0.40 to $0.44 per contract as well as requiring a greater amount of total industry customer equity and ETF options ADV contracts per day in a month (from 0.30% to 0.40%) and also replacing the current criteria to qualify for the Tier 6 Customer and/or Professional Rebate to Add Liquidity in Penny Pilot Options with the requirement to transact in all securities through one or more of its Nasdaq Market Center MPIDs that represent 0.40% or more of Consolidated Volume (''CV'') which adds liquidity in the same month on The Nasdaq Stock Market will attract greater volume to both NOM and The Nasdaq Stock Market. Any NOM Market Maker may obtain the Tier 5 rebate provided the qualifications are met. The Exchange notes that Market Makers have certain obligations [8] on NOM, unlike other market participants. Market Maker are a source of liquidity. The proposed amendments are generally designed to attract additional order flow to the Exchange by incentivizing NOM Market Makers. Greater liquidity benefits all market participants by providing more trading opportunities and attracting greater participation by market makers. An increase in the activity of these market participants in turn facilitates tighter spreads.

Furthermore, the additional incentive to receive an even greater Tier 5 rebate of $0.46 per contract to add liquidity in Penny Pilot Options as Market Maker, provided the NOM Participant qualified for the Tier 5 NOM Market Maker Rebate to Add Liquidity in Penny Pilot Options and added NOM Market Maker liquidity in Penny Pilot Options and/or Non-Penny Pilot Options of above 0.50% of total industry customer equity and ETF option ADV contracts per day in a month, will further incentivize NOM Market Makers to add liquidity to NOM. These incentives are intended to benefit all NOM market participants who will be able to interact with additional liquidity which this incentive attracts to the Exchange.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[9] in general, and furthers the objectives of Sections 6(b)(4) and 6(b)(5) of the Act,[10] in particular, in that it provides for the equitable allocation of reasonable dues, fees and other charges among members and issuers and other persons using any facility, and is not designed to permit unfair

ADV contracts per day in a month, or Participant adds: (1) Customer and/or Professional liquidity in Penny Pilot Options and/or Non-Penny Pilot Options of 0.20% or more of total industry customer equity and ETF option ADV contracts per day in a month, and (2) has added liquidity in all securities through one or more of its Nasdaq Market Center MPIDs that represent 1.00% or more of Consolidated Volume in a month or qualifies for MARS (defined below).''

[5] Consolidated Volume shall mean the total consolidated volume reported to all consolidated transaction reporting plans by all exchanges and trade reporting facilities during a month in equity securities, excluding executed orders with a size of less than one round lot. For purposes of calculating Consolidated Volume and the extent of an equity member's trading activity, expressed as a percentage of or ratio to Consolidated Volume, the date of the annual reconstitution of the Russell Investments Indexes shall be excluded from both total Consolidated Volume and the member's trading activity.

[6] In calculating total volume, the Exchange would add the Participant's total volume transacted on The Nasdaq Stock Market in a given month across its Nasdaq Market Center MPIDs which adds liquidity, and will divide this number by the total industry Consolidated Volume.

[7] On May 21, 2019, the SEC Division of Trading and Markets (the ''Division'') issued fee filing guidance titled ''Staff Guidance on SRO Rule Filings Relating to Fees'' (''Guidance''). Within the Guidance, the Division noted, among other things, that the purpose discussion should address ''how the fee may apply differently (*e.g.,* additional cost vs. additional discount) to different types of market participants (*e.g.,* market makers, institutional brokers, retail brokers, vendors, etc.) and different sizes of market participants.'' *See* Guidance (available at *https://www.sec.gov/tm/staff-guidance-sro-rule-filings-fees*).

[8] Pursuant to Chapter VII (Market Participants), Section 5 (Obligations of Market Makers), in registering as a market maker, an Options Participant commits himself to various obligations. Transactions of a Market Maker in its market making capacity must constitute a course of dealings reasonably calculated to contribute to the maintenance of a fair and orderly market, and Market Makers should not make bids or offers or enter into transactions that are inconsistent with such course of dealings. Further, all Market Makers are designated as specialists on NOM for all purposes under the Act or rules thereunder. *See* Chapter VII, Section 5.

[9] 15 U.S.C. 78f(b).

[10] 15 U.S.C. 78f(b)(4) and (5).

discrimination between customers, issuers, brokers, or dealers. The proposal is also consistent with Section 11A of the Act relating to the establishment of the national market system for securities. Moreover, the Exchange believes that its proposal complies with Commission guidance on SRO fee filings that the Commission Staff issued on May 21, 2019.[11]

The Proposal Is Reasonable

The Exchange's proposed amendments to Options 7, Section 2 relating to the Tier 5 NOM Market Maker Rebate to Add Liquidity in Penny Pilot Options are reasonable in several respects. As a threshold matter, the Exchange is subject to significant competitive forces in the market for options transaction services that constrain its pricing determinations in that market. The fact that this market is competitive has 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'. . . .'' [12]

Numerous indicia demonstrate the competitive nature of this market. For example, clear substitutes to the Exchange exist in the market for options transaction services. The Exchange is one of several options venues to which market participants may direct their order flow, and it represents a small percentage of the overall market. Competing options exchanges offer similar options functionality, with varying pricing schedules. Within this environment, market participants can freely and often do shift their order flow among the Exchange and competing venues in response to changes in their respective pricing schedules.[13]

Within the foregoing context, the proposal represents a reasonable attempt by the Exchange to increase its liquidity and market share relative to its competitors. The Exchange believes that its proposed rebate is a reasonable attempt to achieve this end as this rebate represents competitive pricing as compared to other options markets. Market participants have a number of choices in deciding where to direct their options orders. Options exchanges offer different markets offering incentives and rebates to market participants to lower transaction fees. With this proposal, the Exchange is attempting to attract additional order flow to both NOM and The Nasdaq Stock Market. The Exchange may be unsuccessful in its initial attempt to attract order flow with the proposed rebate.

NOM Market Maker Rebates

With respect to the proposed Tier 5 NOM Market Maker rebate amendment, the Exchange believes that increasing the Tier 5 Market Maker Rebate to Add Liquidity in Penny Pilot Options from $0.40 to $0.44 per contract while also amending the qualifications for the Tier 5 rebate is reasonable. The Exchange believes that increasing the volume requirement for NOM Market Maker liquidity in Penny Pilot Options and/or Non-Penny Pilot Options, from above 0.30% to above 0.40% of total industry customer equity and ETF options ADV contracts per day in a month, will attract additional liquidity to NOM. Further, the proposal to amend the second part of the Tier 5 rebate requirement by eliminating the requirement that a Participant qualify for the Tier 6 Customer and/or Professional Rebate to Add Liquidity in Penny Pilot Options [14] and instead require a Participant transact in all securities through one or more of its Nasdaq Market Center MPIDs that represent 0.40% or more of Consolidated Volume (''CV'') which adds liquidity in the same month on The Nasdaq Stock Market, will also attract liquidity to NOM and also The Nasdaq Stock Market. Specifically, the new second requirement for the Tier 5 rebate is intended to incentivize Participants to transact greater volume on The Nasdaq Stock Market in order to qualify for the Tier 5 rebate on NOM. Because the Exchange requires a Participant to comply with both the first requirement,[15] to add NOM Market Maker liquidity, and the second requirement,[16] to transact in securities and add liquidity on The Nasdaq Stock Market, in order to qualify for the proposed increased $0.44 per contract Tier 5 rebate, the Exchange believes that Market Makers will be incentivized to direct additional order flow to NOM and The Nasdaq Stock Market and, in turn, market participants will benefit from the opportunity to interact with such order flow.

The Exchange acknowledges that the proposed new criteria would require additional volume to achieve the first requirement [17] of the Tier 5 rebate and different volume to achieve the second requirement [18] of the Tier 5 rebate to qualify for the increased proposed $0.44 per contract Tier 5 rebate, as compared to the current Tier 5 rebate qualifications.[19] The Exchange's proposal offers to pay a higher Tier 5 rebate ($0.44 per contract as compared to the current $0.40 per contract) to NOM Market Makers who qualify for the rebate with the new requirements. The Exchange believes that it is reasonable to create an additional opportunity for Participants to earn the Tier 5 rebate by incentivizing Participants to transact greater volume on The Nasdaq Stock Market in order to qualify for the Tier 5 rebate on NOM. The Exchange notes that this proposal is designed as a means to improve market quality by providing Participants with an incentive to increase their provision of liquidity on the Exchange's equity and options markets. This proposal will encourage Participants to send order flow to both the options and equity markets to receive the Tier 5 rebate. The Exchange believes that replacing the second requirement of the Tier 5 rebate, which currently requires Participants to achieve the Tier 6 Customer and Professional Rebate to Add Liquidity in

[11] *See* Guidance, *supra* note 7. Although the Exchange believes that this filing complies with the Guidance, the Exchange does not concede that the standards set forth in the Guidance are consistent with the Exchange Act and reserves its right to challenge those standards through administrative and judicial review, as appropriate.

[12] *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)).

[13] The Exchange perceives no regulatory, structural, or cost impediments to market participants shifting order flow away from it as a result of this rule change.

[14] *See* note 4 above.

[15] The first requirement to qualify for the Tier 5 rebate requires a Participant to add NOM Market Maker liquidity in Penny Pilot Options and/or Non-Penny Pilot Options of above 0.40% of total industry customer equity and ETF options ADV contracts per day in a month.

[16] The second requirement to qualify for the Tier 5 rebate requires a Participant to transact in all securities through one or more of its Nasdaq Market Center MPIDs that represent 0.40% or more of CV which adds liquidity in the same month on The Nasdaq Stock Market.

[17] *See* note 15 above.

[18] *See* note 16 above.

[19] Today, the Tier 5 NOM Market Maker Rebate to Add Liquidity in Penny Pilot Options requires a Participant to add NOM Market Maker liquidity in Penny Pilot Options and/or Non-Penny Pilot Options of above 0.30% of total industry customer equity and ETF option ADV contracts per day in a month and qualifies for the Tier 6 Customer and/or Professional Rebate to Add Liquidity in Penny Pilot Options.

Penny Pilot Options, with the proposed requirement to add liquidity to The Nasdaq Stock Market will permit a greater number of market participants to qualify for the Tier 5 rebate. Today, NOM Market Makers also transact an equities business on The Nasdaq Stock Market. The proposed qualifications for the Tier 5 rebate will incentivize those Participants that are engaged in an equities business to add a greater amount of liquidity both on NOM and The Nasdaq Stock Market. Furthermore, the concept of linking an incentive on NOM to activity on The Nasdaq Stock Market exists today. The Exchange currently offers rebates on NOM that relate to activity on The Nasdaq Stock Market.[20] Similarly, The Nasdaq Stock Market offers credits that are based on activity on NOM.[21] As such, the Exchange believes that the volume requirement to transact in all securities through one or more of the Participant's Nasdaq Market Center MPIDs that represent 0.40% or more of Consolidated Volume (''CV'') which adds liquidity in the same month on The Nasdaq Stock Market is reasonable because the Exchange already offers rebates based on similar volume requirements.[22]

Further, the Exchange proposes to add a new note to Options 7, Section 2 of the Pricing Schedule which provides that NOM Participants that qualify for the Tier 5 NOM Market Maker Rebate to Add Liquidity in Penny Pilot Options, as proposed herein, and add NOM Market Maker liquidity in Penny Pilot Options and/or Non-Penny Pilot Options of above 0.50% of total industry customer equity and ETF option ADV contracts per day in a month, will receive an increased Tier 5 rebate of $0.46 per contract rebate (in lieu of the $0.44 per contract Tier 5 rebate) to add liquidity in Penny Pilot Options as Market Maker in lieu of the Tier 5 rebate. The Exchange notes that in comparison to the proposed Tier 5 qualifications, which require Participant to add NOM Market Maker liquidity in Penny Pilot Options and/or Non-Penny Pilot Options of above 0.40% of total industry customer equity and ETF option ADV contracts per day in a month, and pays a proposed $0.44 per contract rebate, this additional incentive would pay an increased rebate of $0.46 per contract to add liquidity in Penny Pilot Options as Market Maker, provided the Participants adds liquidity in Penny Pilot Options and/or Non-Penny Pilot Options of above 0.50% of total industry customer equity and ETF option ADV contracts per day in a month. The Exchange believes that this incentive will attract additional liquidity to NOM.

The Exchange's proposal to increase the Tier 5 NOM Market Maker Rebate to Add Liquidity in Penny Pilot Options from $0.40 to $0.44 per contract while also amending the qualifications for the Tier 5 rebate is equitable and not unfairly discriminatory. All eligible Participants that qualify for the Tier 5 rebate will uniformly receive the rebate. The Exchange believes that the proposed volume requirements to qualify for the Tier 5 rebate are proportionate to the amount of the increased Tier 5 rebate of $0.44 per contract and equitably reflect the purpose of the rebate, which is to incentivize Participants to transact greater volume on both the Exchange's equity and options markets. In addition, the Exchange believes that it is equitable and not unfairly discriminatory to offer this rebate to NOM Participants that transact as NOM Market Makers and also transact on The Nasdaq Stock Market. Any NOM Participant may trade on The Nasdaq Stock Market because they are approved members.[23] Furthermore, unlike other market participants, NOM Market Makers add value through continuous quoting and the commitment of capital.[24] Because NOM Market Makers have these obligations to the market and regulatory requirements that normally do not apply to other market participants, the Exchange believes that offering these rebates to only NOM Market Makers is equitable and not unfairly discriminatory in light of their obligations. Finally, encouraging NOM Market Makers to add greater liquidity on the Exchange benefits all market participants in the quality of order interaction.

The Exchange's proposal to offer Participants that qualify for the Tier 5 rebate and add NOM Market Maker liquidity in Penny Pilot Options and/or Non-Penny Pilot Options of above 0.50% of total industry customer equity and ETF option ADV contracts per day in a month, a rebate of $0.46 per contract to add liquidity in Penny Pilot Options as Market Maker is reasonable. This additional incentive will further incentivize NOM Market Makers to add liquidity to NOM and The Nasdaq Stock Market to achieve the greater rebate. The incentive is intended to benefit all NOM market participants who will be able to interact with additional liquidity which this incentive attracts to the Exchange.

The Exchange's proposal to offer Participants that qualify for the Tier 5 rebate and add NOM Market Maker liquidity in Penny Pilot Options and/or Non-Penny Pilot Options of above 0.50% of total industry customer equity and ETF option ADV contracts per day in a month, a rebate of $0.46 per contract to add liquidity in Penny Pilot Options as Market Maker is equitable and not unfairly discriminatory. As noted above, NOM Market Makers add value through continuous quoting and the commitment of capital.[25] Because NOM Market Makers have these obligations to the market and regulatory requirements that normally do not apply to other market participants, the Exchange believes that offering these rebates to only NOM Market Makers is equitable and not unfairly discriminatory in light of their obligations. Finally, encouraging NOM Market Makers to add greater liquidity benefits all market participants, on both NOM and The Nasdaq Stock Market, in the quality of order interaction.

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 not necessary or appropriate in furtherance of the purposes of the Act. Greater liquidity benefits all market participants by providing more trading opportunities and attracting greater participation by Market Makers. An increase in the activity of these market participants in turn facilitates tighter spreads.

[20] For example, the Tier 3 NOM Market Maker Rebate to Add Liquidity requires: Participant: (a) Adds NOM Market Maker liquidity in Penny Pilot Options and/or Non-Penny Pilot Options above 0.20% to 0.60% of total industry customer equity and ETF option ADV contracts per day in a month: Or (b)(1) transacts in all securities through one or more of its Nasdaq Market Center MPIDs that represent 0.70% or more of Consolidated Volume (''CV'') which adds liquidity in the same month on The Nasdaq Stock Market, (2) transacts in Tape B securities through one or more of its Nasdaq Market Center MPIDs that represent 0.18% or more of CV which adds liquidity in the same month on The Nasdaq Stock Market, and (3) executes greater than 0.01% of CV via Market-on- Close/Limit-on-Close (''MOC/LOC'') volume within The Nasdaq Stock Market Closing Cross in the same month. See Options 7, Section 2(1).

[21] For example, Nasdaq offers a credit of $0.0029 per share if the member adds Customer, Professional, Firm, Non-NOM Market Maker and/or Broker-Dealer liquidity in Penny Pilot Options and/or Non- Penny Pilot Options of 1.15% or more of total industry ADV in the customer clearing range for Equity and ETF option contracts per day in a month on NOM. *See* Equity 7, Section 118(a)(1).

[22] *Id.*

[23] Although a NOM Participant may incur additional labor and/or costs to establish connectivity to The Nasdaq Stock Market, there are no additional membership fees for NOM Participants that want to transact on The Nasdaq Stock Market.

[24] *See* note 8 above.

[25] *See* note 8 above.

Inter-Market Competition

The proposed amendments to the Tier 5 NOM Market Maker Rebate to Add Liquidity in Penny Pilot Options do not impose an undue burden on inter-market competition. The pricing changes proposed above are generally designed to attract additional order flow to the Exchange, which strengthens the Exchange's competitive position.

The Exchange notes that it operates in a highly competitive market in which market participants can readily favor competing venues if they deem fee levels at a particular venue to be excessive, or rebate opportunities available at other venues to be more favorable. In such an environment, the Exchange must continually adjust its fees and rebates to remain competitive with other exchanges that have been exempted from compliance with the statutory standards applicable to exchanges. Because competitors are free to modify their own fees and rebates in response, and because market participants may readily adjust their order routing practices, the Exchange believes that the degree to which pricing changes in this market may impose any burden on competition is extremely limited.

NOM is a relatively small market so its ability to burden intermarket competition is limited. Moreover, as noted above, price competition between exchanges is fierce, with liquidity and market share moving freely between exchanges in reaction to fee and credit changes.

In sum, if the changes proposed herein are unattractive to market participants, it is likely that the Exchange will lose market share as a result. Accordingly, the Exchange does not believe that the proposed changes will impair the ability of members or competing order execution venues to maintain their competitive standing in the financial markets.

Intra-Market Competition

The proposed amendments to the Tier 5 NOM Market Maker Rebate to Add Liquidity in Penny Pilot Options do not impose an undue burden on intra-market competition. Increasing the Tier 5 NOM Market Maker Rebate to Add Liquidity in Penny Pilot Options and also requiring participants to add more volume on NOM and add liquidity on The Nasdaq Stock Market will attract liquidity to the Exchange. The additional rebate incentive that is being offered to Participants that qualify for the Tier 5 rebate and also add NOM Market Maker liquidity in Penny Pilot Options and/or Non-Penny Pilot Options of above 0.50% of total industry customer equity and ETF option ADV contracts per day in a month will further incentivize Market Makers to direct order flow to the Exchange. Greater liquidity benefits all market participants by providing more trading opportunities and attracting greater participation by Market Makers. An increase in the activity of these market participants in turn facilitates tighter spreads. Overall, the Exchange believes that the tiered NOM Market Maker Rebates to Add Liquidity in Penny Pilot Options along with the proposed Tier 5 increased rebate incentive will continue to reflect the progressively increasing rebate requirements offered to NOM Market Maker to incentivize them to earn the highest possible rebates by bringing the most order flow to the Exchange.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

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)(ii) of the Act.[26]

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: (i) Necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule 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 (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NASDAQ–2019–084 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–NASDAQ–2019–084. 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 (*http://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. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NASDAQ–2019–084 and should be submitted on or before November 7, 2019.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[27]

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2019–22594 Filed 10–16–19; 8:45 am]

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[26] 15 U.S.C. 78s(b)(3)(A)(ii).

[27] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

Proposed Collection; Comment Request

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736

Extension:

Rule 22c–1, SEC File No. 270–793, OMB Control No. 3235–0734

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520), the Securities and Exchange Commission (the ''Commission'') is soliciting comments on the collections of information summarized below. The Commission plans to submit this existing collection of information to the Office of Management and Budget for extension and approval.

Rule 22c–1 (17 CFR 270.22c–1) under the Investment Company Act of 1940 (15 U.S.C. 80a) (the ''Investment Company Act'' or ''Act'') enables a fund to choose to use ''swing pricing'' as a tool to mitigate shareholder dilution. Rule 22c–1 is intended to promote investor protection by providing funds with an additional tool to mitigate the potentially dilutive effects of shareholder purchase or redemption activity and a set of operational standards that allow funds to gain comfort using swing pricing as a means of mitigating potential dilution.

The respondents to amended rule 22c–1 are open-end management investment companies (other than money market funds or exchange-traded funds) that engage in swing pricing. Compliance with rule 22c–1(a)(3) is mandatory for any fund that chooses to use swing pricing to adjust its NAV in reliance on the rule.

While we are not aware of any funds that have engaged in swing pricing,[1] we are estimating for the purpose of this analysis that 5 fund complexes have funds that may adopt swing pricing policies and procedures in the future pursuant to the rule. We estimate that the total burden associated with the preparation and approval of swing pricing policies and procedures by those fund complexes that would use swing pricing will be 280 hours.[2] We also estimate that it will cost a fund complex $43,406 to document, review and initially approve these policies and procedures, for a total cost of $217,030.[3]

Rule 22c–1 requires a fund that uses swing pricing to maintain the fund's swing policies and procedures that are in effect, or at any time within the past six years were in effect, in an easily accessible place.[4] The rule also requires a fund to retain a written copy of the periodic report provided to the board prepared by the swing pricing administrator that describes, among other things, the swing pricing administrator's review of the adequacy of the fund's swing pricing policies and procedures and the effectiveness of their implementation, including the impact on mitigating dilution and any back-testing performed.[5] The retention of these records is necessary to allow the staff during examinations of funds to determine whether a fund is in compliance with its swing pricing policies and procedures and with rule 22c–1. We estimate a time cost per fund complex of $292.[6] We estimate that the total for recordkeeping related to swing pricing will be 20 hours, at an aggregate cost of $1,460, for all fund complexes that we believe include funds that have adopted swing pricing policies and procedures.[7]

Amortized over a three-year period, we believe that the hour burdens and time costs associated with rule 22c–1, including the burden associated with the requirements that funds adopt policies and procedures, obtain board approval, and periodic review of an annual written report from the swing pricing administrator, and retain certain records and written reports related to swing pricing, will result in an average aggregate annual burden of 113.3 hours, and average aggregate time costs of $73,803.[8]

We request written comment on: (a) Whether the collections of information are necessary for the proper performance of the functions of the Commission, including whether the information has practical utility; (b) the accuracy of the Commission's estimate of the burdens of the collection of information; (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 respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted in writing within 60 days of this publication.

Please direct your written comments to Charles Riddle, Acting Director/Chief Information Officer, Securities and Exchange Commission, C/O Candace Kenner, 100 F Street NE, Washington, DC 20549; or send an email to: *PRA_Mailbox@sec.gov.*

Dated: October 10, 2019.

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2019–22578 Filed 10–16–19; 8:45 am]

BILLING CODE 8011–01–P

[1] No funds have engaged in swing pricing as reported on Form N–CEN as of August 14, 2019.

[2] This estimate is based on the following calculation: (48 + 2 + 6) hours × 5 fund complexes = 280 hours.

[3] These estimates are based on the following calculations: 24 hours × $201 (hourly rate for a senior accountant) = $4,824; 24 hours × $463 (blended hourly rate for assistant general counsel ($433) and chief compliance officer ($493)) = $11,112; 2 hours (for a fund attorney's time to prepare materials for the board's determinations) × $340 (hourly rate for a compliance attorney) = $680; 6 hours × $4,465 (hourly rate for a board of 8 directors) = $26,790; ($4,824 + $11,112 + $680 + $26,790) = $43,406; $43,406 × 5 fund complexes = $217,030. The hourly wages used are from SIFMA's Management & Professional Earnings in the Securities Industry 2013, modified by Commission staff to account for an 1800-hour work-year and inflation, and multiplied by 5.35 to account for bonuses, firm size, employee benefits, and overhead. The staff previously estimated in 2009 that the average cost of board of director time was $4,000 per hour for the board as a whole, based on information received from funds and their counsel. Adjusting for inflation, the staff estimates that the current average cost of board of director time is approximately $4,465.

[4] *See* rule 22c–1(a)(3)(iii).

[5] *See id.*

[6] This estimate is based on the following calculations: 2 hours × $58 (hourly rate for a general clerk) = $116; 2 hours × $88 (hourly rate for a senior computer operator) = $176. $116 + $176 = $292.

[7] These estimates are based on the following calculations: 4 hours × 5 fund complexes = 20 hours. 5 fund complexes × $292 = $1,460.

[8] These estimates are based on the following calculations: (280 hours (year 1) + (3 × 20 hours) (years 1, 2 and 3)) ÷ 3 = 113.3 hours; ($217,030 (year 1) + (3 × $1,460) (years 1, 2 and 3)) ÷ 3 = $73,803.

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–87275; File No. SR–ICEEU–2019–020]

Self-Regulatory Organizations; ICE Clear Europe Limited; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Relating to the ICE Clear Europe Clearing Rules and Procedures

October 10, 2019.

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 September 30, 2019, ICE Clear Europe Limited (''ICE Clear Europe'' or the ''Clearing House'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule changes described in Items I, II, and III below, which Items have been primarily prepared by ICE Clear Europe. ICE Clear Europe filed the proposed rule change pursuant to Section 19(b)(3)(A) of the Act[3] and Rule 19b–4(f)(6)[4] thereunder, such that the proposed rule change was immediately effective upon filing with the Commission. The Commission is publishing this notice to solicit

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A).

[4] 17 CFR 240.19b–4(f)(6).

comments on the proposed rule change from interested persons.

I. Clearing Agency's Statement of the Terms of Substance of the Proposed Rule Change

ICE Clear Europe proposes to amend its Clearing Rules (the ''Rules'') and Procedures to make various drafting updates, clarifications and corrections, including to remove obsolete provisions, to reflect changes to the names of trading venues cleared by the Clearing House and facilities and systems used by the Clearing House, and to better reflect certain current operational practices.[5]

II. Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, ICE Clear Europe 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. ICE Clear Europe has prepared summaries, set forth in sections (A), (B), and (C) below, of the most significant aspects of such statements.

(A) Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

(a) Purpose

ICE Clear Europe proposes to amend its Rules and Procedures to make various drafting updates, clarifications and corrections, including to various references throughout the Rules and Procedures to the names of trading venues for which ICE Clear Europe provides clearing services, to delivery facilities and information systems used by the Clearing House, and to certain contracts cleared by the Clearing House. Certain changes are also being made to use more generic references to trading facilities and contracts to limit the need for future changes to the ICE Clear Europe Rules as a result of non-substantive changes to names and other corporate events.

Specifically, ICE Clear Europe proposes to make amendments to Parts 1, 2, 4, 5, 8, 9, 11, 12, 15, 16, 19, 20 and 22 of the Rules, the Standard Terms annexes contained in the Exhibits to the Rules, and to the Clearing Procedures, Finance Procedures, Delivery Procedures, CDS Procedures, FX Procedures, Business Continuity Procedures, Contract Terms Procedures and Membership Procedures. The text of the proposed amendments to the Rules and Procedures is attached in Exhibit 5, with additions underlined and deletions in strikethrough text. The proposed amendments are described in detail as follows.

1. Removal of References to LIFFE

The amendments would remove throughout the Rules unused references to the LIFFE market (and related terms referencing LIFFE or LIFFE contracts). Trading in all LIFFE contracts was transitioned to ICE Futures Europe in 2014,[6] and LIFFE is no longer an operational exchange. The LIFFE exchange has since been de-recognized as a recognized investment exchange under UK law and the corporate vehicle has been wound up. The Rules and Procedures nonetheless retain certain outdated references to LIFFE and related terms that would now be deleted. These include the definitions of ''LIFFE'', ''LIFFE Block Contract'', ''LIFFE Block Trade Facility'', ''LIFFE Block Transaction'', ''LIFFE Clearing Member'', ''LIFFE Contract'', ''LIFFE Matched Contract'', ''LIFFE Matched Transaction'' and ''LIFFE Rules'' in Rule 101 (and related uses of such definitions throughout the Rules, including in the definitions of ''Financials & Softs'', ''Financials & Softs Clearing Member'', ''Financials & Softs Transaction'' and ''Market''). Corresponding changes have also been proposed to the Delivery Procedures to remove references to ''LIFFE'' and the ''LIFFE Rules'' in relation to Financials & Softs Contracts that are now traded on ICE Futures Europe. These changes have been made in paragraphs 8 and 15 of the general provisions of the Delivery Procedures and in the product-specific sections as follows: Part O, paragraphs 1.1–1.3; Part O, Delivery Timetable; Part Q, paragraphs 1.1–1.3; Part Q, Delivery Timetable; Part R, paragraphs 1.1–1.3; Part R, Delivery Timetable; Part T, paragraphs 1.3 and 1.11; Part U, paragraphs 1.2, 1.4 and 1.5; and Part U, Delivery Timetables.

2. Corporate Reorganization of Endex Markets

A number of changes to the Rules are proposed to reflect changes in the corporate structure of the ICE Endex markets cleared by ICE Clear Europe. Specifically, ICE Endex Gas B.V. (which operated the spot market, and was referred to in the Rules as ''ICE Endex Continental'') was merged into ICE Endex Derivatives B.V. (which operated the regulated market, and was referred to in the Rules as ''ICE Endex''), with the surviving entity renamed ICE Endex Markets B.V.[7] Accordingly, the defined term ''ICE Endex'' in the Rules would be revised to refer to ICE Endex Markets B.V. As a result of the transaction, ICE Endex now operates two markets, its regulated market and the ICE Endex Spot Market (formerly the ICE Endex Continental market). In Rule 101 the following definitions would be revised accordingly: ''Energy'', ''Energy Transaction'', ''ICE Endex'', ''ICE Endex Block Transaction'', ''ICE Endex Matched Transaction'', ''ICE Endex Rules'' and ''Market''. In addition, the defined terms ''ICE Endex Continental'' and ''ICE Endex Continental Rules'' are to be replaced with ''ICE Endex Spot Market'' and ''ICE Endex Spot Market Rules''. The definitions of ''ICE Natural Gas Continental Spot'', ''ICE Natural Gas Continental Spot Contract'', ''ICE Natural Gas Continental Spot Matched Contract'', ''ICE Natural Gas Continental Spot Matched Transaction'' and ''ICE Natural Gas Continental Spot Transaction'' are to be replaced with ''ICE Endex Spot Market Transaction'' and ''ICE Endex Spot Market Contract.'' Corresponding changes would be made throughout the Rules and Procedures, including in Rules 201, 404 and 1906 and in the Delivery Procedures in paragraph 5.1 and Part J. A new Rule 401(r) would be added to clarify that a Contract will only arise in relation to an ICE Endex Spot Market Transaction where the product is designated by ICE Endex Spot Market as a cleared product. This clarification is needed because not all products traded on the ICE Endex Spot Market are cleared by ICE Clear Europe; some are held on an over-the-counter basis Parts 20 and 22 of the Rules would be deleted as no longer necessary, as those Parts provided transitional rules relating to various ICE Endex contracts at the time of the transition of these contracts to the Clearing House from another clearing house in 2013. All affected contracts have now expired.

3. Removal of Unused Participating Exchange Link Provisions

The Rules currently contain a number of defined terms and other provisions

[5] Capitalized terms used but not defined herein have the meaning specified in the ICE Clear Europe Clearing Rules.

[6] See Exchange Act Release No. 34–73348 (SR–ICEEU–2014–017) (Oct. 14, 2014); 79 FR 62688 (Oct. 20, 2014); see also ICE Futures Europe's 'LIFFE to ICE Futures Europe Transition Notice' dated September 2014, available at *https://www.theice.com/publicdocs/circulars/14108_attach.pdf*.

[7] This merger is described in more detail in ICE Endex Circular E16/045 of 30 November 2016, available at *https://www.theice.com/publicdocs/endex/circulars/E16045.pdf*.

relating to linkages between ICE exchanges and non-ICE exchanges (referred to in the Rules as ''Participating Exchanges''), principally set out in current Rule 410. Although such linkages at one time existed between LIFFE and two Japanese exchanges, and were briefly on-boarded by the Clearing House after the LIFFE transition in 2014, they have been terminated, there are no such linkages currently in effect, and none are contemplated at this time. As a result, ICE Clear Europe proposes to delete Rule 410. ICE Clear Europe further proposes to delete references to Participating Exchanges, and related terms and provisions, throughout the Rules, including in Rules 102(j)(ii), 106(a)(iv), 401(a)(xiv), 405(b), 408(a)(vi), 905(a)(iii), 905(b)(xix), 1201(f)(xii), 1201(l), 1201(n), 1202(b)(ix)–(x), 1202(m), 1202(n), 1202(o)(xi) (which will become 1202(m)(xi)), 1203(k), 1204(a)(v), 1204(j) and 1205(d).

4. References to Delivery Facilities

The definition of ''Delivery Facility'' in Rule 101 would be amended to reflect the full range of delivery mechanisms and providers used in connection with various cleared Contracts, including balancing systems, gas networks, securities settlement systems, custodians, vessels, terminals, ports and emissions registries. The broader definition reflects current practice for the facilities used for delivery under the diversity of contracts cleared by the Clearing House, and is intended to reduce the need to change the rules for the launch of new deliverable contracts. Relatedly, Rule 106(a)(xiv) would be amended to delete the references to obligations under the specific rules of each particular delivery facility and replace these with a generic reference to obligations under ''*the rules or terms of a Delivery Facility or as [are] needed to comply with any obligation or to exercise any right under these Rules*''. This would make use of the broadened ''Delivery Facility'' definition. A similar change is proposed to Rule 404(a)(x) to use the generic ''Delivery Facility'' defined term.

5. General References to Markets

Related to the amendments discussed above relating to LIFFE and ICE Endex, ICE Clear Europe proposes to replace other individual references to specific markets for which it clears, throughout the Rules and Procedures, with the more general term ''Market.'' The definition of ''Market'' in Rule 101 would be amended so that it covers the specified ICE trading venues for which arrangements already exist ''and any other Exchange for which the Clearing House provides or may provide Clearing services''. These changes would simplify various references throughout the Rules to exchanges, trading facilities and markets generally (without need to identify each such facility), and in particular will allow for certain references to ''Exchange'' to be amended to ''Market'' throughout the Rules and Procedures, resulting in greater consistency. This will also reduce documentation risks associated with corporate reorganizations at exchange level, as occurred for LIFFE and ICE Endex (discussed above). The proposed changes also remove the various references to market-specific rules (for example, to the rules of ICE Futures Europe) and replace these with a more generic definition of ''Market Rules'' where possible. The definition of ''Market Rules'' in Rule 101 would be amended to refer more generically to ''the rules, regulations, procedures of, and agreements governing, a Market''. New definitions of ''EFRP'', ''Energy Block Trade Facility'', ''Energy Block Transaction'', ''F&O Block Contract'', ''F&O Block Transaction'', F&O Matched Contract'' and ''F&O Matched Transaction'' would be added to remove the need to refer to trading venue-specific contracts and transactions throughout the Rules. For example, the definition of ''F&O Matched Transaction'' would cover all F&O Transactions occurring on a Market (without need to use separate defined terms to refer to F&O Transactions occurring on each of ICE Endex, ICE Endex UK, ICE Futures Europe and ICE Futures US). Similarly, the proposed ''F&O Block Transaction'' defined term covers all Financials & Softs Block Transactions and Energy Block Transactions. Corresponding changes will be made to the definitions of ''Basis Trades'', ''Bclear'', ''Business Day'', ''Contract Terms'', ''EFPs'', ''EFSs'', ''Financials & Softs Block Trade Facility'', ''Financials & Softs Block Transaction'' and ''Soft Commodity EFRP'' in Rule 101 and also at Rules 102(f), 111(c)(ii), 201(a)(ii)–(iv), 401(a)(i)–(v), 401(n), 405(b)(i), 1201(f)(x), 1202(b)(iii), 1202(h) and 1202(m)(vi). Similar changes are also proposed to paragraphs 2.4(c), 6.2(b)(iii) and 6.4(b) of the Clearing Procedures and paragraph 1.1(c) of the Delivery Procedures. It will still be necessary to list the Markets cleared by the Clearing House in Rule 101; these changes merely reduce the complexity of any future changes in those Markets.

6. Changes to Delivery Procedures

In the Delivery Procedures, various drafting changes are proposed to ensure that the Delivery Procedures are consistent with the Rules and with the current operational practices of ICE Clear Europe. The proposed changes would include replacing outdated references to the ''Market Delivery Settlement Price'' (MDSP) with references to the ''Exchange Delivery Settlement Price'' (EDSP), which is the term now used in the Rules to refer to the settlement price for F&O Contracts. In addition, a small change is proposed to remove a requirement to mark delivery documentation as ''urgent'' (as this is not done, and is not necessary, in operational practice). A number of drafting improvements have also been proposed to address inconsistencies and errata from previous changes to the Delivery Procedures and to align the document with current operational models, system functionality and system names. The relevant changes are to be made to paragraph 2 of the general provisions of the Delivery Procedures and to the following product-specific sections: Part A, paragraphs 2.2, 7.3 and 8; Part B, paragraphs 1.2, 5.1, 5.2 and 5.5; Part C, paragraph 2.3; Part D, paragraph 7.1; Part N, paragraph 2.3; Part O, paragraph 1.2; Part P, paragraphs 1.1–1.3 and Delivery Timetable; Part Q, paragraph 1.2; Part R, paragraph 1.2; Part T, paragraph 1.3; Part U, paragraphs 1.3 and 1.6; and Part BB, paragraph 1.2. In addition, changes to paragraph 1.2 of the general provisions of the Delivery Procedures are proposed to refer to the ''clearing operations department'' of ICE Clear Europe, which is the correct name of the relevant department.

In paragraph 5.4 of the general provisions of the Delivery Procedures, the words ''of such Transferor/Transferee'' are to be added at the end of the last sentence to clarify that the relevant form must be signed by an authorized signatory of the Transferor or Transferee (as applicable). Changes are also proposed to paragraph 17.5 of the Delivery Procedures to refer more generally to the provisions of ''Contract Terms'' and ''Market Rules'' that apply following non-performance of contractual obligations, rather than just the ICE Futures Europe Rules (since ICE Clear Europe provides clearing services to various Markets). In addition, the reference to the specific provisions of the ICE Futures Rules would be updated to refer to the correct provisions.

Various changes have also been proposed to the Delivery Procedures to remove references to certain products that are no longer cleared by ICE Clear

Europe following de-listings by the relevant exchange. These include ICE Futures ERU Futures Contracts, ICE UK Base Electricity Futures Contracts (EFA), ICE UK Peak Electricity Futures Contracts (EFA), ICE Endex TTF Natural Gas Working Days Next Week (WDNW) Futures Contracts, ICE Endex GASPOOL Natural Gas Daily Futures Contracts, ICE Endex NCG Natural Gas Daily Futures Contracts, ICE Endex ZTP Natural Gas Daily Futures Contracts and Japanese Government Bond Contracts. In addition, for Equity Futures/Options Contracts changes have been proposed to reflect the fact that Turkish securities are not available as an underlying. In the case of the ICE Futures ERU Futures Contracts, the changes proposed involve not only deleting references to the contracts but also removing all defined terms relating to Emission Reduction Units (''ERUs''), for example ''Emission Reduction Unit'', ''ERU Contract'', ''ERU Delivery Amount'' and ''ERU Transfer Request'', and the instances in which these appear, because such units are no longer valid deliverables for the relevant contracts. The relevant changes are to be made to paragraphs 5.1, 6.1 and 11 of the general provisions of the Delivery Procedures and to the following product-specific sections: Part A, heading and preamble; Part A, paragraphs 1.1, 2.1–2.4, 3.2, 5.1, 6.1, 8 and 9.1; Part F, heading and paragraphs 1.1(j), 3.3, 3.5(a), 3.6, 6.1, 7.1 and 9.1; Part G, heading and paragraphs 1.1(j), 2.2, 2.4–2.5, 5.2, 6.2 and 8.2; Part H, heading and paragraphs 1.1(f), 2.3, 2.5–2.6, 5.2, 6.2 and 8.2; Part I, heading and paragraphs 1.1(n), 3.3, 3.5–3.6, 6.2, 7.2 and 9.2; Part V (proposed deletion); and Part Z, paragraphs 1.2 and 2.1. The table of contents is also to be updated accordingly.

It is proposed that the Delivery Procedures be amended to reflect the current systems used by ICE Clear Europe to communicate with Clearing Members and facilitate delivery. There are a number of references to obsolete systems in the current published version of the Delivery Procedures. In some cases, there is no reference at all to the appropriate system used by ICE Clear Europe to communicate a particular piece of information to Clearing Members (or vice versa). The proposed changes involve removing references to systems that are no longer used for the relevant purpose, for example the Universal Clearing Platform (UCP), Trade Registration System (TRS) and Crystal, and adding new references to the current systems such as the Extensible Clearing System (ECS) and Managed File Transfer System (MFT). The changes are to be made to paragraph 16 of the general provisions of the Delivery Procedures and to the following product-specific sections: Part A, paragraph 5.3; Part B, sections 2 and 4; Part K, section 4; Part L, section 4; Part O, section 1 (Delivery Timetable); Part P, section 1 (Delivery Timetable); Part Q, section 1 (Delivery Timetable); Part R, sections 1 (Delivery Timetable) and 2 (Delivery Documentation Summary); Part S, paragraph 1.1; Part T, paragraph 1.3; Part U, paragraphs 1.6 and 1.9; Part W, paragraph 1.8; and Part X, paragraph 1.8.

7. Other Updates to Definitions

The amendments would include a number of other drafting clarifications, typographical corrections and drafting improvements to the definitions in Rule 101. In particular, the definition of ''Portfolio Risk Margin'' is being removed as unnecessary in the Rules (as it is part of the concept of Initial Margin) and other references in the Rules to Portfolio Risk Margin will be removed or replaced with Initial Margin, as applicable. The definitions of ''Transferor'' and ''Transferee'' would be amended to include an explicit reference to Part 7 of the Rules and the Delivery Procedures, in order to clarify that the terms are intended to refer to persons nominated by Buyers or Sellers to make or receive delivery of products in the course of the delivery process under the Rules and the Delivery Procedures. The definition of ''Person'' in clauses (a) and (b) thereof would be revised to refer to ''any similar structure in any other jurisdiction,'' a clarification requested by market participants to clearly cover funds and similar structures that exist in civil law jurisdictions in Europe such as Germany. The definition of ''Force Majeure Event'' would be amended to include a missing word to clarify the application of the term to Sponsored Principals and ensure consistency with other aspects of the definition. The definition of ''Future'' would be clarified such that it does not include Options (which are covered by a separate defined term). The definition of ''Mark-to-Market Margin'' would be clarified by addition of a reference to cover such margin transferred to a Sponsored Principal as well as a Clearing Member. Clause (b) of the definition of ''Set'' would be amended to use the defined term ''Strike Price'' instead of an undefined term. In the definition of ''Settlement and Notices Terms,'' a reference to FCM/BD Clearing Members that are CDS Clearing Members would be corrected.

In addition, with respect to certain other definitions, typographical corrections, updates to cross-references to various Rules and Procedures and corrections to alphabetical ordering would be made.

8. Additional Clarifications and Updates

ICE Clear Europe is proposing to make a number of additional clarifications, drafting updates and similar corrections to other provisions of the Rules.

In Rule 102(i), a change is proposed to clarify, for completeness, that social security contributions also fall within the meaning of the term ''tax'' throughout the Rules. In the UK, as well as income tax, there are ''national insurance contributions'' payable by employers and employees, and similar concepts apply in several other countries. This amendment would ensure that all taxes would be covered when representations and indemnities exist under the rules. In several places throughout the Rules and Procedures, amendments are proposed to replace undefined terms with defined terms, for greater clarity and drafting precision. In this regard, a drafting change has been proposed to Rule 106(a)(vii) to use the defined term ''Person'' in place of the undefined term ''body''. In Rules 106(e)(i) and 113(e), paragraph 6.1(i)(v) of the Finance Procedures and paragraph 17.6 of the Delivery Procedures, similar changes have been proposed to use the defined term ''Applicable Law'' instead of undefined terms such as ''applicable law'' or ''law''. In the net sum calculation in Rule 906(a), the word ''margin'' in the explanation of the variable ''M'' has been replaced with the defined term ''Margin''. Similarly, Rule 913(a)(xiv) is proposed to be amended to remove the terms ''strike price'' and ''exercise price'' and replace these with the defined term ''Strike Price.'' In Rule 1604(b), the lower case term ''transfer'' is to be replaced with the defined term ''Transfer,'' which is given a particular meaning by Rule 904(a) in the context of the default management steps that ICE Clear Europe is permitted to take under the Rules and Procedures. In paragraph 2.2(e) of the Clearing Procedures, it is proposed that ''commodities'' be replaced with the defined term ''Deliverables'', which is the defined term that includes commodities in addition to other types of deliverable. In the Finance Procedures, at paragraph 4.2, references to ''accounts'' are to be replaced with the defined term ''Nominated Bank Accounts''. These changes are generally intended to clarify the Rules but are not intended to change the substantive

rights or obligations of the Clearing House or Clearing Members.

In Rule 106(b), an amendment would be made to clarify that Clearing Members and Customers are deemed to consent to disclosure of information by ICE Clear Europe where made pursuant to Applicable Law generally, rather than just pursuant to the provisions of the Financial Services and Markets Act 2000, which may not be the only applicable law for non-UK Clearing Members.

Various changes have been proposed throughout the Rules and Procedures in order to be consistent in the use of such terms as ''section'' and ''paragraph,'' including to Rule 109(j), Rule 904(g), Sections 3(n), 3(o), 10, 13(a) and 13(c) of the Standard Terms, paragraphs 2.2, 4.5 6.1(i) and 13.3 of the Finance Procedures, paragraphs 3.1 and 10.2 of the FX Procedures and paragraph 8.2(h)(ii) of the CDS Procedures.

In Rule 110(b), a drafting clarification is proposed to highlight that this provision is also subject to Rule 110(g) (in addition to Rule 110(c)). Rule 110(g) (which by its terms overrides Rule 110(b)) provides that ICE Clear Europe does not have the right to extend the time at which a payment is due to a Clearing Member beyond the time immediately prior to the commencement of the daily payment cycle for the relevant payment currency.

Changes at Rule 117(a) have been proposed to remove the words ''Subject to Rule 1518'' and provide that any Dispute not subject to the procedures of Part 10 of the Rules or the Complaint Resolution Procedures shall be subject to arbitration. This change is intended to reduce the risk of procedural questions as to the dispute resolution process which is applicable in a given scenario. Rule 1518 by its terms overrides Rule 117 in the relevant circumstances stated thereunder and so the deleted language is not needed.

The words ''and the deposit of securities'' and ''and securities'' are proposed to be deleted in Rule 202(a)(xi). This reflects current operational processes, under which amounts transferred to and from ICE Clear Europe by Clearing Members for the purposes of Margin, Guaranty Fund Contributions, fees and amounts due under contracts pursuant to a margin call will only be in the form of cash (and not securities or other financial instruments). Securities may be substituted for cash margin pursuant to a separate process.

Changes at Rule 206(a) are proposed to include Clearing Member Capital requirements in the Membership Procedures, in addition to under the CDS Procedures and Finance Procedures. The Capital requirements themselves would not be changed.

A clarification is proposed to Rule 401(b) to improve the current drafting by providing that new contracts arising at the moment that alternative delivery is agreed are ''Contracts reversing the existing Contract or Contracts.'' An alternative delivery agreement results in the cancellation of the existing cleared contract through an offsetting contract. The change reflects current practice and is not intended to have any effect on the way in which the offsetting process operates.

In Rule 401(n), changes would be made to clarify the application of the Rule to Customer-CM Transactions that arise when an F&O Contract arises pursuant to Rule 401. (In such case, an offsetting Customer-CM F&O Transaction arises simultaneously between the Customer and Clearing Member.) The Customer-CM Transaction would be subject to the same conditions as to when contracts can be voided as other contracts under Part 4 of the Rules.

Changes are proposed to Rule 405(b)(i) to correctly refer to the execution venues which can submit contracts to ICE Clear Europe for clearing, namely CDS or FX trade execution processing platforms and venues falling within the definition of ''Market''. These changes clarify that the deemed representations given by counterparties to contracts as to the accuracy of transaction data equally arise in a scenario where the transaction was originally executed through one of these alternative venues, and not solely in relation to transactions that take place on Exchanges.

It is proposed that the word ''day'' in Rule 406(a) be replaced with ''Business Day'' to reflect the fact that Open Contract Positions are not calculated on non-Business Days. Changes are proposed to refer to ''Contracts that are Futures'' and ''Contracts that are Options'', to replace the current references ''Futures that are F&O Contracts'' and ''Options that are F&O Contracts'', which are redundant.

A minor drafting change is proposed to Rule 502(c) to clarify that the particular set of Procedures referred to here are the Finance Procedures. Relatedly, a clarification is proposed in Rule 502(d) to confirm that the ability of the Clearing House to ''specify proportions or maximum proportions of asset classes'' extends to cash and relates solely to cash or assets ''to be provided as Margin.''

Changes in Rule 502(k) (which relates to certain considerations in making certain changes in eligible assets for Margin and Permitted Cover and related haircuts) would clarify the application of this provision to all Contract types and not just F&O Contracts, consistent with existing practice. Rule 503(d) would be amended to clarify the calculation of intra-day margin in the context of certain customer positions carried on a gross basis. The new drafting clarifies that Margin is calculated based on the Open Contract Position plus ''the net additional exposure relating to any Contracts held gross which have not been contractually netted or aggregated in accordance with Rule 406''. The amendment is not intended to change margin calculations, but avoid uncertainty as to the treatment of gross positions under the current drafting of the Rules consistent with provisions used by other ICE clearing houses.

In Rule 803(c), drafting changes have been proposed to clarify that only ''Long'' Option Contracts can be abandoned by notice to ICE Clear Europe, consistent with the rights applicable to options under the existing Contract Terms and existing operational processes. Minor drafting improvements have also been made in Rules 803(a), 804 and 808(a).

Rules 908(b), (c) and (d) would be revised to make certain non-substantive drafting clarifications. Further, in those subsections, with regard to amounts falling within ''N'' (the post-default net sum calculation), which form the first layer of the default waterfall (subparagraph (i) in Rules 908(b), (c) and (d)), amendments would provide that such amounts must be applied ''subject to the restrictions set out in Rule 906(c)''. Rule 906(c) imposes restrictions on the setting off of assets recorded in different Customer Accounts of a Defaulter against shortfalls on Proprietary Accounts or other Customer Accounts of the same Defaulter, promoting segregation under the European Market Infrastructure Regulation and U.S. laws. The proposed drafting would not affect the operation of Rule 906(c), but would make the Rules easier to follow by directing readers to Rule 906(c) in the context of the default waterfall provisions in Rule 908. Finally, changes are proposed to subparagraph (iii) to clarify that this layer of the waterfall would not include guaranty fund contributions of a Sponsor of a Defaulter (that is a Sponsored Principal).

Minor drafting changes have been proposed to Rule 908(g)(i)(A)–(D) to add the words ''in question'' after the second instance of ''Defaulter''. These changes are intended to resolve any ambiguity as

to which guaranty fund contributions are to be used in the situation where more than one default takes place simultaneously.

It is proposed that the exclusion of ICE Clear Europe's liability in Rule 919(r) be amended to remove the reference to requirements of ''law'' generally and replace this with a reference to requirements of ''Applicable Laws or this Rule 919''. The amendments also clarify that the exclusion of liability does not apply to the extent that Rule 919 itself provides that a particular sum is payable by ICE Clear Europe. This is consistent with ICE Clear Europe's interpretation of the existing effect of this provisions, but adds clarity for users.

An amendment is proposed to Rule 1103(f) to add a reference to Part 9 of the Rules in the provision setting out that Clearing House Contributions will be used ''only for the purposes of meeting shortfalls arising directly or indirect from Defaults'' in accordance with specified provisions of the Rules and existing requirements of Applicable Laws. The added reference to Part 9 is appropriate as it contains the majority of the provisions governing Clearing Member defaults, after some provisions were moved out of Part 11 several years ago.

A drafting change is proposed in Rule 1202(b)(vii) to reflect the fact that Financials & Softs Contracts are already contemplated within the definition of a ''Future'' and accordingly the reference to Financials & Softs Contracts can be deleted. (''Future'' refers to ''an F&O Contract or FX Contract''; ''F&O Contracts'' include Financials & Softs Contracts (in addition to Energy Contracts).) A similar change is to be made in Rule 1202(k) to refer to ''Contracts'' rather than ''Financials & Softs Contracts'' specifically (which would fall within the more general ''Contracts'' definition).

In the Clearing Procedures, in paragraphs 2.3(b)(xxv), (xxvii), (xxxix) and (xli), changes are proposed to remove references to the ''Standard Omnibus Indirect Account For CDS'' and the ''Standard TTFCA Omnibus Indirect Account For CDS'' in account codes ''X'' and ''Y''. These net margin omnibus accounts for indirect clearing are not actually used for CDS Contracts.

A drafting clarification would be made in paragraph 4.2(a) of the Clearing Procedures to provide that that initial margin calculations will be ''based on'' the net positions for each Contract Set in a Proprietary Account. (This does not entail any change in the way margin is currently calculated.) In paragraph 4.2(b), the reference to the ''Risk Committee'' is to be replaced with a reference to the relevant ''product risk committee,'' which is the correct name of the relevant committee that reviews the policy for setting initial margin parameters.

References to ''Buyer's Security'' and ''Seller's Security'' in paragraphs 4.6(c)(i) and 4.8 the Clearing Procedures are to be amended to replace ''Security'' with ''security'' (reflecting that ''Security'' is not a defined term in the Rules or Procedures). Changes are also proposed to paragraphs 4.6(c) and 4.8 to refer to particular items that may be specified in the Delivery Procedures.

In paragraph 6.1(a)(i) of the Clearing Procedures, an incorrect reference to ''Proprietary Account Position'' would be corrected. The capitalized term ''Collateral'' in paragraph 6.3(b) of the Clearing Procedures is to be replaced with the lower case term ''collateral'', as there is no definition of the former term in the Rules or Procedures. It is also proposed that the word ''Initial'' be deleted before the words ''Margin requirement'' in the same provision since the relevant requirement concerns all kinds of Margin (including Variation Margin or Mark-to-Market Margin).

In the Finance Procedures, a new paragraph 1.11 is proposed to be added to provide definitions for the various currencies referenced the Finance Procedures which are not defined in the Rules. Related to this, the reference to Canadian Dollars, Swiss Francs and Swedish Kroner in paragraph 2.1 is to be deleted and replaced by the words ''Other currencies'' to reflect the fact that a broader range of currencies are actually received as income on non-cash collateral. Changes are proposed to paragraph 4.1(a)(vi) to clarify that Clearing Members that transfer non-cash assets to ICE Clear Europe as collateral must have an account in the currency of the income payable on the non-cash asset. A non-substantive drafting clarification would be made in paragraph 4.2 to address Clearing Members that act in more than one product category.

In paragraph 6.1(i) of the Finance Procedures, the current reference to ''bank holidays'' would be amended to refer also to ''public holidays,'' because ''bank holiday'' is a UK-specific term that is not necessarily used in other jurisdictions. Certain other changers would clarify that relevant actions must be taken ''by'' a specified date, rather than ''on'' that date. Paragraph 8.2 of the Finance Procedures would be amended to refer to the ''risk department'', since ''Risk'' is an undefined term.

Changes are proposed to paragraph 10.9 of the Finance Procedures to reflect the fact that the London Gold Fixing has been replaced as the relevant global benchmark for gold prices by the London Bullion Market Association Gold Price, which is administered by ICE Benchmark Administration Limited.

In the Contract Terms Procedures, the term ''Clearing Counterparty'' (which is not used or defined in the Rules or other Procedures) would be changed to ''Clearing Member'' for consistency.

In the Membership Procedures, in paragraph 1.3, the full name of the relevant committee, the ''Executive Risk Committee'', would be used. Various drafting changes have also been proposed to the table at paragraph 4.2. These updates reflect the relevant defined terms used in the Rules (as proposed to be amended hereby).

In addition to the foregoing, certain corrections and updates to cross-references and numbering, as well as minor and non-substantive corrections to capitalization and other typographical corrections, have been made throughout the Rules and Procedures.

(b) Statutory Basis

ICE Clear Europe believes that the proposed amendments are consistent with the requirements of Section 17A of the Act [8] and the regulations thereunder applicable to it, including the standards under Rule 17Ad–22.[9] In particular, Section 17A(b)(3)(F) of the Act [10] requires, among other things, that the rules of a clearing agency be designed to promote the prompt and accurate clearance and settlement of securities transactions and, to the extent applicable, derivative agreements, contracts, and transactions, the safeguarding of securities and funds in the custody or control of the clearing agency or for which it is responsible, and the protection of investors and the public interest.

The proposed amendments are intended principally to update and clarify certain references in the Rules and Procedures to reflect more clearly current practices, remove outdated references and provisions, simplify and harmonize references to the different Markets cleared by ICE Clear Europe and to the different delivery facilities used by ICE Clear Europe. The changes would also remove references to contracts no longer cleared, and make various other drafting improvements and modifications that would generally not affect the terms of contracts, or the rights or obligations of Clearing

[8] 15 U.S.C. 78q–1.

[9] 17 CFR 240.17Ad–22.

[10] 15 U.S.C. 78q–1(b)(3)(F).

Members. In ICE Clear Europe's view, these changes will generally help clarify and simplify the Rules and Procedures, and make it easier for ICE Clear Europe to keep such documents up to date notwithstanding potential future changes in the Markets cleared and similar events. In ICE Clear Europe's view, these changes are therefore generally consistent with the prompt and accurate clearance and settlement of cleared transactions. For similar reasons, the amendments will also help ensure that the Rules and Procedures are aligned with operational procedures concerning the holding of funds and securities, and are therefore consistent with safeguarding of securities and funds in the custody or control of the Clearing House or which it is responsible. Overall, in ICE Clear Europe's view, the amendments are for these reasons also consistent with the protection of investors and the public interest, within the meaning of Section 17A(b)(3)(F) of the Act.[11]

The proposed Rule changes are also consistent with the relevant requirements of Rule 17Ad–22. In particular, Rule 17Ad–22(e)(1)[12] requires that each covered clearing agency establish, implement, maintain and enforce written policies and procedures reasonably designed to provide for a well-founded, clear, transparent, and enforceable legal basis for each aspect of its activities in all relevant jurisdictions. As discussed herein, the amendments are designed to clarify, simplify and harmonize various aspects of the Rules and Procedures, to be consistent with current operations, remove outdated references, address changes in Markets served and delivery facilities used, and similar matters. Taken together, these amendments will enhance the clarity of the legal framework provided by the Rules and Procedures under which the Clearing House operates, and are therefore consistent with Rule 17Ad–22(e)(1).[13]

(B) Clearing Agency's Statement on Burden on Competition

ICE Clear Europe does not believe the proposed rule changes would have any impact, or impose any burden, on competition not necessary or appropriate in furtherance of the purpose of the Act. The amendments do not change the legal rights of members or users in any material way and are being adopted to update and clarify various references in the Rules and Procedures and to remove obsolete provisions and covered errors. ICE Clear Europe does not believe such amendments will result in material changes in its current operations or practices, or the rights or obligations of Clearing Members. Such amendments will apply to all Clearing Members. ICE Clear Europe does not believe such amendments would in themselves materially affect the cost of, or access to clearing. Legal costs of users should be reduced by correcting errors and removing ambiguity which might otherwise require legal advice. As a result, ICE Clear Europe does not believe such amendments would adversely affect competition among Clearing Members or the market for clearing services generally.

(C) Clearing Agency's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

ICE Clear Europe has conducted a public consultation on amendments to its Rules that included the proposed rule changes set forth herein.[14] It should be noted that this consultation included not only the changes discussed herein, but also a number of other changes which ICE Clear Europe has addressed in prior filings and intends to address in future filings. ICE Clear Europe received three detailed and written responses to the overall consultation, which included four specific comments relating to the amendments described in this filing. It has discussed aspects of the proposed Rule changes, as were presented in such consultation, with those interested Clearing Members who responded. Based on feedback received by ICE Clear Europe, those Clearing Members who responded supported all the changes proposed herein. Clearing Members' comments were generally concentrated on other matters arising in the consultation which have been or will be addressed in other rule filings (it being important to stress that all Clearing Member comments on the set as a whole have been addressed to consultation respondents' satisfaction). With respect to the amendments that are subject to this filing, one Clearing Member in each case asked certain questions concerning the rationale for proposed amendments to the definition of ''Person'', Rule 401(b), Rule 503(d) and Rule 503(f)(i), the rationale for each of which is presented above. The rationale for these changes was clarified in a call with the relevant Clearing Members. ICE Clear Europe determined that the questions were adequately addressed by oral explanations and discussions with Clearing Members and that no material changes to the consulted-upon Rules were required. ICE Clear Europe will notify the Commission of any further written comments with respect to the proposed rules received by ICE Clear Europe.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not:

(i) Significantly affect the protection of investors or the public interest;

(ii) impose any significant burden on competition; and

(iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act and Rule 19b–4(f)(6) 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.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change, security-based swap submission or advance notice is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*) or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–ICEEU–2019–020 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–ICEEU–2019–020. 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 (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent

[11] *Id.*

[12] 17 CFR 240.17Ad–22(e)(1).

[13] 17 CFR 240.17Ad–22(e)(1).

[14] ICE Clear Europe Circular C19/046 (March 8, 2019), available at *https://www.theice.com/publicdocs/clear_europe/circulars/C19046.pdf.*

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 such filings will also be available for inspection and copying at the principal office of ICE Clear Europe and on ICE Clear Europe's website at *https://www.theice.com/clear-europe/regulation*. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly.

All submissions should refer to File Number SR–ICEEU–2019–020 and should be submitted on or before November 7, 2019.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[15]

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2019–22593 Filed 10–16–19; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–87274; File No. SR–CBOE–2019–098]

Self-Regulatory Organizations; Cboe Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change Relating To Amend the Appointment Weight Table in Rule 5.50 in the Shell Structure for the Exchange's Rulebook

October 10, 2019.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on October 4, 2019, Cboe Exchange, Inc. (the ''Exchange'' or ''Cboe Options'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Exchange filed the proposal as a ''non-controversial'' proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act[3] and Rule 19b–4(f)(6) thereunder.[4] 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 Exchange, Inc. (the ''Exchange'' or ''Cboe Options'') proposes to amend the appointment weight table in Rule 5.50 in the shell structure for the Exchange's Rulebook that will become effective upon the migration of the Exchange's trading platform to the same system used by the Cboe Affiliated Exchanges (as defined below) (''shell Rulebook''). 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://www.cboe.com/AboutCBOE/CBOELegalRegulatoryHome.aspx*), 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

In 2016, the Exchange's parent company, Cboe Global Markets, Inc. (formerly named CBOE Holdings, Inc.) (''Cboe Global''), which is also the parent company of Cboe C2 Exchange, Inc. (''C2''), acquired Cboe EDGA Exchange, Inc. (''EDGA''), Cboe EDGX Exchange, Inc. (''EDGX'' or ''EDGX Options''), Cboe BZX Exchange, Inc. (''BZX'' or ''BZX Options''), and Cboe BYX Exchange, Inc. (''BYX'' and, together with Cboe Options, C2, EDGX, EDGA, and BZX, the ''Cboe Affiliated Exchanges''). The Cboe Affiliated Exchanges are working to align certain system functionality, retaining only intended differences, between the Cboe Affiliated Exchanges, in the context of a technology migration. Cboe Options intends to migrate its trading platform to the same system used by the Cboe Affiliated Exchanges, which the Exchange expects to complete on October 7, 2019. In connection with this technology migration, the Exchange has a shell Rulebook that resides alongside its current Rulebook, which shell Rulebook will contain the Rules that will be in place upon completion of the Cboe Options technology migration.

The Exchange proposes to amend an inadvertent error currently in the appointment weight table in shell Rule 5.50(g). Currently, the appointment weight table shows ''Options on the iPath S&P 500 VIX Short-Term Futures'' with an appointment weight of .100 in one row of the table and ''Index ETN (VXX)'' with a weight of .001 in the row directly below. The Exchange notes that this is incorrect and should be displayed in a single row containing ''Options on the iPath S&P 500 VIX Short-Term Futures Index ETN (VXX)'' with a weight of .100. A formatting error occurred that inadvertently broke apart Options on the iPath S&P 500 VIX Short-Term Futures Index ETN (VXX) into two rows.[5] Indeed, the Exchange notes that neither Options on the iPath S&P 500 VIX Short-Term Futures, nor Index ETN, are separate products on the Exchange and instead, Options on the iPath S&P 500 VIX Short-Term Futures Index ETN (symbol: VXX) is, in fact, the correct name of the product.[6] Therefore, the Exchange now proposes to correct this in the appointment table to show Options on the iPath S&P 500 VIX Short-Term Futures Index ETN (VXX) with an appointment weight of .100. Additionally, the proposed rule change also removes the rows in the appointment table which refer to Options on the NASDAQ 100 Index

[15] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A)(iii).

[4] 17 CFR 240.19b–4(f)(6).

[5] *See* Securities and Exchange Act Release No. 81879 (October 16, 2017), 82 FR 48858 (October 20, 2017) (Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To List and Trade S&P Select Sector Index Options) (SR–CBOE–2017–065), wherein the Exhibit 5 to SR–CBOE–2017–065 it shows, correctly, Options on the iPath S&P 500 VIX Short-Term Futures Index ETN (VXX), as one product with an appointment cost (the prior term) of .10.

[6] *See* Cboe Options on Volatility-based ETPs (October 4, 2019), available at *http://www.cboe.com/products/options-on-single-stocks-and-exchange-traded-products/options-on-exchange-traded-products/cboe-options-on-volatility-based-etps.*

(NDX) and Morgan Stanley Retail Index Options (MVR), on which the Exchange is authorized to list options, but on which the Exchange does not currently, and does not intend, to list options. Because there are currently no options listed on either of these indexes, the proposed rule change has no impact on trading on the Exchange. The proposed rule change also corrects a cross-reference in the table. The rule provision regarding the Exchange's ability to list SPX or VIX on a group basis is in Rule 4.13 rather Rule 4.14, so the proposed rule change updates the cross-reference accordingly.[7] The proposed changes are of a non-substantive nature and are only making changes to correct an formatting error that had resulted in an inaccurate row within the appointment weight table under shell Rule 5.50(g) and to remove references to indexes on which the Exchange does not list (and does not intend to list) options.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Securities Exchange Act of 1934 (the ''Act'') and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.[8] Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[9] 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)[10] requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

As stated, the proposed rule change makes no substantive changes to the rules. The proposed rule change is merely intended to correct an inadvertent formatting error in the appointment weight table which mistakenly broke apart the product name ''Options on the iPath S&P 500 VIX Short-Term Futures Index ETN (VXX)'' into two rows, delete references to indexes on which the Exchange does not list (and does not intend to list) options, and correct a cross-reference to another rule in order to avoid potential confusion and provide market participants with accurate rules within the shell Rulebook upon the technology migration on October 7, 2019. As such, the proposed rule change is designed to promote just and equitable principles of trade, 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, by providing market participants with rules of the Exchange that are clear and, thus, easy to understand.

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. The proposed rule change is not intended as a competitive change, but rather, seeks to make non-substantive rule changes in amending a table formatting error, remove references to certain indexes no longer applicable to trading on the Exchange, and correct a cross-reference to shell Rule 5.50(g) in anticipation of the October 7, 2019 technology migration. The Exchange also does not believe that the proposed rule change will impose any undue burden on competition because, as stated, the proposed changes will not impact trading on the Exchange as they are non-substantive changes designed to correct rule formatting and provide an up-to-date list of indexes in order to alleviate any potential confusion and provide market participants with clear and accurate rules.

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

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A)(iii) of the Act[11] and subparagraph (f)(6) of Rule 19b–4 thereunder.[12]

A proposed rule change filed pursuant to Rule 19b–4(f)(6) under the Act[13] normally does not become operative for 30 days after the date of its filing. However, Rule 19b–4(f)(6)(iii)[14] permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the five day prefiling requirement and the 30-day operative delay so that it may implement the proposed rule change without delay. According to the Exchange, waiver of the prefiling requirement and the operative delay will help to avoid any potential confusion by providing market participants with accurate rules within the shell Rulebook upon the technology migration on October 7, 2019. The Commission believes that waiver of the 30-day operative delay is consistent with the protection of investors and the public interest because the proposed rule change raises no new or novel issues. Therefore, the Commission hereby waives the prefiling requirement and the operative delay and designates the proposal operative upon filing.[15]

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

[7] *See* Rule 4.13(f) in the shell Rulebook.

[8] 15 U.S.C. 78f(b).

[9] 15 U.S.C. 78f(b)(5).

[10] *Id.*

[11] 15 U.S.C. 78s(b)(3)(A)(iii).

[12] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Commission has waived that requirement in this case.

[13] 17 CFR 240.19b–4(f)(6).

[14] 17 CFR 240.19b–4(f)(6)(iii).

[15] For purposes only of waiving the 30-day operative delay, the Commission has also considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

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 (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–CBOE–2019–098 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–CBOE–2019–098. 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 (*http://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. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–CBOE–2019–098 and should be submitted on or before November 7, 2019.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[16]

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2019–22592 Filed 10–16–19; 8:45 am]

BILLING CODE 8011–01–P

[16] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–87277; File No. SR–NYSEArca–2019–60]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Designation of a Longer Period for Commission Action on a Proposed Rule Change, as Modified by Amendment No. 1 Thereto, To List and Trade Shares of the KFA Global Carbon ETF Under NYSE Arca Rule 8.600–E

October 10, 2019.

On August 14, 2019, NYSE Arca, Inc. (''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 list and trade shares of the KFA Global Carbon ETF under NYSE Arca Rule 8.600–E. The proposed rule change was published for comment in the **Federal Register** on August 29, 2019.[3] On September 12, 2019, the Exchange filed Amendment No. 1 to the proposed rule change, which replaced and superseded the proposed rule change as originally filed.[4] The Commission has received no comment letters on the proposed rule change.

Section 19(b)(2) of the Act [5] 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 October 13, 2019. The Commission is extending this 45-day time period.

The Commission finds it 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,[6] designates November 27, 2019 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–NYSEArca–2019–60), as modified by Amendment No. 1.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[7]

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2019–22595 Filed 10–16–19; 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. 86752 (Aug. 23, 2019), 84 FR 45557.

[4] Amendment No. 1 is available on the Commission's website at: *https://www.sec.gov/comments/sr-nysearca-2019-60/srnysearca201960-6117868-192147.pdf.*

[5] 15 U.S.C. 78s(b)(2).

[6] *Id.*

[7] 17 CFR 200.30–3(a)(31).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–87282; File No. SR–MIAX–2019–43]

Self-Regulatory Organizations; Miami International Securities Exchange LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Its Fee Schedule

October 10, 2019.

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 October 1, 2019, Miami International Securities Exchange LLC (''MIAX Options'' or ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''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

The Exchange is filing a proposal to amend the MIAX Options Fee Schedule (the ''Fee Schedule'') to extend the waiver period for certain non-transaction fees applicable to Market Makers [3] that trade solely in Proprietary Products [4] until December 31, 2019.

The text of the proposed rule change is available on the Exchange's website at

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] The term ''Market Makers'' refers to ''Lead Market Makers'', ''Primary Lead Market Makers'' and ''Registered Market Makers'' collectively. *See* Exchange Rule 100.

[4] The term ''Proprietary Product'' means a class of options that is listed exclusively on the Exchange. *See* Exchange Rule 100.

http://www.miaxoptions.com/rule-filings, at MIAX's principal office, 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

Background

On October 12, 2018, the Exchange received approval from the Commission to list and trade on the Exchange, options on the SPIKES® Index, a new index that measures expected 30-day volatility of the SPDR S&P 500 ETF Trust (commonly known and referred to by its ticker symbol, ''SPY'').[5] The Exchange adopted its initial SPIKES transaction fees on February 15, 2019.[6]

On May 31, 2019, the Exchange filed a proposal with the Commission to amend the Fee Schedule to waive certain non-transaction fees applicable to Market Makers that trade solely in Proprietary Products (including options on the SPIKES Index) until September 30, 2019.[7] In particular, the Exchange adopted waivers for Membership Application fees, monthly Market Maker Trading Permit fees, Application Programming Interface (''API'') Testing and Certification fees for Members, and monthly MEI Port fees assessed to Market Makers that trade solely in Proprietary Products (including options on SPIKES) until September 30, 2019.

Proposal

The Exchange now proposes to extend the waiver period for the same non-transaction fees applicable to Market Makers that trade solely in Proprietary Products (including options on SPIKES) until December 31, 2019. In particular, the Exchange proposes to waive Membership Application fees, monthly Market Maker Trading Permit fees, Member API Testing and Certification fees, and monthly MEI Port fees assessed to Market Makers that trade solely in Proprietary Products (including options on SPIKES) until December 31, 2019.

Membership Application Fees

The Exchange currently assesses Membership fees for applications of potential Members. The Exchange assesses a one-time Membership Application fee on the earlier of (i) the date the applicant is certified in the membership system, or (ii) once an application for MIAX membership is finally denied. The one-time application fee is based upon the applicant's status as either a Market Maker or an Electronic Exchange Member (''EEM'').[8] A Market Maker is assessed a one-time Membership Application fee of $3,000.00.

The Exchange proposes that the waiver for the one-time Membership Application fee of $3,000.00 for Market Makers that trade solely in Proprietary Products (including options on SPIKES) will be extended from September 30, 2019 until December 31, 2019, which the Exchange proposes to state in the Fee Schedule. The purpose of this proposed change is to continue to provide an incentive for potential Market Makers to submit membership applications, which should result in increasing potential liquidity in Proprietary Products, including options on SPIKES. Even though the Exchange is proposing to extend the waiver of this particular fee for Market Makers who will trade solely in Proprietary Products from September 30, 2019 until December 31, 2019, the overall structure of the fee is outlined in the Fee Schedule so that there is general awareness that the Exchange intends to assess such a fee after December 31, 2019.

Trading Permit Fees

The Exchange issues Trading Permits that confer the ability to transact on the Exchange. MIAX Trading Permits are issued to Market Makers and EEMs. Members receiving Trading Permits during a particular calendar month are assessed monthly Trading Permit fees as set forth in the Fee Schedule. As it relates to Market Makers, MIAX currently assesses a monthly Trading Permit fee in any month the Market Maker is certified in the membership system, is credentialed to use one or more MIAX Express Interface Ports (''MEI Ports'')[9] in the production environment and is assigned to quote in one or more classes. MIAX assesses its Market Makers the monthly Market Maker Trading Permit fee based on the greatest number of classes listed on MIAX that the MIAX Market Maker was assigned to quote in on any given day within a calendar month and the applicable fee rate is the lesser of either the per class basis or percentage of total national average daily volume measurements. A MIAX Market Maker is assessed a monthly Trading Permit Fee according to the following table:

Type of trading permit	Monthly MIAX trading permit fee	Market Maker assignments (the lesser of the applicable measurements below) Ω	
		Per class	% of national average daily volume
Market Maker (includes RMM, LMM, PLMM).	$7,000.00	Up to 10 Classes	Up to 20% of Classes by volume.
	12,000.00	Up to 40 Classes	Up to 35% of Classes by volume.
	* 17,000.00	Up to 100 Classes	Up to 50% of Classes by volume.

[5] *See* Securities Exchange Act Release No. 84417 (October 12, 2018), 83 FR 52865 (October 18, 2018) (SR–MIAX–2018–14) (Order Granting Approval of a Proposed Rule Change by Miami International Securities Exchange, LLC to List and Trade on the Exchange Options on the SPIKES® Index).

[6] *See* Securities Exchange Release No. 85283 (March 11, 2019), 84 FR 9567 (March 15, 2019) (SR–MIAX–2019–11). The Exchange initially filed the proposal on February 15, 2019 (SR–MIAX–2019–04). That filing was withdrawn and replaced with (SR–MIAX–2019–11).

[7] *See* Securities Exchange Act Release No. 86109 (June 14, 2019), 84 FR 28860 (June 20, 2019) (SR–MIAX–2019–28).

[8] The term ''Electronic Exchange Member'' or ''EEM'' means the holder of a Trading Permit who is not a Market Maker. Electronic Exchange Members are deemed ''members'' under the Exchange Act. *See* Exchange Rule 100.

[9] Full Service MEI Ports provide Market Makers with the ability to send Market Maker simple and complex quotes, eQuotes, and quote purge messages to the MIAX System. Full Service MEI Ports are also capable of receiving administrative information. Market Makers are limited to two Full Service MEI Ports per matching engine. *See* Fee Schedule, note 27.

Type of trading permit	Monthly MIAX trading permit fee	Market Maker assignments (the lesser of the applicable measurements below) Ω	
		Per class	% of national average daily volume
	*22,000.00	Over 100 Classes	Over 50% of Classes by volume up to all Classes listed on MIAX.

Ω Excludes Proprietary Products.
* For these Monthly MIAX Trading Permit Fee levels, if the Market Maker's total monthly executed volume during the relevant month is less than 0.060% of the total monthly executed volume reported by OCC in the market maker account type for MIAX-listed option classes for that month, then the fee will be $15,500 instead of the fee otherwise applicable to such level.

MIAX proposes that the waiver for the monthly Trading Permit fee for Market Makers that trade solely in Proprietary Products (including options on SPIKES) will be extended from September 30, 2019 to December 31, 2019, which the Exchange proposes to state in the Fee Schedule. The purpose of this proposed change is to continue to provide an incentive for Market Makers to provide liquidity in Proprietary Products on the Exchange, which should result in increasing potential order flow and volume in Proprietary Products, including options on SPIKES. Even though the Exchange is proposing to extend the waiver of this particular fee for Market Makers trading solely in Proprietary Products from September 30, 2019 until December 31, 2019, the overall structure of the fee is outlined in the Fee Schedule so that there is general awareness by potential Members seeking a Trading Permit on the Exchange that the Exchange intends to assess such a fee after December 31, 2019.

The Exchange also proposes that Market Makers who trade Proprietary Products (including options on SPIKES) along with multi-listed classes will continue to not have Proprietary Products (including SPIKES) counted toward those Market Makers' class assignment count or percentage of total national average daily volume. This exclusion is noted with the symbol ''Ω'' following the table that shows the monthly Trading Permit Fees currently assessed for Market Makers in Section 3)b) of the Fee Schedule.

API Testing and Certification Fee

The Exchange assesses an API Testing and Certification fee to all Members depending upon the type of Member. An API makes it possible for Members' software to communicate with MIAX software applications, and is subject to Members testing with, and certification by, MIAX. The Exchange offers four types of interfaces: (i) The Financial Information Exchange Port (''FIX Port''),[10] which enables the FIX Port user (typically an EEM or a Market Maker) to submit simple and complex orders electronically to MIAX; (ii) the MEI Port, which enables Market Makers to submit simple and complex electronic quotes to MIAX; (iii) the Clearing Trade Drop Port (''CTD Port''),[11] which provides real-time trade clearing information to the participants to a trade on MIAX and to the participants' respective clearing firms; and (iv) the FIX Drop Copy Port (''FXD Port''),[12] which provides a copy of real-time trade execution, correction and cancellation information through a FIX Port to any number of FIX Ports designated by an EEM to receive such messages.

API Testing and Certification fees for Market Makers are assessed (i) initially per API for CTD and MEI in the month the Market Maker has been credentialed to use one or more ports in the production environment for the tested API and the Market Maker has been assigned to quote in one or more classes, and (ii) each time a Market Maker initiates a change to its system that requires testing and certification. API Testing and Certification fees will not be assessed in situations where the Exchange initiates a mandatory change to the Exchange's system that requires testing and certification. The Exchange currently assesses a Market Maker an API Testing and Certification fee of $2,500.00. The API Testing and Certification fees represent costs incurred by the Exchange as it works with each Member for testing and certifying that the Member's software systems communicate properly with MIAX's interfaces.

MIAX proposes to extend the waiver of the API Testing and Certification fee for Market Makers that trade solely in Proprietary Products (including options on SPIKES) from September 30, 2019 until December 31, 2019, which the Exchange proposes to state in the Fee Schedule. The purpose of this proposed change is to continue to provide an incentive for potential Market Makers to develop software applications to trade in Proprietary Products, including options on SPIKES. Even though the Exchange is proposing to extend the waiver of this particular fee for Market Makers who trade solely in Proprietary Products from September 30, 2019 until December 31, 2019, the overall structure of the fee is outlined in the Fee Schedule so that there is general awareness that the Exchange intends to assess such a fee after December 31, 2019.

MEI Port Fees

MIAX provides four (4) Port types, including (i) the FIX Port, which enables the FIX Port user (typically an EEM or a Market Maker) to submit simple and complex orders electronically to MIAX; (ii) the MEI Port, which enables Market Makers to submit simple and complex electronic quotes to MIAX; (iii) the CTD Port, which provides real-time trade clearing information to the participants to a trade on MIAX and to the participants' respective clearing firms; and (iv) the FXD Port, which provides a copy of real-time trade execution, correction and cancellation information through a FIX Port to any number of FIX Ports

[10] A FIX Port is an interface with MIAX systems that enables the Port user (typically an Electronic Exchange Member or a Market Maker) to submit simple and complex orders electronically to MIAX. *See* Fee Schedule, note 24.

[11] Clearing Trade Drop (''CTD'') provides Exchange members with real-time clearing trade updates. The updates include the Member's clearing trade messages on a low latency, real-time basis. The trade messages are routed to a Member's connection containing certain information. The information includes, among other things, the following: (i) Trade date and time; (ii) symbol information; (iii) trade price/size information; (iv) Member type (for example, and without limitation, Market Maker, Electronic Exchange Member, Broker-Dealer); (v) Exchange Member Participant Identifier (''MPID'') for each side of the transaction, including Clearing Member MPID; and (vi) strategy specific information for complex transactions. CTD Port Fees will be assessed in any month the Member is credentialed to use the CTD Port in the production environment. *See* Fee Schedule, Section 5)d)iii.

[12] The FIX Drop Copy Port (''FXD'') is a messaging interface that will provide a copy of real-time trade execution, trade correction and trade cancellation information for simple and complex orders to FIX Drop Copy Port users who subscribe to the service. FIX Drop Copy Port users are those users who are designated by an EEM to receive the information and the information is restricted for use by the EEM only. FXD Port Fees will be assessed in any month the Member is credentialed to use the FXD Port in the production environment. *See* Fee Schedule, Section 5)d)iv.

designated by an EEM to receive such messages.

MIAX assesses monthly MEI Port Fees to Market Makers in each month the Member has been credentialed to use the MEI Port in the production environment and has been assigned to quote in at least one class. The amount of the monthly MEI Port Fee is based upon the number of classes in which the Market Maker was assigned to quote on any given day within the calendar month, and upon the class volume percentages set forth in the above table. The class volume percentage is based on the total national average daily volume in classes listed on MIAX in the prior calendar quarter. Newly listed option classes are excluded from the calculation of the monthly MEI Port Fee until the calendar quarter following their listing, at which time the newly listed option classes will be included in both the per class count and the percentage of total national average daily volume. The Exchange assesses MIAX Market Makers the monthly MEI Port Fee based on the greatest number of classes listed on MIAX that the MIAX Market Maker was assigned to quote in on any given day within a calendar month and the applicable fee rate that is the lesser of either the per class basis or percentage of total national average daily volume measurement. MIAX assesses MEI Port Fees on Market Makers according to the following table:

Monthly MIAX MEI fees	Market Maker assignments (the lesser of the applicable measurements below) Ω	
	Per class	% of national average daily volume
$5,000.00	Up to 5 Classes	Up to 10% of Classes by volume.
$10,000.00	Up to 10 Classes	Up to 20% of Classes by volume.
$14,000.00	Up to 40 Classes	Up to 35% of Classes by volume.
$17,500.00 *	Up to 100 Classes	Up to 50% of Classes by volume.
$20,500.00 *	Over 100 Classes	Over 50% of Classes by volume up to all Classes listed on MIAX.

Ω Excludes Proprietary Products.

* For these Monthly MIAX MEI Fees levels, if the Market Maker's total monthly executed volume during the relevant month is less than 0.060% of the total monthly executed volume reported by OCC in the market maker account type for MIAX-listed option classes for that month, then the fee will be $14,500 instead of the fee otherwise applicable to such level.

MIAX proposes to extend the waiver of the monthly MEI Port Fee for Market Makers that trade solely in Proprietary Products (including options on SPIKES) from September 30, 2019 until December 31, 2019, which the Exchange proposes to state in the Fee Schedule. The purpose of this proposal is to continue to provide an incentive to Market Makers to connect to MIAX through the MEI Port such that they will be able to trade in MIAX Proprietary Products. Even though the Exchange is proposing to extend the waiver of this particular fee for Market Makers trading solely in Proprietary Products until September 30, 2019, the overall structure of the fee is outlined in the Fee Schedule so that there is general awareness that the Exchange intends to assess such a fee after December 31, 2019.

The Exchange notes that for the purposes of this proposed change, other Market Makers who trade MIAX Proprietary Products (including options on SPIKES) along with multi-listed classes will continue to not have Proprietary Products (including SPIKES) counted toward those Market Makers' class assignment count or percentage of total national average daily volume. This exclusion is noted by the symbol ''Ω'' following the table that shows the monthly MEI Port Fees currently assessed for Market Makers in Section 5)d)ii) of the Fee Schedule.

The proposed extension of the fee waivers are targeted at market participants, particularly market makers, who are not currently members of MIAX, who may be interested in being a Market Maker in Proprietary Products on the Exchange. The Exchange estimates that there are fewer than ten (10) such market participants that could benefit from the extension of these fee waivers. The proposed extension of the fee waivers does not apply differently to different sizes of market participants, however the fee waivers do only apply to Market Makers (and not EEMs).

Market Makers, unlike other market participants, take on a number of obligations, including quoting obligations that other market participants do not have. Further, Market Makers have added market making and regulatory requirements, which normally do not apply to other market participants. For example, Market Makers have obligations to maintain continuous markets, engage in a course of dealings reasonably calculated to contribute to the maintenance of a fair and orderly market, and to not make bids or offers or enter into transactions that are inconsistent with a course of dealing. Accordingly, the Exchange believes it is reasonable and not unfairly discriminatory to continue to offer the fee waivers to Market Makers because the Exchange is seeking additional liquidity providers for Proprietary Products, in order to enhance liquidity and spreads in Proprietary Products, which is traditionally provided by Market Makers, as opposed to EEMs.

2. Statutory Basis

The Exchange believes that its proposal to amend its Fee Schedule is consistent with Section 6(b) of the Act [13] in general, and furthers the objectives of Section 6(b)(4) of the Act [14] in particular, in that it is an equitable allocation of reasonable fees and other charges among its members and issuers and other persons using its facilities. The Exchange also believes the proposal furthers the objectives of Section 6(b)(5) of the Act in that it is designed to promote just and equitable principles of trade, 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 and is not designed to permit unfair discrimination between customers, issuers, brokers and dealers.

The Exchange believes that the proposal to extend the fee waiver period for certain non-transaction fees for Market Makers in Proprietary Products is an equitable allocation of reasonable fees because the proposal continues to waive non-transaction fees for a limited period of time in order to enable the Exchange to improve its overall competitiveness and strengthen its market quality for all market participants in MIAX's Proprietary Products, including options on SPIKES. The Exchange believe the proposed extension of the fee waivers is fair and

[13] 15 U.S.C. 78f(b).

[14] 15 U.S.C. 78f(b)(4) and (5).

equitable and not unreasonably discriminatory because it applies to all market participants not currently registered as Market Makers at the Exchange. Any market participant may choose to satisfy the additional requirements and obligations of being a Market Maker and trade solely in Proprietary Products in order to qualify for the fee waivers.

The Exchange believes that the proposed extension of the fee waivers is equitable and not unfairly discriminatory for Market Makers as compared to EEMs because Market Makers, unlike other market participants, take on a number of obligations, including quoting obligations that other market participants do not have. Further, Market Makers have added market making and regulatory requirements, which normally do not apply to other market participants. For example, Market Makers have obligations to maintain continuous markets, engage in a course of dealings reasonably calculated to contribute to the maintenance of a fair and orderly market, and to not make bids or offers or enter into transactions that are inconsistent with a course of dealing.

The Exchange believes it is reasonable and equitable to continue to waive the one-time Membership Application Fee, monthly Trading Permit Fee, API Testing and Certification Fee, and monthly MEI Port Fee for Market Makers that trade solely in Proprietary Products (including options on SPIKES) until December 31, 2019, since the waiver of such fees provides incentives to interested market participants to trade in Proprietary Products. This should result in increasing potential order flow and liquidity in MIAX Proprietary Products, including options on SPIKES.

The Exchange believes it is reasonable and equitable to continue to waive the API Testing and Certification fee assessable to Market Makers that trade solely in Proprietary Products (including options on SPIKES) until December 31, 2019, since the waiver of such fees provides incentives to interested Members to develop and test their APIs sooner. Determining system operability with the Exchange's system will in turn provide MIAX with potential order flow and liquidity providers in Proprietary Products.

The Exchange believes it is reasonable, equitable and not unfairly discriminatory that Market Makers who trade in Proprietary Products along with multi-listed classes will continue to not have Proprietary Products counted toward those Market Makers' class assignment count or percentage of total national average daily volume for monthly Trading Permit Fees and monthly MEI Port Fees in order to incentivize existing Market Makers who currently trade in multi-listed classes to also trade in Proprietary Products, without incurring certain additional fees.

The Exchange believes that the proposed extension of the fee waivers constitutes an equitable allocation of reasonable fees and other charges among its members and issuers and other persons using its facilities. The proposed extension of the fee waivers means that all prospective market makers that wish to become Market Maker Members of the Exchange and quote solely in Proprietary Products may do so and have the above-mentioned fees waived until December 31, 2019. The proposed extension of the fee waivers will continue to not apply to potential EEMs because the Exchange is seeking to enhance the quality of its markets in Proprietary Products through introducing more competition among Market Makers in Proprietary Products. In order to increase the competition, the Exchange believes that it must continue to waive entry type fees for such Market Makers. EEMs do not provide the benefit of enhanced liquidity which is provided by Market Makers, therefore the Exchange believes it is reasonable and not unfairly discriminatory to continue to only offer the proposed fee waivers to Market Makers (and not EEMs). Further, the Exchange believes it is reasonable and not unfairly discriminatory to continue to exclude Proprietary Products from an existing Market Maker's permit fees and port fees, in order to incentive such Market Makers to quote in Proprietary Products. The amount of a Market Maker's permit and port fee is determined by the number of classes quoted and volume of the Market Maker. By excluding Proprietary Products from such fees, the Exchange is able to incentivize Market Makers to quote in Proprietary Products. EEMs do not pay permit and port fees based on the classes traded or volume, so the Exchange believes it is reasonable, equitable, and not unfairly discriminatory to only offer the exclusion to Market Makers (and not EEMs).

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 not necessary or appropriate in furtherance of the purposes of the Act.

Intra-Market Competition

The Exchange believes that the proposal to extend certain of the non-transaction fee waivers until December 31, 2019 for Market Makers in Proprietary Products would increase intra-market competition by incentivizing new potential Market Makers to quote in Proprietary Products, which will enhance the quality of quoting and increase the volume of contracts in Proprietary Products traded on MIAX. To the extent that this purpose is achieved, all the Exchange's market participants should benefit from the improved market liquidity for the Exchange's Proprietary Products. Enhanced market quality and increased transaction volume in Proprietary Products that results from the anticipated increase in Market Maker activity on the Exchange will benefit all market participants and improve competition on the Exchange.

The Exchange does not believe that the proposed rule change will impose any burden on intra-market competition that is not necessary or appropriate in furtherance of the purposes of the Act because the proposed changes for each separate type of market participant (new Market Makers and existing Market Makers) will be assessed equally to all such market participants. While different fees are assessed to different market participants in some circumstances, these different market participants have different obligations and different circumstances as discussed above. For example, Market Makers have quoting obligations that other market participants (such as EEMs) do not have.

Inter-Market Competition

The Exchange does not believe that the proposed rule change will impose any burden on inter-market competition that is not necessary or appropriate in furtherance of the purposes of the Act because the proposed extension of the fee waivers apply only to the Exchange's Proprietary Products (including options on SPIKES), which are traded exclusively on the Exchange.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

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)(ii) of the Act,[15] and Rule 19b–4(f)(2)[16] 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 shall institute proceedings to determine whether the proposed rule 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 (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–MIAX–2019–43 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–MIAX–2019–43. 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 (*http://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 offices of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–MIAX–2019–43, and should be submitted on or before November 7, 2019.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[17]

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2019–22599 Filed 10–16–19; 8:45 am]

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[15] 15 U.S.C. 78s(b)(3)(A)(ii).

[16] 17 CFR 240.19b–4(f)(2).

[17] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–87272; File No. SR–CBOE–2019–090]

Self-Regulatory Organizations; Cboe Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change Relating To Move the Rules in Chapter V of the Currently Effective Rulebook to Proposed Section A of Chapter 4 of the Shell Structure for the Exchange's Rulebook That Will Become Effective Upon the Migration of the Exchange's Trading Platform

October 10, 2019.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on October 3, 2019, Cboe Exchange, Inc. (the ''Exchange'' or ''Cboe Options'') filed with the Securities and Exchange Commission (the ''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 Exchange, Inc. (the ''Exchange'' or ''Cboe Options'') proposes to move the Rules in Chapter V of the currently effective Rulebook (''current Rulebook''), which governs securities dealt in on the Exchange, to proposed Section A of Chapter 4 of the shell structure for the Exchange's Rulebook that will become effective upon the migration of the Exchange's trading platform to the same system used by the Cboe Affiliated Exchanges (as defined below) (''shell Rulebook''). 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://www.cboe.com/AboutCBOE/CBOELegalRegulatoryHome.aspx*), 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

In 2016, the Exchange's parent company, Cboe Global Markets, Inc. (formerly named CBOE Holdings, Inc.) (''Cboe Global''), which is also the parent company of Cboe C2 Exchange, Inc. (''C2''), acquired Cboe EDGA Exchange, Inc. (''EDGA''), Cboe EDGX Exchange, Inc. (''EDGX'' or ''EDGX Options''), Cboe BZX Exchange, Inc. (''BZX'' or ''BZX Options''), and Cboe BYX Exchange, Inc. (''BYX'' and, together with Cboe Options, C2, EDGX, EDGA, and BZX, the ''Cboe Affiliated Exchanges''). The Cboe Affiliated Exchanges are working to align certain system functionality, retaining only intended differences, between the Cboe Affiliated Exchanges, in the context of a technology migration. Cboe Options intends to migrate its trading platform to the same system used by the Cboe Affiliated Exchanges, which the Exchange expects to complete on October 7, 2019. In connection with this technology migration, the Exchange has a shell Rulebook that resides alongside its current Rulebook, which shell Rulebook will contain the Rules that

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

will be in place upon completion of the Cboe Options technology migration.

The Exchange proposes to relocate the rules in Chapter V, which govern securities dealt in on the Exchange, to proposed Section A of Chapter 4 in the shell Rulebook. The Exchange notes that in addition to relocating the rules under current Chapter V to proposed Section A of Chapter 4 in the shell Rulebook, the proposed rule change deletes the rules from the current Rulebook. The proposed rule change relocates the rules as follows:

Current rule	Proposed rule
4.1 Designation of Underlying Securities	5.1 Designation of Securities.
4.2 Rights and Obligations of Holders and Writers	5.2 Rights and Obligations of Holders and Writers.
4.3 Criteria for Underlying Securities	5.3 Criteria for Underlying Securities.
4.4 Withdrawal of Approval of Underlying Securities	5.4 Withdrawal of Approval of Underlying Securities.
4.5 Series of Option Contracts Open for Trading	5.5 Series of Option Contracts Open for Trading.
4.5(f) (*Long-Term Equity Option Series (LEAPS)*)	5.8 Long-Term Equity Option Series (LEAPS).
4.6 Adjustments	5.7 Adjustments.
4.7 Select Provisions of Options Listing Procedures Plan	5.5A Select Provisions of Options Listing Procedures Plan.
4.8 Single Stock Dividend Options	5.9. Single Stock Dividend Options.

The proposed changes are of a non-substantive nature and will not amend the relocated rules other than to update their rule numbers, conform paragraph structure and number/lettering format to that of the shell Rulebook, and make cross-reference changes to shell rules. The Exchange notes that the proposed change updates the heading to proposed Rule 4.1 (current Rule 5.1) from ''Designation of Securities'' to ''Designation of Underlying Securities'' which more accurately aligns with the other rules under current Chapter V (proposed Section A of Chapter 4); *i.e.* the heading to proposed Rule 4.3 (current Rule 5.3) is ''Criteria for Underlying Securities'' and to proposed Rule 4.4 (current Rule 5.4) is ''Withdrawal of Approval of Underlying Securities''. Finally, the proposed rule change removes Rule 5.5.11 and .12 which cover strike intervals for BXM option series and for Cboe S&P 500 Realized Volatility option series, respectively, on which the Exchange is authorized to list options, but on which the Exchange does not currently, and does not intend, to list options.[3] Because there are currently no options listed on any of these indexes, the proposed rule change has no impact on trading on the Exchange.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Securities Exchange Act of 1934 (the ''Act'') and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.[4] Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[5] 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)[6] requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

As stated, the proposed rule change makes no substantive changes to the rules. The proposed rule change is merely intended to relocate the Exchange's rules to the shell Rulebook and update their numbers, paragraph structure, including number and lettering format, and cross-references, as well as delete references to indexes on which the Exchange does not list (and does not intend to list) options, [7] to conform to the shell Rulebook as a whole in anticipation of the technology migration on October 7, 2019. As such, the proposed rule change is designed to promote just and equitable principles of trade, 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, by improving the way the Exchange's Rulebook is organized, making it easier to read, and, particularly, helping market participants better understand the rules of the Exchange, which will also result in less burdensome and more efficient regulatory compliance.

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 not necessary or appropriate in furtherance of the purposes of the Act. The proposed rule change is not intended as a competitive change, but rather, seeks to make non-substantive rule changes in relocating the rules and updating cross-references, as well as references to certain indexes, to shell rules in anticipation of the October 7, 2019 technology migration. The Exchange also does not believe that the proposed rule change will impose any undue burden on competition because the relocated rule text is exactly the same as the Exchange's current rules, all of which have all been previously filed with the Commission.

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 Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act[8] and Rule 19b–4(f)(6) thereunder.[9] Because the proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it

[3] The Exchange is simultaneously submitting a similar rule filing regarding current Chapter XXIV (proposed shell Section B of Chapter 4), governing index options, which proposes to remove the same references under current Chapter XXIV.

[4] 15 U.S.C. 78f(b).

[5] 15 U.S.C. 78f(b)(5).

[6] *Id.*

[7] *See supra* note 3. The deletion of these indexes will conform to the other proposed Sections under Chapter 4, and thus, the shell Rulebook as a whole.

[8] 15 U.S.C. 78s(b)(3)(A)(iii).

[9] 17 CFR 240.19b–4(f)(6).

was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act [10] and Rule 19b–4(f)(6) thereunder.[11]

A proposed rule change filed under Rule 19b–4(f)(6) [12] normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b–4(f)(6)(iii),[13] the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that the proposed rule change may become operative immediately. The Exchange notes that the proposed rule change is merely relocating certain rules to its shell rulebook—which includes corresponding updates to rule numbers, cross-references, and other references—in order to conform these rules to the shell rulebook upon the technology migration explained above. The Exchange believes that the proposed rule change will make its rules easier to read and understand for all investors. The Exchange also asserts that the relocation of the rules explained above will not impose any significant burden on competition as the substance of the rules remains unchanged. The Commission agrees that allowing this proposed rule change to become operative upon filing in order to facilitate the Exchange's technology migration—without changing the substance of these Exchange Rules—is consistent with the protection of investors and the public interest. For this reason, the Commission hereby waives the 30-day operative delay and designates the proposal operative upon filing.[14]

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 shall 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 (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–CBOE–2019–090 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–CBOE–2019–090. 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 (*http://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 offices of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–CBOE–2019–090, and should be submitted on or before November 7, 2019.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[15]

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2019–22590 Filed 10–16–19; 8:45 am]

BILLING CODE 8011–01–P

[10] 15 U.S.C. 78s(b)(3)(A).

[11] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) requires the Exchange to give the Commission written notice of the Exchange's intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Commission has waived that requirement in this case.

[12] 17 CFR 240.19b–4(f)(6).

[13] 17 CFR 240.19b–4(f)(6)(iii).

[14] For purposes only of waiving the 30-day operative delay, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[15] 17 CFR 200.30–3(a)(12), (59).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–87278; File No. SR–NYSEArca–2019–68]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Permit the Listing and Trading of Shares Under NYSE Arca Rule 8.600–E of the Overlay Shares Large Cap Equity ETF, Overlay Shares Small Cap Equity ETF, Overlay Shares Foreign Equity ETF, Overlay Shares Core Bond ETF and Overlay Shares Municipal Bond ETF

October 10, 2019.

Pursuant to Section 19(b)(1) [1] of the Securities Exchange Act of 1934 (the ''Act'') [2] and Rule 19b–4 thereunder,[3] notice is hereby given that, on September 27, 2019, NYSE Arca, Inc. (''NYSE Arca'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II 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

The Exchange proposes to permit the listing and trading of shares under NYSE Arca Rule 8.600–E of the Overlay Shares Large Cap Equity ETF, Overlay Shares Small Cap Equity ETF, Overlay Shares Foreign Equity ETF, Overlay Shares Core Bond ETF and Overlay Shares Municipal Bond ETF, each a series of the Listed Funds Trust, notwithstanding that the Funds' investments do not meet the requirements of Commentary .01(d)(2) to Rule 8.600–E.

The proposed rule change is available on the Exchange's website at

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

www.nyse.com, at the principal office of the Exchange, 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 self-regulatory organization 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 those 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 parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to permit the listing and trading under NYSE Arca Rule 8.600–E (''Managed Fund Shares'') [4] of shares (''Shares'') of the Overlay Shares Large Cap Equity ETF, Overlay Shares Small Cap Equity ETF, Overlay Shares Foreign Equity ETF, Overlay Shares Core Bond ETF and Overlay Shares Municipal Bond ETF (each a ''Fund'' and, collectively, the ''Funds''), each a series of the Listed Funds Trust (the ''Trust''), notwithstanding that the Funds' investments do not meet the requirements of Commentary .01(d)(2) to Rule 8.600–E.

The Shares are offered by the Trust, which is registered with the Commission as an open-end management investment company consisting of multiple investment series.[5] Each Fund is a series of the Trust.

Liquid Strategies, LLC (the ''Adviser'') is the investment adviser to the Funds. Commentary .06 to Rule 8.600–E provides that, if the investment adviser to the investment company issuing Managed Fund Shares is affiliated with a broker-dealer, such investment adviser shall erect and maintain a ''fire wall'' between the investment adviser and the broker-dealer with respect to access to information concerning the composition and/or changes to such investment company portfolio.[6] In addition, Commentary .06 further requires that personnel who make decisions on the investment company's portfolio composition must be subject to procedures designed to prevent the use and dissemination of material nonpublic information regarding the applicable investment company portfolio. The Adviser is not a registered broker-dealer, and the Adviser is not affiliated with broker-dealers. In addition, the Adviser's personnel who make decisions regarding a Fund's portfolio are subject to procedures designed to prevent the use and dissemination of material nonpublic information regarding a Fund's portfolio. In the event that (a) the Adviser becomes registered as a broker-dealer or newly affiliated with a broker-dealer, or (b) any new adviser or sub-adviser is a registered broker-dealer or becomes affiliated with a broker-dealer, it will implement and maintain a fire wall with respect to its relevant personnel or such broker-dealer affiliate, as applicable, regarding access to information concerning the composition and/or changes to the portfolio, and will be subject to procedures designed to prevent the use and dissemination of material non-public information regarding such portfolio.

U.S. Bancorp Fund Services, LLC, doing business as U.S. Bank Global Fund Services, will serve as administrator and transfer agent for the Funds. Foreside Fund Services, LLC will serve as the Funds' distributor. U.S. Bank National Association is the custodian of the Trust (the ''Custodian'').

Investment Objective of the Funds

According to the Registration Statement, the investment objective of each Fund is total return. Each Fund is an actively-managed exchange-traded fund (''ETF'') that seeks to achieve its objective principally by (1) investing in one or more other ETFs [7] that seek to obtain exposure to the performance of a specific segment of the equity or fixed income market (*e.g.,* large cap U.S. equities or investment-grade corporate bonds) or directly in the securities held by such ETFs, and (2) selling and purchasing listed put options to generate income to the Fund (together, the ''Overlay Strategy'').

Overlay Shares Large Cap Equity ETF

According to the Registration Statement, under normal market conditions,[8] at least 80% of the Overlay Shares Large Cap Equity ETF's net assets, plus borrowings for investment purposes, will be invested in one or more other ETFs that seek to obtain exposure to equity securities of large-cap companies or directly in the securities held by such ETFs. For purposes of the foregoing, the Overlay Shares Large Cap Equity ETF defines ''large-cap companies'' as those within the range of capitalizations of the S&P 500 Index. The Overlay Shares Large Cap Equity ETF will count investments in ETFs that invest at least 80% of their net assets, plus borrowings for investment purposes, in equity securities of large-cap companies (as defined above) as investments in ETFs

[4] A Managed Fund Share is a security that represents an interest in an investment company registered under the Investment Company Act of 1940 (15 U.S.C. 80a–1) (''1940 Act'') organized as an open-end investment company or similar entity that invests in a portfolio of securities selected by its investment adviser consistent with its investment objectives and policies. In contrast, an open-end investment company that issues Investment Company Units, listed and traded on the Exchange under NYSE Arca Rule 5.2–E(j)(3), seeks to provide investment results that correspond generally to the price and yield performance of a specific foreign or domestic stock index, fixed income securities index or combination thereof.

[5] The Trust is registered under the 1940 Act. On June 26, 2019, the Trust filed with the Securities and Exchange Commission (''SEC'' or Commission'') its registration statement on Form N–1A under the Securities Act of 1933 (15 U.S.C. 77a), and under the 1940 Act relating to the Funds (File Nos. 333–215588 and 811–23226) (''Registration Statement''). The description of the operation of the Trust and of the Funds and Shares herein is based, in part, on the Registration Statement. There are no permissible holdings for the Funds that are not described in this proposal. The Commission has issued an order granting certain exemptive relief to the Trust under the 1940 Act. *See* Investment Company Act Release No. 33596 (August 20, 2019) (order).

[6] An investment adviser to an open-end fund is required to be registered under the Investment Advisers Act of 1940 (the ''Advisers Act''). As a result, the Adviser and its related personnel are subject to the provisions of Rule 204A–1 under the Advisers Act relating to codes of ethics. This Rule requires investment advisers to adopt a code of ethics that reflects the fiduciary nature of the relationship to clients as well as compliance with other applicable securities laws. Accordingly, procedures designed to prevent the communication and misuse of non-public information by an investment adviser must be consistent with Rule 204A–1 under the Advisers Act. In addition, Rule 206(4)–7 under the Advisers Act makes it unlawful for an investment adviser to provide investment advice to clients unless such investment adviser has (i) adopted and implemented written policies and procedures reasonably designed to prevent violation, by the investment adviser and its supervised persons, of the Advisers Act and the Commission rules adopted thereunder; (ii) implemented, at a minimum, an annual review regarding the adequacy of the policies and procedures established pursuant to subparagraph (i) above and the effectiveness of their implementation; and (iii) designated an individual (who is a supervised person) responsible for administering the policies and procedures adopted under subparagraph (i) above.

[7] For purposes of this filing, the term ''ETFs'' means Investment Company Units (as described in NYSE Arca Rule 5.2–E(j)(3)); Portfolio Depositary Receipts (as described in NYSE Arca Rule 8.100–E); and Managed Fund Shares (as described in NYSE Arca Rule 8.600–E). All ETFs will be listed and traded in the U.S. on a national securities exchange. The Funds will not invest in inverse or leveraged (*e.g.,* 2X, −2X, 3X or −3X) ETFs.

[8] The term ''normal market conditions'' is defined in NYSE Arca Rule 8.600–E(c)(5).

that seek to obtain exposure to equity securities of large-cap companies.

Overlay Shares Small Cap Equity ETF

According to the Registration Statement, under normal market conditions, at least 80% of the Overlay Shares Small Cap Equity ETF's net assets, plus borrowings for investment purposes, will be invested in one or more other ETFs that seek to obtain exposure to equity securities of small-cap companies or directly in the securities held by such ETFs. For purposes of the foregoing, the Overlay Shares Small Cap Equity ETF defines ''small-cap companies'' as those within the range of capitalizations of the Russell 2000 Index. The Overlay Shares Small Cap Equity ETF will count investments in ETFs that invest at least 80% of their net assets, plus borrowings for investment purposes, in equity securities of small-cap companies (as defined above) as investments in equity securities of small-cap companies.

Overlay Shares Foreign Equity ETF

According to the Registration Statement, under normal market conditions, at least 80% of the Overlay Shares Foreign Equity ETF's net assets, plus borrowings for investment purposes, will be invested in one or more other ETFs that seek to obtain exposure to equity securities of non-U.S. companies or directly in the securities held by such ETFs. For purposes of the foregoing, the Overlay Shares Foreign Equity ETF defines ''securities of non-U.S. companies'' as those that are principally traded on a non-U.S. exchange, are issued by companies incorporated in a non-U.S. country, or depositary receipts representing such securities. The Overlay Shares Foreign Equity ETF will count investments in ETFs that invest at least 80% of their net assets, plus borrowings for investment purposes, in securities of non-U.S. companies (as defined above) as investments in securities of non-U.S. companies.

Overlay Shares Core Bond ETF

According to the Registration Statement, under normal market conditions, at least 80% of the Overlay Shares Core Bond ETF's net assets, plus borrowings for investment purposes, will be invested in one or more other ETFs that seek to obtain exposure to bonds or directly in the securities held by such ETFs. The Overlay Shares Core Bond ETF will count investments in ETFs that invest at least 80% of their net assets, plus borrowings for investment purposes, in bonds as investments in bonds.

Overlay Shares Municipal Bond ETF

According to the Registration Statement, under normal market conditions, at least 80% of the Overlay Shares Municipal Bond ETF's net assets, plus borrowings for investment purposes, will be invested in one or more other ETFs that seek to obtain exposure to municipal bonds and will not hold municipal bonds directly. The Overlay Shares Municipal Bond ETF will count investments in ETFs that invest at least 80% of their net assets, plus borrowings for investment purposes, in municipal bonds as investments in municipal bonds.

The Overlay Strategy

According to the Registration Statement, the Overlay Strategy seeks to generate income for a Fund by utilizing a ''put spread'' consisting of the sale of exchange-listed put options (''Short Puts'') on the S&P 500 Index with a notional value up to 100% of a Fund's net assets and the purchase of an identical number of put options (''Long Puts'') on the S&P 500 Index with a lower strike price with a notional value up to 100% of a Fund's net assets. Each Fund will seek to generate income from the sale of put options and purchase of put options with a lower strike price to hedge against a decline in the U.S. equity market.

The options sold and bought by each Fund will typically have an expiration date within one to two weeks of their purchase date, although each Fund may sell and buy options with a longer time-to-expiration. The strike price of the Short Puts will be less than the value of the S&P 500 Index at the time such options are sold, and the strike price of the Long Puts will be less than the strike price of the Short Puts. The difference between such strike prices is based on the Adviser's judgment as to the level of expected volatility in the market prior to the options' expiration. Because the Long Puts will have a lower strike price than the Short Puts, the Long Puts are not expected to completely protect the Fund from a decline in the S&P 500 Index.

Each Fund may also hold cash and cash equivalents.[9]

Application of Generic Listing Requirements

The Exchange submits this proposal in order to list and trade Shares of each Fund and to allow each Fund to hold listed derivatives, in particular put options on the S&P 500 Index, in a manner that does not comply with Commentary .01(d)(2) to Rule 8.600–E.[10] Otherwise, each Fund will comply with all other listing requirements of the Generic Listing Standards [11] for Managed Fund Shares on an initial and continued listing basis.[12]

The market for options contracts on the S&P 500 Index (''S&P 500 Index Options'') is highly liquid.[13] In August 2019, approximately 1.488 million options contracts on the S&P 500 Index were traded per day, which is more than $430 billion in notional volume traded on a daily basis. The Exchange believes that the liquidity in the S&P 500 Index Options markets mitigates the concerns that Commentary .01(d)(2) to Rule 8.600–E is intended to address and that such liquidity would prevent the Shares from being susceptible to manipulation.

In addition, the Exchange believes that sufficient protections are in place to

[9] For purposes of this filing, cash equivalents means the securities included in Commentary .01(c) to NYSE Arca Rule 8.600–E.

[10] Commentary .01(d)(2) to Rule 8.600–E provides that ''the aggregate gross notional value of listed derivatives based on any five or fewer underlying reference assets shall not exceed 65% of the weight of the portfolio (including gross notional exposures), and the aggregate gross notional value of listed derivatives based on any single underlying reference asset shall not exceed 30% of the weight of the portfolio (including gross notional exposures).'' The Funds do not meet the generic listing standards because they fail to meet the requirement of Commentary .01(d)(2) that prevents the aggregate gross notional value of listed derivatives based on any single underlying reference asset from exceeding 30% of the weight of the portfolio (including gross notional exposures) and the requirement that the aggregate gross notional value of listed derivatives based on any five or fewer underlying reference assets shall not exceed 65% of the weight of the portfolio (including gross notional exposures).

[11] For purposes of this proposal, the term ''Generic Listing Standards'' means the generic listing rules for Managed Fund Shares under Commentary .01 to Rule 8.600–E.

[12] The Exchange notes that this proposed rule change is similar to previous rule changes involving Managed Fund Shares with similar exposures to a single underlying reference asset. *See* Securities Exchange Act Release No. 86773 (August 27, 2019), 84 FR 46051 (September 3, 2019) (SR–CboeBZX–2019–077); Securities Exchange Act Release No. 83146 (May 1, 2018), 83 FR 20103 (May 7, 2018) (SR–CboeBZX–2018–029); Securities Exchange Act Release No. 80529 (April 26, 2017), 82 FR 20506 (May 2, 2017) (SR–BatsBZX–2017–14). *See also* Securities Exchange Act Release No. 82906 (March 20, 2018), 83 FR 12992 (March 26, 2018) (SR–CboeBZX–2017–012) (order approving the listing and trading of the LHA Market State Tactical U.S. Equity ETF); Securities Exchange Act Release No. 83679 (July 20, 2018), 83 FR 35505 (July 26, 2018) (SR–BatsBZX–2017–72) (Notice of Filing of Amendment No. 4 and Order Granting Accelerated Approval of a Proposed Rule Change, as Modified by Amendment No. 4 Thereto, to List and Trade Shares of the Innovator S&P 500 Buffer ETF Series, Innovator S&P 500 Power Buffer ETF Series, and Innovator S&P 500 Ultra Buffer ETF Series Under Rule 14.11(i)).

[13] S&P 500 Index [sic] are traded on the Cboe Exchange, Inc. (''Cboe Options''). The Exchange, Cboe Options and all other national securities exchanges are members of the Intermarket Surveillance Group (''ISG'').

protect against market manipulation of the Shares and S&P 500 Index Options for several reasons: (i) The diversity, liquidity, and market cap of the securities underlying the S&P 500 Index; (ii) the significant liquidity in the market for S&P 500 Index Options; and (iii) surveillance by the Exchange, options exchanges [14] and the Financial Industry Regulatory Authority (''FINRA'') designed to detect violations of the federal securities laws and self-regulatory organization (''SRO'') rules. The Exchange has in place a surveillance program for transactions in ETFs to ensure the availability of information necessary to detect and deter potential manipulations and other trading abuses, thereby making the Shares less readily susceptible to manipulation. Further, the Exchange believes that because the S&P 500 Index Options in each Fund's portfolio will be acquired in extremely liquid and highly regulated markets,[15] the Shares are less readily susceptible to manipulation.

As noted above, S&P 500 Index Options are among the most liquid options in the world and derive their value from the actively traded S&P 500 Index components. The contracts are cash-settled with no delivery of stocks or ETFs, and trade in competitive auction markets with price and quote transparency. The Exchange believes the highly regulated options markets and the broad base and scope of the S&P 500 Index make securities that derive their value from that index less susceptible to market manipulation in view of market capitalization and liquidity of the S&P 500 Index components, price and quote transparency, and arbitrage opportunities.

The Exchange believes that the liquidity of the markets for securities in the S&P 500 Index and S&P 500 Index Options is sufficiently great to deter fraudulent or manipulative acts associated with the Funds' Shares price. Coupled with the extensive surveillance programs of the Exchange and other SROs described below, the Exchange does not believe that trading in the Shares would present manipulation concerns.

All of the options contracts held by the Funds will trade on Cboe Options, a member of ISG.

Availability of Information

The Funds' website (*www.overlayshares.com*) will include the prospectus for each of the Funds that may be downloaded. The Funds' website will include ticker, CUSIP and exchange information, along with additional quantitative information updated on a daily basis, including, for each Fund: (1) The prior Business Day's net asset value (''NAV'') per share and the market closing price or mid-point of the bid/ask spread at the time of calculation of such NAV per share (the ''Bid/Ask Price''),[16] and a calculation of the premium or discount of the market closing price or Bid/Ask Price against such NAV per share; and (2) a table showing the number of days of such premium or discount for the most recently completed calendar year, and the most recently completed calendar quarters since that year (or the life of Fund, if shorter). On each business day, before commencement of trading in Shares in the Core Trading Session on the Exchange, each Fund will disclose on its website the Disclosed Portfolio as defined in NYSE Arca Rule 8.600–E(c)(2) that forms the basis for each Fund's calculation of NAV at the end of the business day.

On a daily basis, the Funds will disclose the information required under NYSE Arca Rule 8.600–E(c)(2) to the extent applicable. The website information will be publicly available at no charge.

Investors can also obtain the Trust's Statement of Additional Information (''SAI''), the Funds' Shareholder Reports, and the Funds' Forms N–CSR and Forms N–CEN. The Funds' SAI and Shareholder Reports will be available free upon request from the Trust, and those documents and the Form N–CSR, Form N–PX, Form N–PORT and Form N–CEN may be viewed on-screen or downloaded from the Commission's website at *www.sec.gov*.

Information regarding market price and trading volume of the Shares will be continually available on a real-time basis throughout the day on brokers' computer screens and other electronic services. Information regarding the previous day's closing price and trading volume information for the Shares will be published daily in the financial section of newspapers.

Quotation and last sale information for the Shares and ETFs and other exchange traded equities will be available via the Consolidated Tape Association (''CTA'') high-speed line. In addition, the Portfolio Indicative Value (''PIV''), as defined in NYSE Arca Rule 8.600–E(c)(3), will be widely disseminated by one or more major market data vendors at least every 15 seconds during the Core Trading Session.

The intra-day, closing and settlement prices of exchange-traded options will be readily available from the Options Price Reporting Authority (''OPRA''), Cboe Options' website, automated quotation systems, published or other public sources, or online information services such as Bloomberg or Reuters.

Additionally, FINRA's Trade Reporting and Compliance Engine (''TRACE'') will be a source of price information for certain fixed income securities to the extent transactions in such securities are reported to TRACE.

Price information regarding U.S. government securities and other cash equivalents generally may be obtained from brokers and dealers who make markets in such securities or through nationally recognized pricing services through subscription agreements.

Quotation and last sale information for equity securities of non-U.S. companies will be available from the exchanges on which they trade and from major market data vendors, as applicable.

Trading Halts

With respect to trading halts, the Exchange may consider all relevant factors in exercising its discretion to halt or suspend trading in the Shares of a Fund.[17] Trading in Shares of each Fund will be halted if the circuit breaker parameters in NYSE Arca Rule 7.12–E have been reached. Trading also may be halted because of market conditions or for reasons that, in the view of the Exchange, make trading in the Shares inadvisable. Trading in the Funds' Shares also will be subject to Rule 8.600–E(d)(2)(D) (''Trading Halts'').

Trading Rules

The Exchange deems the Shares to be equity securities, thus rendering trading in the Shares subject to the Exchange's existing rules governing the trading of equity securities. Shares will trade on the NYSE Arca Marketplace from 4 a.m. to 8 p.m., E.T. in accordance with NYSE Arca Rule 7.34–E (Early, Core, and Late

[14] The Exchange and all nine U.S. options exchanges are members of the Option Regulatory Surveillance Authority, which was established in 2006 to provide efficiencies in looking for insider trading and serves as a central organization to facilitate collaboration in insider trading investigations for the U.S. options exchanges.

[15] All exchange-listed securities that the Funds may hold will trade on a market that is a member of the ISG and the Funds will not hold any non-exchange-listed equities or options. For a list of the current members of ISG, *see www.isgportal.org. See also* note 13, *supra*.

[16] The Bid/Ask Price of a Fund's Shares will be determined using the mid-point of the highest bid and the lowest offer on the Exchange as of the time of calculation of the NAV. The records relating to Bid/Ask Prices will be retained by a Fund and its service providers.

[17] *See* NYSE Arca Rule 7.12–E.

Trading Sessions). The Exchange has appropriate rules to facilitate transactions in the Shares during all trading sessions. As provided in NYSE Arca Rule 7.6–E, the minimum price variation (''MPV'') for quoting and entry of orders in equity securities traded on the NYSE Arca Marketplace is $0.01, with the exception of securities that are priced less than $1.00 for which the MPV for order entry is $0.0001.

With the exception of the requirements of Commentary .01(d)(2) (with respect to listed derivatives) as described above, the Shares of each Fund will conform to the initial and continued listing criteria under NYSE Arca Rule 8.600–E. Consistent with Commentary .06 of NYSE Arca Rule 8.600–E, the Adviser will implement and maintain, or be subject to, procedures designed to prevent the use and dissemination of material non-public information regarding the actual components of each Fund's portfolio. The Exchange represents that, for initial and continued listing, the Funds will be in compliance with Rule 10A–3 [18] under the Act, as provided by NYSE Arca Rule 5.3–E. The Exchange will obtain a representation from the issuer of the Shares that the NAV per Share for each Fund will be calculated daily and that the NAV and the Disclosed Portfolio for each Fund will be made available to all market participants at the same time.

Surveillance

The Exchange believes that its surveillance procedures are adequate to properly monitor the trading of the Shares on the Exchange during all trading sessions and to deter and detect violations of Exchange rules and the applicable federal securities laws. The Exchange represents that trading in the Shares will be subject to the existing trading surveillances, administered by FINRA on behalf of the Exchange or by regulatory staff of the Exchange, which are designed to detect violations of Exchange rules and applicable federal securities laws. The Exchange represents that these procedures are adequate to properly monitor Exchange trading of the Shares in all trading sessions and to deter and detect violations of Exchange rules and federal securities laws applicable to trading on the Exchange.[19]

The surveillances referred to above generally focus on detecting securities trading outside their normal patterns, which could be indicative of manipulative or other violative activity. When such situations are detected, surveillance analysis follows and investigations are opened, where appropriate, to review the behavior of all relevant parties for all relevant trading violations.

The Exchange or FINRA, on behalf of the Exchange, or both, will communicate as needed regarding trading in the Shares, exchange-traded options and equities with other markets and other entities that are members of the ISG, and the Exchange or FINRA, on behalf of the Exchange, or both, may obtain trading information regarding trading in such securities and financial instruments from such markets and other entities. The Exchange may obtain information regarding trading in such securities and financial instruments from markets and other entities that are members of ISG. In addition, the Exchange also has a general policy prohibiting the distribution of material, non-public information by its employees.

All statements and representations made in this filing regarding (a) the description of the portfolio or reference assets, (b) limitations on portfolio holdings or reference assets, or (c) the applicability of Exchange listing rules specified in this rule filing shall constitute continued listing requirements for listing the Shares of the Funds on the Exchange.

The issuer must notify the Exchange of any failure by the Funds to comply with the continued listing requirements, and, pursuant to its obligations under Section 19(g)(1) of the Act, the Exchange will monitor for compliance with the continued listing requirements. If a Fund is not in compliance with the applicable listing requirements, the Exchange will commence delisting procedures under NYSE Arca Rule 5.5–E (m).

Information Bulletin

Prior to the commencement of trading, the Exchange will inform its Equity Trading Permit Holders in an Information Bulletin (''Bulletin'') of the special characteristics and risks associated with trading the Shares. Specifically, the Bulletin will discuss the following: (1) The procedures for purchases and redemptions of Shares in Creation Unit aggregations (and that Shares are not individually redeemable); (2) NYSE Arca Rule 9.2–E(a), which imposes a duty of due diligence on its Equity Trading Permit Holders to learn the essential facts relating to every customer prior to trading the Shares; (3) the risks involved in trading the Shares during the Early and Late Trading Sessions when an updated PIV will not be calculated or publicly disseminated; (4) how information regarding the PIV and the Disclosed Portfolio is disseminated; (5) the requirement that Equity Trading Permit Holders deliver a prospectus to investors purchasing newly issued Shares prior to or concurrently with the confirmation of a transaction; and (6) trading information.

In addition, the Bulletin will reference that the Funds are subject to various fees and expenses described in the Registration Statement. The Bulletin will discuss any exemptive, no-action, and interpretive relief granted by the Commission from any rules under the Act. The Bulletin will also disclose that the NAV for the Shares will be calculated after 4:00 p.m., Eastern time each trading day.

2. Statutory Basis

The basis under the Act for this proposed rule change is the requirement under Section 6(b)(5) [20] that an exchange have rules that are designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to remove impediments to, and perfect the mechanism of a free and open market and, in general, to protect investors and the public interest.

The Exchange believes that the proposed rule change is 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 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 in that the Shares will meet each of the initial and continued listing criteria in Commentary .01 to NYSE Arca Rule 8.600–E, with the exception of Commentary .01(d)(2) to NYSE Arca Rule 8.600–E, which requires that the aggregate gross notional value of listed derivatives based on any five or fewer underlying reference assets shall not exceed 65% of the weight of the portfolio (including gross notional exposures), and the aggregate gross notional value of listed derivatives based on any single underlying reference asset shall not exceed 30% of the weight of the portfolio (including gross notional

[18] 17 CFR 240.10A–3.

[19] FINRA conducts cross-market surveillances on behalf of the Exchange pursuant to a regulatory services agreement. The Exchange is responsible for FINRA's performance under this regulatory services agreement.

[20] 15 U.S.C. 78f(b)(5).

exposures).[21] Commentary .01(d)(2) to NYSE Arca Rule 8.600–E is intended to ensure that a fund is not subject to manipulation by virtue of significant exposure to a manipulable underlying reference asset by establishing concentration limits among the underlying reference assets for listed derivatives held by a particular fund. The Exchange notes that this proposed rule change is similar to previous rule changes involving Managed Fund Shares with similar exposures to a single underlying reference asset.[22]

The market for S&P 500 Index Options is highly liquid. In August 2019, approximately 1.488 million options contracts on the S&P 500 Index were traded per day, which is more than $430 billion in notional volume traded on a daily basis. The Exchange believes that the liquidity in the S&P 500 Index Options markets mitigates the concerns that Commentary .01(d)(2) to Rule 8.600–E is intended to address and that such liquidity would prevent the Shares from being susceptible to manipulation.

In addition, the Exchange believes that sufficient protections are in place to protect against market manipulation of the Shares and S&P 500 Index Options for several reasons: (i) The diversity, liquidity, and market cap of the securities underlying the S&P 500 Index; (ii) the significant liquidity in the market for S&P 500 Index Options; and (iii) surveillance by the Exchange, options exchanges and FINRA designed to detect violations of the federal securities laws and SRO rules. The Exchange has in place a surveillance program for transactions in ETFs to ensure the availability of information necessary to detect and deter potential manipulations and other trading abuses, thereby making the Shares less readily susceptible to manipulation. Further, the Exchange believes that because the S&P 500 Index Options in each Fund's portfolio will be acquired in extremely liquid and highly regulated markets, the Shares are less readily susceptible to manipulation.

The Exchange believes that its surveillance procedures are adequate to properly monitor the trading of the Shares on the Exchange during all trading sessions and to deter and detect violations of Exchange rules and the applicable federal securities laws. The Exchange or FINRA, on behalf of the Exchange, or both, will communicate as needed regarding trading in the Shares, exchange-traded options and equities with other markets and other entities that are members of the ISG, and the Exchange or FINRA, on behalf of the Exchange, or both, may obtain trading information regarding trading in such securities and financial instruments from such markets and other entities. The Exchange may obtain information regarding trading in such securities and financial instruments from markets and other entities that are members of ISG. In addition, the Exchange also has a general policy prohibiting the distribution of material, non-public information by its employees.

As noted above, S&P 500 Index Options are highly liquid and derive their value from the actively traded S&P 500 Index components. The Exchange believes the highly regulated options markets and the broad base and scope of the S&P 500 Index make securities that derive their value from the S&P 500 Index less susceptible to market manipulation in view of market capitalization and liquidity of the components of the S&P 500 Index, price and quote transparency, and arbitrage opportunities.

The Exchange believes that the liquidity of the markets for securities in the S&P 500 Index, S&P 500 Index Options, and other related derivatives is sufficiently great to deter fraudulent or manipulative acts associated with the Funds' Shares price. The Exchange also believes that such liquidity is sufficient to support the creation and redemption mechanism. Coupled with the extensive surveillance programs of the SROs described above, the Exchange does not believe that trading in the Funds' Shares would present manipulation concerns.

All of the options contracts held by the Funds will trade on Cboe Options, a member of ISG.

The Exchange represents that, except as described above, the Funds will meet and be subject to all other requirements of the Generic Listing Standards and other applicable continued listing requirements for Managed Fund Shares under Rule 8.600–E, including those requirements regarding the Disclosed Portfolio, Portfolio Indicative Value, suspension of trading or removal, trading halts, disclosure, and firewalls. The Trust is required to comply with Rule 10A–3 under the Act for the initial and continued listing of the Shares of each Fund.

For the above reasons, the Exchange believes that the proposed rule change is consistent with the requirements of Section 6(b)(5) of the Act.

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 purpose of the Act. The Exchange notes that the proposed rule change will permit the listing and trading of additional types of Managed Fund Shares that will enhance competition among market participants, to the benefit of investors and the marketplace.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act[23] and Rule 19b–4(f)(6) thereunder.[24]

[21] As noted above, the Exchange is submitting this proposal because the Funds would not meet the requirements of Commentary .01(d)(2) to Rule 8.600–E which prevents the aggregate gross notional value of listed derivatives based on any single underlying reference asset from exceeding 30% of the weight of the portfolio (including gross notional exposures) and the aggregate gross notional value of listed derivatives based on any five or fewer underlying reference assets from exceeding 65% of the weight of the portfolio (including gross notional exposures).

[22] *See* note 12, *supra.*

[23] 15 U.S.C. 78s(b)(3)(A).

[24] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

A proposed rule change filed under Rule 19b–4(f)(6) [25] normally does not become operative for 30 days after the date of the filing. However, pursuant to Rule 19b–4(f)(6)(iii),[26] the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that the proposal may become operative immediately upon filing. The Exchange states that the Funds currently intend to begin trading under the Generic Listing Standards on or about October 1, 2019, and waiver of the 30-day operative delay would allow the Funds to immediately fully employ the Overlay Strategy. In addition, the Exchange notes that the proposal would allow the Funds to hold listed derivatives based on a single underlying reference asset in a manner that is similar to previous rule changes involving Managed Fund Shares.[27] For these reasons, the Commission believes that waiver of the 30-day operative delay is consistent with the protection of investors and the public interest. Accordingly, the Commission waives the 30-day operative delay and designates the proposed rule change operative upon filing.[28]

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 shall 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 (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NYSEArca–2019–68 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–NYSEArca–2019–68. 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 (*http://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. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSEArca–2019–68 and should be submitted on or before November 7, 2019.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[29]

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2019–22596 Filed 10–16–19; 8:45 am]

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[25] 17 CFR 240.19b–4(f)(6).

[26] 17 CFR 240.19b–4(f)(6)(iii).

[27] *See supra* note 12.

[28] For purposes only of waiving the 30-day operative delay, the Commission has also considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[29] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–87273; File No. SR–CBOE–2019–091]

Self-Regulatory Organizations; Cboe Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend the Name of a Reporting Authority for Certain Indexes on Which the Exchange May List Options

October 10, 2019.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on October 3, 2019, Cboe Exchange, Inc. (the ''Exchange'' or ''Cboe Options'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Exchange filed the proposal as a ''non-controversial'' proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act [3] and Rule 19b–4(f)(6) thereunder.[4] 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

The Exchange proposes to amend the name of a reporting authority for certain indexes on which the Exchange may list options. The text of the proposed rule change is provided below.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A)(iii).

[4] 17 CFR 240.19b–4(f)(6).

(additions are *italicized;* deletions are [bracketed])

* * * * *

Rules of Cboe Exchange, Inc.

* * * * *

Rule 24.1. Definitions

No change.

. . . *Interpretations and Policies:*

.01 The reporting authorities designated by the Exchange in respect of each index underlying an index option contract traded on the Exchange are as follows:

Index	*Reporting Authority*
S&P 100	Standard & Poor's.
S&P 500	Standard & Poor's.
Cboe Bio Tech	Cboe [Exchange, Inc.]*Global Indices, LLC.*
FTSE 100 Index (1/10th)	FTSE International Limited.
FT–SE 200 Eurotrack	London Stock Exchange.
Russell 2000	Frank Russell Co.
S&P Transportation	Standard & Poor's.
S&P Retail	Standard & Poor's.
S&P Health Care	Standard & Poor's.
S&P Entertainment & Leisure	Standard & Poor's.
S&P Banking	Standard & Poor's.
S&P Insurance	Standard & Poor's.
S&P Chemical	Standard & Poor's.
Cboe Options Software	Cboe [Exchange, Inc.]*Global Indices, LLC.*
Cboe Options Environmental	Cboe [Exchange, Inc.]*Global Indices, LLC.*
S&P 500/Barra Growth	Standard & Poor's.
S&P 500/Barra Value	Standard & Poor's.
Nasdaq 100	Nasdaq, Inc.
Cboe Options Gaming	Cboe [Exchange, Inc.]*Global Indices, LLC.*
Cboe Options Global Telecommunications	Cboe [Exchange, Inc.]*Global Indices, LLC.*
Cboe Options Mexico	Cboe [Exchange, Inc.]*Global Indices, LLC.*
Cboe Options Israeli	Cboe [Exchange, Inc.]*Global Indices, LLC.*
Cboe REIT Index	Cboe [Exchange, Inc.]*Global Indices, LLC.*
Nikkei Stock Index 300	Nihon Keizai Shimbun, Inc.
Cboe Options Emerging Asian Markets	Cboe [Exchange, Inc.]*Global Indices, LLC.*
Cboe Options Emerging Markets	Cboe [Exchange, Inc.]*Global Indices, LLC.*
S&P SmallCap 600 Index	Standard & Poor's.
Cboe Options Latin 15	Cboe [Exchange, Inc.]*Global Indices, LLC.*
Cboe Technology Index	Cboe [Exchange, Inc.]*Global Indices, LLC.*
Cboe Germany 25 Index	Cboe [Exchange, Inc.]*Global Indices, LLC.*
Mexico 30 Index	Cboe [Exchange, Inc.]*Global Indices, LLC.*
Cboe Options Automotive	Cboe [Exchange, Inc.]*Global Indices, LLC.*
Cboe Internet Index	Cboe [Exchange, Inc.]*Global Indices, LLC.*
Cboe Oil Index	Cboe [Exchange, Inc.]*Global Indices, LLC.*
Cboe Gold Index	Cboe [Exchange, Inc.]*Global Indices, LLC.*
Cboe Computer Networking Index	Cboe [Exchange, Inc.]*Global Indices, LLC.*
Cboe PC Index	Cboe [Exchange, Inc.]*Global Indices, LLC.*
IPC	Mexican Stock Exchange.
GSTI Composite Index	Goldman, Sachs & Co.
GSTI Internet Index	Goldman, Sachs & Co.
GSTI Software Index	Goldman, Sachs & Co.
GSTI Semiconductor Index	Goldman, Sachs & Co.
GSTI Hardware Index	Goldman, Sachs & Co.
GSTI Multimedia Networking Index	Goldman, Sachs & Co.
GSTI Services Index	Goldman, Sachs & Co.
Morgan Stanley Multinational Company Index	Morgan Stanley.
Reduced Value NYSE Composite Index	Dow Jones & Company, Inc.
Dow Jones Industrial Average	Dow Jones & Company, Inc.
Dow Jones Transportation Average	Dow Jones & Company, Inc.
Dow Jones Utility Average	Dow Jones & Company, Inc.
Lipper Analytical/Salomon Bros. Growth Fund Index	Lipper Analytical Services, Inc.
Lipper Analytical/Salomon Bros. Growth & Income Fund Index.	Lipper Analytical Services, Inc.
Dow Jones High Yield Select 10 Index	Cboe [Exchange, Inc.]*Global Indices, LLC.*
Dow Jones Equity REIT Index	Dow Jones & Company, Inc.
Dow Jones E*Commerce Index	Dow Jones & Company, Inc.
Cboe Euro 25 Index	Cboe [Exchange, Inc.]*Global Indices, LLC.*
Cboe Asian 25 Index	Cboe [Exchange, Inc.]*Global Indices, LLC.*
Russell 1000 Index	Frank Russell Co.

Russell 1000 Growth Index	Frank Russell Co.
Russell 1000 Value Index	Frank Russell Co.
Russell 2000 Growth Index	Frank Russell Co.
Russell 2000 Value Index	Frank Russell Co.
Russell 3000 Index	Frank Russell Co.
Russell 3000 Growth Index	Frank Russell Co.
Russell 3000 Value Index	Frank Russell Co.
Russell Midcap Index	Frank Russell Co.
Russell Midcap Growth Index	Frank Russell Co.
Russell Midcap Value Index	Frank Russell Co.
Russell Top 200 Index	Frank Russell Co.
Russell Top 200 Growth Index	Frank Russell Co.
Russell Top 200 Value Index	Frank Russell Co.
Cboe China Index	Cboe [Exchange, Inc.]*Global Indices, LLC.*
Cboe Volatility Index® (VIX®)	Cboe [Exchange, Inc.]*Global Indices, LLC.*
Cboe Nasdaq 100® Volatility Index (VXN®)	Cboe [Exchange, Inc.]*Global Indices, LLC.*
Cboe Dow Jones Industrial Average® Volatility Index (VXD®)	Cboe [Exchange, Inc.]*Global Indices, LLC.*
Cboe Increased-Value Volatility Index®	Cboe [Exchange, Inc.]*Global Indices, LLC.*
Cboe Increased-Value Nasdaq 100® Volatility Index	Cboe [Exchange, Inc.]*Global Indices, LLC.*
Cboe Increased-Value Dow Jones Industrial Average® Volatility Index.	Cboe [Exchange, Inc.]*Global Indices, LLC.*
Cboe PowerPacks℠ Bank Index	Cboe [Exchange, Inc.]*Global Indices, LLC.*
Cboe PowerPacks℠ Biotechnology Index	Cboe [Exchange, Inc.]*Global Indices, LLC.*
Cboe PowerPacks℠ Gold Index	Cboe [Exchange, Inc.]*Global Indices, LLC.*
Cboe PowerPacks℠ Internet Index	Cboe [Exchange, Inc.]*Global Indices, LLC.*
Cboe PowerPacks℠ Iron & Steel Index	Cboe [Exchange, Inc.]*Global Indices, LLC.*
Cboe PowerPacks℠ Oil Index	Cboe [Exchange, Inc.]*Global Indices, LLC.*
Cboe PowerPacks℠ Oil Services Index	Cboe [Exchange, Inc.]*Global Indices, LLC.*
Cboe PowerPacks℠ Pharmaceuticals Index	Cboe [Exchange, Inc.]*Global Indices, LLC.*
Cboe PowerPacks℠ Retail Index	Cboe [Exchange, Inc.]*Global Indices, LLC.*
Cboe PowerPacks℠ Semiconductor Index	Cboe [Exchange, Inc.]*Global Indices, LLC.*
Cboe PowerPacks℠ Technology Index	Cboe [Exchange, Inc.]*Global Indices, LLC.*
Cboe PowerPacks℠ Telecom Index	Cboe [Exchange, Inc.]*Global Indices, LLC.*
Cboe Russell 2000 Volatility Index℠ (''RVX℠'')	Cboe [Exchange, Inc.]*Global Indices, LLC.*
Cboe S&P 500 Three-Month Realized Variance	Cboe [Exchange, Inc.]*Global Indices, LLC.*
Cboe S&P 500 Three-Month Realized Volatility	Cboe [Exchange, Inc.]*Global Indices, LLC.*
Cboe S&P 500 BuyWrite Index (1/10th value)	Cboe [Exchange, Inc.]*Global Indices, LLC.*
S&P 500 Dividend Index	Standard & Poor's .01.
Cboe Gold ETF Volatility Index	Cboe [Exchange, Inc.]*Global Indices, LLC.*
Cboe Equity VIX on Apple	Cboe [Exchange, Inc.]*Global Indices, LLC.*
Cboe Equity VIX on Amazon	Cboe [Exchange, Inc.]*Global Indices, LLC.*
Cboe Equity VIX on Goldman Sachs	Cboe [Exchange, Inc.]*Global Indices, LLC.*
Cboe Equity VIX on Google	Cboe [Exchange, Inc.]*Global Indices, LLC.*
Cboe Equity VIX on IBM	Cboe [Exchange, Inc.]*Global Indices, LLC.*
Cboe Crude Oil ETF Volatility Index	Cboe [Exchange, Inc.]*Global Indices, LLC.*
Cboe Emerging Markets ETF Volatility Index	Cboe [Exchange, Inc.]*Global Indices, LLC.*
Cboe China ETF Volatility Index	Cboe [Exchange, Inc.]*Global Indices, LLC.*
Cboe Brazil ETF Volatility Index	Cboe [Exchange, Inc.]*Global Indices, LLC.*
Cboe Gold Miners ETF Volatility Index	Cboe [Exchange, Inc.]*Global Indices, LLC.*
Cboe Energy Sector ETF Volatility Index	Cboe [Exchange, Inc.]*Global Indices, LLC.*
Cboe Silver ETF Volatility Index	Cboe [Exchange, Inc.]*Global Indices, LLC.*
Cboe S&P 500 AM/PM Basis	Cboe [Options] *Global Indices, LLC.*
Cboe Short-Term Volatility Index	Cboe [Exchange, Inc.]*Global Indices, LLC.*
MSCI EAFE Index (EAFE)	MSCI Inc.
MSCI Emerging Markets Index (EM)	MSCI Inc.
FTSE China 50 Index (1/100th)	FTSE International Limited.
FTSE Emerging Index	FTSE International Limited.
FTSE Developed Europe Index	FTSE International Limited.
S&P Financial Select Sector Index (IXM)	S&P Dow Jones Indices.
S&P Energy Select Sector Index (IXE)	S&P Dow Jones Indices.
S&P Technology Select Sector Index (IXT)	S&P Dow Jones Indices.
S&P Health Care Select Sector Index (IXV)	S&P Dow Jones Indices.
S&P Utilities Select Sector Index (IXU)	S&P Dow Jones Indices.
S&P Consumer Staples Select Sector Index (IXR)	S&P Dow Jones Indices.
S&P Industrials Select Sector Index (IXI)	S&P Dow Jones Indices.
S&P Consumer Discretionary Select Sector Index (IXY)	S&P Dow Jones Indices.
S&P Materials Select Sector Index (IXB)	S&P Dow Jones Indices.
S&P Real Estate Select Sector Index (IXRE)	S&P Dow Jones Indices.
S&P Communication Services Select Sector Index (IXC)	S&P Dow Jones Indices.

* * * * *

The text of the proposed rule change is also available on the Exchange's website (*http://www.cboe.com/AboutCBOE/CBOELegalRegulatoryHome.aspx*), 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

Cboe Options currently operates a business, separate from its operation of an options exchange, in which it creates, administers, and distributes proprietary financial and benchmarks, calculates index values and benchmarks for third-party customers, and calculates and licenses indexes for third-party derivative indexes and products, among other things. Cboe Options calculates and disseminates the values of these indexes to market participants. Pursuant to the Cboe Options Rules, the Exchange is also authorized to list options on certain of these indexes, for which Cboe Options acts as the reporting authority.[5] The reporting authority in respect of a particular index means the institution or reporting service designated by the Exchange as the official source for calculating the level of the index from the reporting prices of the underlying securities that are the basis of the index and reporting such level.[6] Recently, Cboe Options determined to conduct an internal reorganization, pursuant to which it created a new entity, called Cboe Global Indices, LLC (which is a direct, wholly owned subsidiary of the Exchange's parent company, Cboe Global Markets, Inc.), into which it transferred its assets related to this index business. This transfer is expected to be effective as of September 30, 2019.[7] As a result, the Exchange designates Cboe Global Indices, LLC as the reporting authority for the indexes on which the Exchange may list options, and amends Rule 24.1, Interpretation and Policy .01.[8] The Exchange represents this will have no impact on the dissemination of index values for any of these indexes. Values for these indexes will continue to be disseminated and available to market participants in the same manner and in the same intervals.[9]

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Securities Exchange Act of 1934 (the ''Act'') and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.[10] Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[11] 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)[12] requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers. The proposed rule change removes impediments to and perfects the mechanism of a free and open market a national market system, and protects investors and the public interest, by updating its rules to reflect the current name of a reporting authority for various indexes on which the Exchange is authorized to list options. The Exchange believes this promotes transparency in its Rules and may eliminate any potential confusion among market participants. The proposed rule change has no impact on trading on the Exchange, or on the dissemination of index values, but merely reflects a change to the name of a reporting authority for various indexes on which the Exchange is authorized to list options due to a recent internal reorganization and transfer of assets.

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. The proposed rule change is not intended to be a competitive rule filing. Rather, the proposed rule change merely reflects a change to the name of a reporting authority for various indexes on which the Exchange is authorized to list options due to a recent internal reorganization and transfer of assets. The proposed rule change has no impact on trading on the Exchange, or on the dissemination of index values.

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

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act[13] and Rule 19b–4(f)(6) thereunder.[14]

[5] *See* Rule 24.1, Interpretation and Policy .01 in the current Rulebook.

[6] *See* Rule 24.1(h).

[7] The Exchange initially filed the proposed change to the reporting authority name on September 30, 2019 (SR–CBOE–2019–074). On October 3, 2019, the Exchange withdrew that filing and submitted this filing.

[8] The Exchange notes it currently only lists options on the Cboe Volatility Index (VIX).

[9] Pursuant to Rule 24.2(b)(10), (d)(8), (e)(7), and (f)(11), the current value of an index must be disseminated at least once every 15 seconds by one or more major market data vendors. That will continue to be the case.

[10] 15 U.S.C. 78f(b).

[11] 15 U.S.C. 78f(b)(5).

[12] *Id.*

[13] 15 U.S.C. 78s(b)(3)(A).

[14] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time

A proposed rule change filed pursuant to Rule 19b–4(f)(6) under the Act [15] normally does not become operative for 30 days after the date of its filing. However, Rule 19b–4(f)(6)(iii) [16] permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay as the proposed rule change only updates its rules to reflect the current name of a reporting authority for various indexes on which the Exchange is authorized to list options. The Exchange believes that waiver of the operative delay is appropriate because, as the Exchange discussed above, its proposal does not make any substantive changes to the Exchange's rules. The Commission believes that waiver of the 30-day operative delay is consistent with the protection of investors and the public interest because the proposal does not raise any new or novel issues and makes only non-substantive changes to the rules. Therefore, the Commission hereby waives the operative delay and designates the proposal as operative upon filing.[17]

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 (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–CBOE–2019–091 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–CBOE–2019–091. 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 (*http://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. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–CBOE–2019–091 and should be submitted on or before November 7, 2019.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[18]

Jill M. Peterson,

Assistant Secretary.

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as designated by the Commission. The Exchange has satisfied this requirement.

[15] 17 CFR 240.19b–4(f)(6).

[16] 17 CFR 240.19b–4(f)(6)(iii).

[17] For purposes only of waiving the 30-day operative delay, the Commission also has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[18] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–87280; File No. SR–MIAX–2019–41]

Self-Regulatory Organizations; Miami International Securities Exchange, LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Exchange Rule 519, MIAX Order Monitor

October 10, 2019.

Pursuant to the provisions of 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 October 2, 2019, Miami International Securities Exchange, LLC (''MIAX Options'' or the ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') a proposed rule change as described in Items I and II 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

The Exchange is filing a proposal to amend Exchange Rule 519, MIAX Order Monitor.

The text of the proposed rule change is available on the Exchange's website at *http://www.miaxoptions.com/rule-filings/* at MIAX Options' principal office, 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 Exchange Rule 519, MIAX Order

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

Monitor (''MOM'') to remove a term in the Exchange's rule which creates an ambiguity concerning the application of the rule. Specifically, subsection (4) of paragraph (a), Limit Orders to Sell, provides that ''[f]or options with a National Best Bid (''NBB'') equal to or greater than $0.25 the System [3] will reject an incoming limit order that has a limit price equal to or less than the NBB by the lesser of (i) $2.50, or (ii) 50% of the NBB price.'' The second provision of the rule provides that, ''[f]or options with an NBB of $0.25 or less the System will accept any incoming limit order.''

The statements an NBB ''equal to or greater than $0.25'' and ''an NBB of $0.25 or less'' both contemplate the NBB being equal to $0.25. The operation of the rule requires a bifurcation at $0.25 and only one action (accepting or rejecting an incoming order) can occur when the NBB is equal to $0.25. The desired behavior by the Exchange, for limit orders to sell, is to accept an order at any price when the NBB is equal to $0.25 or less. Therefore the Exchange proposes to remove the phrase ''equal to or'' from the first sentence in the rule.

The new proposed rule text will provide that, ''[f]or options with a National Best Bid (''NBB'') greater than $0.25 the System will reject an incoming limit order that has a limit price equal to or less than the NBB by the lesser of (i) $2.50, or (ii) 50% of the NBB price. For options with an NBB of $0.25 or less the System will accept any incoming limit order.

The Exchange believes its proposed change provides additional detail and clarity to the Exchange's rule and eliminates any inadvertent ambiguity in the rule text concerning order protections for incoming limit orders to sell.

2. Statutory Basis

MIAX believes that its proposed rule change is consistent with Section 6(b) of the Act [4] in general, and furthers the objectives of Section 6(b)(5) of the Act [5] in particular, in that it is 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 mechanisms of a free and open market and a national market system and, in general, to protect investors and the public interest.

The Exchange believes its proposal promotes just and equitable principles of trade, removes impediments to and perfects the mechanisms of a free and open market and a national market system, and in general, protects investors and the public interest by providing clarity and precision in the Exchange's rule text. Additionally, the proposed change is consistent with the current System behavior as described in the Exchange's User Manual.[6]

The Exchange believes that the proposed change to the rule text provides further clarification to Members,[7] investors, and the public, regarding the Exchange's handling of limit orders to sell. The Exchange believes it is in the interest of investors and the public to accurately describe the behavior of the Exchange's System in its rules as this information may be used by investors to make decisions concerning the submission of their orders. Transparency and clarity are consistent with the Act because it removes impediments to and helps perfect the mechanism of a free and open market and a national market system, and, in general, protects investors and the public interest by accurately describing the behavior of the Exchange's System.

The Exchange believes that the proposed change promotes just and equitable principles of trade and removes impediments to and perfects the mechanism of a free and open market and a national market system and, in general, protects investors and the public interest by providing additional detail and clarity in the Exchange's rules. Further, the Exchange's proposal provides transparency and clarity in the rule and is consistent with the Act because it removes impediments to and helps perfect the mechanism of a free and open market and a national market system, and, in general, protects investors and the public interest by accurately describing the behavior of the Exchange's System. In particular, the Exchange believes that the proposed rule change will provide greater clarity to Members and the public regarding the Exchange's Rules, and it is in the public interest for rules to be accurate and concise so as to eliminate the potential for confusion.

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. The proposed rule change is designed to remove an unintentional ambiguity introduced in a prior rule change.[8]

The Exchange does not believe that the proposed rule change will impose any burden on inter-market competition as the Rules apply equally to all Exchange Members. The proposed rule change is not a competitive filing and is intended to improve the clarity and precision of the Exchange's rule text.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days after the date of the filing, or such shorter time as the Commission may designate, it has become effective pursuant to 19(b)(3)(A) of the Act [9] and Rule 19b–4(f)(6) [10] thereunder.

A proposed rule change filed under Rule 19b–4(f)(6) [11] normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b–4(f)(6)(iii),[12] the Commission may designate a shorter time if such action is consistent with protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay. The Exchange believes that waiver is consistent with the protection of investors and the public

[3] The term ''System'' means the automated trading system used by the Exchange for the trading of securities. *See* Exchange Rule 100.

[4] 15 U.S.C. 78f(b).

[5] 15 U.S.C. 78f(b)(5).

[6] MIAX Options User's Manual, August 2019, p 38, *https://www.miaxoptions.com/exchange-functionality-data*.

[7] The term ''Member'' means an individual or organization approved to exercise the trading rights associated with a Trading Permit. Members are deemed ''members'' under the Exchange Act. *See* Exchange Rule 100.

[8] *See* Securities Exchange Release No. 86024 (June 4, 2019), 84 FR 26924 (June 10, 2019) (SR–MIAX–2019–26).

[9] 15 U.S.C. 78s(b)(3)(A).

[10] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[11] 17 CFR 240.19b–4(f)(6).

[12] 17 CFR 240.19b–4(f)(6).

interest because it would remove any ambiguity in the Exchange's rule concerning its handling of limit orders to sell. The Commission believes that waiver of the 30-day operative delay is consistent with the protection of investors and the public interest because the proposal does not raise any new or novel issues and makes a non-substantive change to clarify the rule text. Accordingly, the Commission designates the proposed rule change to be operative on upon filing.[13]

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 shall institute proceedings to determine whether the proposed rule 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 (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–MIAX–2019–41 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–MIAX–2019–41. 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 (*http://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. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–MIAX–2019–41 and should be submitted on or before November 7, 2019.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[14]

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2019–22598 Filed 10–16–19; 8:45 am]

BILLING CODE 8011–01–P

[13] For purposes only of waiving the 30-day operative delay, the Commission also has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[14] 17 CFR 200.30–3(a)(12).

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #16153 and #16154; SOUTH DAKOTA Disaster Number SD–00097]

Presidential Declaration of a Major Disaster for Public Assistance Only for the State of South Dakota

AGENCY: U.S. Small Business Administration.

ACTION: Notice.

SUMMARY: This is a Notice of the Presidential declaration of a major disaster for Public Assistance Only for the State of South Dakota (FEMA—4467—DR), dated 10/07/2019.

Incident: Severe Storms, Tornadoes, and Flooding.

Incident Period: 06/30/2019 through 07/21/2019.

DATES: Issued on 10/07/2019.

Physical Loan Application Deadline Date: 12/06/2019.

Economic Injury (EIDL) Loan Application Deadline Date: 07/07/2020.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205–6734.

SUPPLEMENTARY INFORMATION: Notice is hereby given that as a result of the President's major disaster declaration on 10/07/2019, Private Non-Profit organizations that provide essential services of a governmental nature may file disaster loan applications at the address listed above or other locally announced locations.

The following areas have been determined to be adversely affected by the disaster:

Primary Counties/Areas: Butte, Gregory, Kingsbury, Lawrence, Meade, and Tripp Counties and the Cheyenne River Tribe of the Cheyenne River Sioux Reservation and the Lower Brule Tribe of the Lower Brule Reservation.

The Interest Rates are:

	Percent
For Physical Damage:	
Non-Profit Organizations with Credit Available Elsewhere ...	2.750
Non-Profit Organizations without Credit Available Elsewhere	2.750
For Economic Injury:	
Non-Profit Organizations without Credit Available Elsewhere	2.750

The number assigned to this disaster for physical damage is 161536 and for economic injury is 161540.

(Catalog of Federal Domestic Assistance Number 59008)

James Rivera,

Associate Administrator for Disaster Assistance.

[FR Doc. 2019–22676 Filed 10–16–19; 8:45 am]

BILLING CODE 8026–03–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #16158 and #16159; ILLINOIS Disaster Number IL–00058]

Administrative Declaration of a Disaster for the State of Illinois

AGENCY: U.S. Small Business Administration.

ACTION: Notice.

SUMMARY: This is a notice of an Administrative declaration of a disaster for the State of ILLINOIS dated 10/10/2019.

Incident: Severe Storms and Flooding.

Incident Period: 08/12/2019 through 08/13/2019.

DATES: Issued on 10/10/2019.

Physical Loan Application Deadline Date: 12/09/2019.

Economic Injury (EIDL) Loan Application Deadline Date: 07/10/2020.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205–6734.

SUPPLEMENTARY INFORMATION: Notice is hereby given that as a result of the Administrator's disaster declaration, applications for disaster loans may be filed at the address listed above or other locally announced locations.

The following areas have been determined to be adversely affected by the disaster:

Primary Counties: Madison.

Contiguous Counties:

Illinois: Bond, Clinton, Jersey, Macoupin, Montgomery, Saint Clair.

Missouri: Saint Charles, Saint Louis, Saint Louis City.

The Interest Rates are:

	Percent
For Physical Damage:	
Homeowners With Credit Available Elsewhere	3.500
Homeowners Without Credit Available Elsewhere	1.750
Businesses With Credit Available Elsewhere	8.000
Businesses Without Credit Available Elsewhere	4.000
Non-Profit Organizations With Credit Available Elsewhere	2.750
Non-Profit Organizations Without Credit Available Elsewhere	2.750
For Economic Injury:	
Businesses Small Agricultural Cooperatives Without Credit Available Elsewhere	4.000
Non-Profit Organizations Without Credit Available Elsewhere	2.750

The number assigned to this disaster for physical damage is 16158 6 and for economic injury is 16159 0.

The States which received an EIDL Declaration # are Illinois, Missouri.

(Catalog of Federal Domestic Assistance Number 59008)

Christopher Pilkerton,

Acting Administrator.

[FR Doc. 2019–22619 Filed 10–16–19; 8:45 am]

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DEPARTMENT OF THE TREASURY

Community Development Financial Institutions Fund

Agency Information Collection Activities; Proposed Collection: Comment Request; Uses of Awards Report Form

ACTION: Notice and request for comments.

SUMMARY: The U.S. Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed information collections, as required by the Paperwork Reduction Act of 1995. Currently, the Community Development Financial Institutions Fund (the CDFI Fund), the Department of the Treasury, is soliciting comments concerning the Uses of Awards Report Form, which is completed by the Bank Enterprise Award Program (BEA Program) Recipients and the Community Development Financial Institutions Program (CDFI Program) and Native American CDFI Assistance Program (NACA Program) Recipients.

DATES: Written comments should be received on or before December 16, 2019 to be assured of consideration.

ADDRESSES: Direct all comments in writing to Mia Sowell, Associate Program Manager, Community Development Financial Institutions Fund, U.S. Department of the Treasury, 1500 Pennsylvania Avenue NW, Washington, DC 20220, by email to *cdfihelp@cdfi.treas.gov,* or by facsimile to (202) 508–0083. Please note that this is not a toll free number.

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be directed to Mia Sowell, Associate Program Manager, Community Development Financial Institutions Fund, U.S. Department of the Treasury, 1500 Pennsylvania Avenue NW, Washington, DC 20220, by email to *cdfihelp@cdfi.treas.gov,* or by phone to (202) 653–0421. Please note that these are not toll free numbers.

SUPPLEMENTARY INFORMATION:

Title: Uses of Award Report Form.

OMB Number: 1559–0032.

There is no significant content change to the form, however the format will be revised to: (1) Include a system-generated validation data point to capture Persistent Poverty County investments made by BEA Program Recipients; and (2) display a table that describes and easily identifies which data points are collected for each program (BEA, CDFI, NACA Programs). The revised form is also consistent with the format of the CDFI Fund's Annual Compliance report.

The Uses of Award Report Form may be obtained from the CDFI Fund's website at *http://www.cdfifund.gov/bea* under How to Apply Step 4: Compliance and Reporting or *http://www.cdfifund.gov/cdfi* under How to Apply Step 5: Compliance and Reporting.

Type of Review: Revision of a currently approved collection.

Description: The CDFI Fund is seeking to revise its Uses of Award Report Form to validate investments made in Persistent Poverty Counties (PPCs) by BEA Program award Recipients in compliance with the PPC Congressional Mandate. The CDFI Fund's appropriation in the Consolidated Appropriations Act, 2019 (Pub. L. 116–6), enacted February 15, 2019, requires that at least 10 percent of BEA Program funds be used for Awards that support investments that serve populations living in PPCs. In order to meet this requirement, Applicants are required to indicate the minimum and maximum percentage of the Estimated BEA Program Award the Applicant will commit to deploying in PPCs.

A Persistent Poverty County is any county that has had 20 percent or more of its population living in poverty over the past 30 years, as measured by the 1990 and 2000 decennial census, and the 2011–2015 5-year data series available from the American Community Survey from the Census Bureau. A Recipient that made commitments to serve Persistent Poverty Counties is required to identify the portion of the total award amount used for BEA Qualified Activities in Persistent Poverty Counties.

The purpose of the BEA Program is to provide an incentive to insured depository institutions to increase their activities in the form of loans, investments, services, and technical assistance within distressed communities and provide financial assistance to certified Community Development Financial Institutions (CDFIs) through grants, stock purchases, loans, deposits, and other forms of financial and technical assistance. Applicants submit applications and are evaluated in accordance with statutory and regulatory requirements (12 CFR 1806), and requirements that are set forth in the annual Notice of Funds Availability. The CDFI Fund requires BEA Program Award Recipients to use BEA Program Awards for BEA Program Qualified Activities, as defined in the BEA Program regulations. Recipients are

required to report to the CDFI Fund on their Qualified Activities per their Award Agreements.

The CDFI Program was established by the Community Development and Regulatory Improvement Act of 1994 to use federal resources to invest in and build the capacity of CDFIs to serve low-income people and communities lacking adequate access to affordable financial products and services. The CDFI Fund created the Native Initiatives, which includes the NACA Program, to further support the creation and expansion of Native CDFIs. Through the CDFI Program and NACA Program, the CDFI Fund provides: (1) Financial Assistance (FA) awards to CDFIs and Native CDFIs that have Comprehensive Business Plans for creating demonstrable community development impact through the deployment of credit, capital, and financial services within Target Markets and/or Eligible Markets; [1] and (ii) Technical Assistance (TA) grants to CDFIs and Native CDFIs and entities proposing to become CDFIs or Native CDFIs in order to build their capacity to better address the community development and capital access needs of their existing or proposed Target Markets and/or to become certified CDFIs. CDFI Program applicants submit applications and are evaluated in accordance with statutory and regulatory requirements (12 CFR 1805), and requirements that are set forth in an annual Notice of Funds Availability. NACA Program applicants submit applications and are evaluated in accordance with requirements that are set forth in an annual Notice of Funds Availability. Recipients with FA or TA awards are required to report to the CDFI Fund on the uses of those funds per their Assistance Agreements.

Affected Public: Recipients of BEA Program awards.

Estimated Number of Respondents: 120.

Frequency of Response: Once.

Estimated Total Number of Annual Responses: 120.

Estimated Annual Time per Respondent: 1 hour.

Estimated Total Annual Burden Hours: 120 hours.

Affected Public: Recipients of CDFI or NACA Program awards.

Estimated Number of Respondents: 700.

Frequency of Response: Annually.

Estimated Total Number of Annual Responses: 700.

Estimated Annual Time per Respondent: 30 min.

Estimated Total Annual Burden Hours: 350 hours.

Requests for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for the Office of Management and Budget (OMB) approval. All comments will become a matter of public record and will be published on the CDFI Fund website at *http://www.cdfifund.gov.* Comments are invited on: (a) Whether the 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 collection of information; (c) ways to enhance the quality, utility, and clarity of the information collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number.

Authority: 12 U.S.C. 4704, 4713; 12 CFR parts 1805 and 1806.

Dated: October 10, 2019.

Jodie L. Harris,

Director, Community Development Financial Institutions Fund.

[FR Doc. 2019–22574 Filed 10–16–19; 8:45 am]

BILLING CODE 4810–70–P

[1] Eligible Market is defined as (i) a geographic area meeting the requirements set forth in 12 CFR 1805.201(b)(3)(ii), or (ii) individuals that are Low-Income, African American, Hispanic, Native American, Native Hawaiians residing in Hawaii, Alaska Natives residing in Alaska, or Other Pacific Islanders residing in American Samoa, Guam or the Northern Mariana Islands.

DEPARTMENT OF TREASURY

Office of the Comptroller of the Currency

[Docket ID OCC–2019–0018]

FEDERAL RESERVE SYSTEM

[Docket ID OP–1679]

FEDERAL DEPOSIT INSURANCE CORPORATION

RIN 3064–ZA09

NATIONAL CREDIT UNION ADMINISTRATION

RIN 3133–AF05

Interagency Guidance on Credit Risk Review Systems

AGENCY: Office of the Comptroller of the Currency (OCC), Treasury; Board of Governors of the Federal Reserve System (Board); Federal Deposit Insurance Corporation (FDIC); and National Credit Union Administration (NCUA).

ACTION: Proposed guidance.

SUMMARY: The OCC, the Board, the FDIC, and the NCUA (collectively, the agencies) are inviting comment on proposed guidance for credit risk review systems. This proposed guidance is relevant to all institutions supervised by the agencies. The proposed guidance discusses sound management of credit risk, a system of independent, ongoing credit review, and appropriate communication regarding the performance of the institution's loan portfolio to its management and board of directors.

DATES: Comments must be received by December 16, 2019.

ADDRESSES: Interested parties are encouraged to submit written comments to any or all of the agencies listed below. The agencies will share comments with each other.

Comments should be directed to:

OCC: You may submit comments to the OCC by any of the methods set forth below. Commenters are encouraged to submit comments through the Federal eRulemaking Portal or email, if possible. Please use the title ''Interagency Guidance on Credit Risk Review Systems'' to facilitate the organization and distribution of the comments. You may submit comments by any of the following methods:

- *Federal eRulemaking Portal—''Regulations.gov'':* Go to *www.regulations.gov.* Enter ''Docket ID OCC–2019–0018'' in the Search Box and click ''Search.'' Click on ''Comment

Now'' to submit public comments. Click on the ''Help'' tab on the *Regulations.gov* home page to get information on using *Regulations.gov*, including instructions for submitting public comments.

- *Email: regs.comments@occ.treas.gov.*
- *Mail:* Chief Counsel's Office, Attn: Comment Processing, Office of the Comptroller of the Currency, 400 7th Street SW, Suite 3E–218, Washington, DC 20219.
- *Hand Delivery/Courier:* 400 7th Street SW, Suite 3E–218, Washington, DC 20219.

Instructions: You must include ''OCC'' as the agency name and ''Docket ID OCC–2019–0018'' in your comment. In general, the OCC will enter all comments received into the docket and publish the comments on the *Regulations.gov* website without change, including any business or personal information provided such as name and address information, email addresses, or phone numbers. Comments received, including attachments and other supporting materials, are part of the public record and subject to public disclosure. Do not include any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure.

You may review comments and other related materials that pertain to this rulemaking action by any of the following methods:

- *Viewing Comments Electronically:* Go to *www.regulations.gov.* Enter ''Docket ID OCC–2019–0018'' in the Search box and click ''Search.'' Click on ''Open Docket Folder'' on the right side of the screen. Comments and supporting materials can be viewed and filtered by clicking on ''View all documents and comments in this docket'' and then using the filtering tools on the left side of the screen. Click on the ''Help'' tab on the *Regulations.gov* home page to get information on using *Regulations.gov.* The docket may be viewed after the close of the comment period in the same manner as during the comment period.
- *Viewing Comments Personally:* You may personally inspect comments at the OCC, 400 7th Street SW, Washington, DC 20219. For security reasons, the OCC requires that visitors make an appointment to inspect comments. You may do so by calling (202) 649–6700 or, for persons who are deaf or hearing impaired, TTY, (202) 649–5597. Upon arrival, visitors will be required to present valid government-issued photo identification and submit to security screening in order to inspect comments.

Board: When submitting comments, please consider submitting your comments by email or fax because paper mail in the Washington, DC area and at the Board may be subject to delay.

You may submit comments, identified by OP–1679, by any of the following methods:

- *Agency website: http://www.federalreserve.gov.* Follow the instructions for submitting comments at *http://www.federalreserve.gov/generalinfo/foia/RevisedRegs.cfm.*
- *Email: regs.comments@federalreserve.gov.* Include docket and RIN numbers in the subject line of the message.
- *Fax:* (202) 452–3819 or (202) 452–3102.
- *Mail:* Ann E. Misback, Secretary, Board of Governors of the Federal Reserve System, 20th Street and Constitution Avenue NW, Washington, DC 20551.

All public comments will be made available on the Board's website at: *http://www.federalreserve.gov/generalinfo/foia/RevisedRegs.cfm* as submitted, unless modified for technical reasons or to remove personally identifiable information at the commenter's request. Accordingly, comments will not be edited to remove any identifying or contact information. Public comments may also be viewed electronically or in paper in Room 3515, 1801 K Street NW (between 18th and 19th Streets NW), between 9:00 a.m. and 5:00 p.m. on weekdays.

FDIC: You may submit comments, identified by FDIC RIN 3064–ZA09, by any of the following methods:

- *Agency website: https://www.fdic.gov/regulations/laws/federal/.* Follow instructions for submitting comments on the Agency website.
- *Mail:* Robert E. Feldman, Executive Secretary, Attention: Comments/Legal ESS, Federal Deposit Insurance Corporation, 550 17th Street NW, Washington, DC 20429.
- *Hand Delivery/Courier:* Comments may be hand-delivered to the guard station at the rear of the 550 17th Street NW building (located on F Street) on business days between 7:00 a.m. and 5:00 p.m.
- *Email: comments@FDIC.gov.* Comments submitted must include ''FDIC'' and ''RIN 3064–ZA09'' on the subject line of the message.
- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Public Inspection:* All comments received must include ''FDIC'' and ''RIN 3064–ZA09'' for this rulemaking. All comments received will be posted without change to *http://www.fdic.gov/regulations/laws/federal/,* including any personal information provided.

NCUA: You may submit comments by any one of the following methods (please send comments by one method only):

- *Federal rulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Email:* Address to *regcomments@ncua.gov.* Include ''[Your name]—Comments on ''Interagency Guidance on Credit Risk Review Systems'' in the email subject line.
- *Fax:* (703) 518–6319. Use the subject line described above for email.
- *Mail:* Address to Gerard Poliquin, Secretary of the Board, National Credit Union Administration, 1775 Duke Street, Alexandria, Virginia 22314–3428.
- *Hand Delivery/Courier:* Same as mail address.

Public Inspection: You can view all public comments on NCUA's website at *https://www.ncua.gov/regulation-supervision/rules-regulations/proposed-pending-and-recently-final-regulations* as submitted, except for those we cannot post for technical reasons. NCUA will not edit or remove any identifying or contact information from the public comments submitted. You may inspect paper copies of comments in NCUA's law library at 1775 Duke Street, Alexandria, Virginia 22314, by appointment weekdays between 9:00 a.m. and 3:00 p.m. To make an appointment, call (703) 518–6546 or send an email to *OGCMail@ncua.gov.*

FOR FURTHER INFORMATION CONTACT:

OCC: Beth Nalyvayko, Bank Examiner, or Lou Ann Francis, Director, Commercial Credit Risk, (202) 649–6670; or Kevin Korzeniewski, Counsel, Chief Counsel's Office, (202) 649–5490. For persons who are hearing impaired, TTY, (202) 649–5597.

Board: Constance Horsley, Deputy Associate Director, (202) 452–5239; Virginia Gibbs, Manager, (202) 452–2521; or Carmen Holly, Lead Financial Institution Policy Analyst (202) 973–6122, the Division of Supervision and Regulation; or Alyssa O'Connor, Attorney, Legal Division, (202) 452–3886, Board of Governors of the Federal Reserve System, 20th and C Streets NW, Washington, DC 20551.

FDIC: Thomas F. Lyons, Chief, Policy & Program Development, *tlyons@fdic.gov* (202) 898–6850; George J. Small, Senior Examination Specialist, Risk Management Policy, *gsmall@fdic.gov* (917) 320–2750, Risk Management Supervision; Ann M. Adams, Senior Examination Specialist, Risk Management Policy,

annadams@fdic.gov (347) 751–2469, Risk Management Supervision; or Andrew B. Williams II, Counsel, *andwilliams@fdic.gov;* (202) 898–3581, Supervision and Legislation Branch, Legal Division, Federal Deposit Insurance Corporation; 550 17th Street NW, Washington, DC 20429.

NCUA: Vincent H. Vieten, Senior Credit Specialist (703) 518–6618; Uduak Essien, Director (703) 518–6399, Division of Credit Markets; or Ian Marenna, Associate General Counsel (703) 518–6554, Office of General Counsel.

SUPPLEMENTARY INFORMATION:

I. Background

The agencies' current credit risk review guidance is contained in Attachment 1—Loan Review Systems—of the *Interagency Policy Statement on the Allowance for Loan and Lease Losses (ALLL)* (2006 attachment 1).[1] The agencies are proposing to update that guidance to reflect the current expected credit losses methodology (CECL).[2] Further, the agencies recognize that credit risk review systems have a broader application in risk management programs than just providing information on the collectibility of an institution's loan portfolio for determining an appropriate level for the ACLs or Allowance for Loan and Lease Losses (ALLL), as applicable. Therefore, the agencies are proposing to issue guidance on credit risk review systems as a standalone guidance document and accordingly rescind the 2006 attachment 1. The proposed guidance on credit risk review will continue to be applicable to all supervised institutions.

II. Overview of the Proposed Interagency Guidance on Credit Risk Review Systems

The proposed guidance aligns with the *Interagency Guidelines Establishing Standards for Safety and Soundness* (Guidelines)[3] which sets out safety and soundness standards for insured depository institutions to establish a system for independent, ongoing credit risk review, and including regular communication to its management and board of directors regarding the institution's loan portfolio performance.[4] This guidance is appropriate for all institutions[5] and describes a broad set of practices that can occur either within a dedicated unit or multiple units throughout an institution to form a credit risk review system consistent with safe-and-sound lending practices and the Guidelines. This guidance outlines principles for use in developing and maintaining an effective credit risk review system. The nature of credit risk review systems typically varies based on an institution's size, complexity, loan types, risk profile, and risk management practices. Therefore, the proposed guidance attempts to highlight principles that can be scaled to an institution's loan activity.

The proposed guidance incorporates and updates the principles enumerated in 2006 attachment 1 and reaffirms the key elements of an effective credit risk review system, including qualifications and independence of credit risk review personnel; the frequency, scope and depth of reviews; and the review of findings and follow-up; communication, and distribution of results. The proposed guidance includes updates to reflect current industry credit review practices and examples of credit risk review procedures and methods to help ensure a proper degree of independence for small institutions. The proposed guidance also outlines characteristics of an effective credit risk rating framework, including the factors used to assign ratings to promote an effective risk review by qualified, independent parties. As described in the proposed guidance, independence from the lending function is an important characteristic for personnel who assess credit risks, develop the credit review plan, and follow-up on review findings.

The proposed guidance discusses various criteria for consideration in determining the scope of a risk-based loan review, including factors such as loan size, credit information, borrower relationship, concentration levels, performance, and other risk indicators. Further, it articulates expectations for communicating review results. The proposed guidance also discusses resolving risk rating differences between loan officers and credit risk review personnel; conducting discussions with appropriate loan officers and department managers; and obtaining management responses for corrective action to address credit risk review findings.

III. Request for Comment

The agencies request comments on all aspects of this proposed guidance, including, but not limited to, those set forth below.

Question 1: To what extent does the proposed credit review guidance reflect current sound practices for an institution's credit risk review activities? What elements should be added or removed, and why?

Question 2: To what extent is the proposed credit review guidance appropriate for institutions of all asset sizes? What elements should be added or removed for institutions of differing sizes, and why?

Question 3: What if any additional factors should the agencies consider incorporating into the guidance to help achieve a sufficient degree of independence and why? To what extent does the approach described for small or rural institutions with fewer resources or employees provide for an appropriate degree of independence in the credit review function? What if any modifications should the agencies consider and why?

IV. The Paperwork Reduction Act

In accordance with the requirements of the Paperwork Reduction Act of 1995 (PRA),[6] the agencies may not conduct or sponsor, and the respondent is not required to respond to, an information collection unless it displays a currently valid Office of Management and Budget (OMB) control number.

The proposed guidance will not create any new or revise any existing collections of information under the PRA. Therefore, no information collection request will be submitted to the OMB for review.

V. Proposed Guidance

The text of the proposed guidance is as follows:

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[1] *See* OCC Bulletin 2006–47 (December 13, 2006); FDIC Financial Institution Letter FIL–105–2006 (December 13, 2006); Federal Reserve Supervision and Regulation (SR) letter 06–17 (December 13, 2006); NCUA Accounting Bulletin No. 06–01 (December 2006).

[2] The Financial Accounting Standards Board's (FASB's) Accounting Standards Update 2016–13, *Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments* and subsequent amendments issued since June 2016 are codified in Accounting Standards Codification (ASC) Topic 326, *Financial Instruments—Credit Losses* (FASB ASC Topic 326). FASB ASC Topic 326 revises the accounting for the allowances for credit losses (ACLs) and introduces CECL. The proposed guidance on CECL is contained in a separate notice published in today's **Federal Register**.

[3] 12 CFR part 30, Appendix A (OCC); 12 CFR part 208 Appendix D–1 (Board); and 12 CFR part 364 Appendix A (FDIC). See Part 723 of the NCUA Rules and Regulations.

[4] For foreign banking organization branches, agencies, or subsidiaries not operating under single governance in the United States, the U.S. risk committee would serve in the role of the board of directors for purposes of this guidance.

[5] For purposes of this guidance, regulated institutions are those supervised by the following agencies: The Board of Governors of the Federal Reserve System (Board), the Federal Deposit Insurance Corporation (FDIC), the National Credit Union Administration (NCUA), and the Office of the Comptroller of the Currency (OCC).

[6] 44 U.S.C. 3501–3521.

INTERAGENCY GUIDANCE ON CREDIT RISK REVIEW SYSTEMS

Introduction

The *Interagency Guidelines Establishing Standards for Safety and Soundness* (Guidelines)[1] underscore the critical importance of credit risk review and set safety and soundness standards for insured depository institutions to establish a system for independent, ongoing credit risk review, and for appropriate communication to its management and board of directors.[2] This guidance, which aligns with the Guidelines, is appropriate for all institutions[3] and describes a broad set of practices that can be used either within a dedicated unit or across multiple units throughout an institution to form a credit risk review system that is consistent with safe-and-sound lending practices. This guidance outlines principles that an institution should consider in developing and maintaining an effective credit risk review system.

Overview of Credit Risk Review Systems

The nature of credit risk review systems[4] varies based on an institution's size, complexity, loan types, risk profile, and risk management practices. For example, in smaller or less complex institutions, a credit risk review system may include qualified members of the staff, including loan officers, other officers, or directors, who are independent of the credits being assessed. In larger or more complex institutions, a credit risk review system may include components of a dedicated credit risk review function that are independent of the institution's lending function. A credit risk review system may also include various responsibilities assigned to credit underwriting, loan administration, a problem loan workout group, or other organizational units of an institution. Among other responsibilities, these groups may administer the internal problem loan reporting process, maintain the integrity of the credit risk rating process, confirm that timely and appropriate changes are made to loan risk ratings, and support the quality of information used to estimate the Allowance for Credit Losses (ACL) or the Allowance for Loan and Lease Losses, (ALLL), as applicable.[5] Additionally, some or all of the credit risk review function may be outsourced to a qualified third party.

Regardless of the structure, an effective credit risk review system accomplishes the following objectives:

- Promptly identifies loans with actual and potential credit weaknesses so that timely action can be taken to strengthen credit quality and minimize losses.
- Appropriately validates and, if necessary, adjusts risk ratings, especially for those loans with potential or well-defined credit weaknesses that may jeopardize repayment.
- Identifies relevant trends that affect the quality of the loan portfolio and highlights segments of the loan portfolio that are potential problem areas.
- Assesses the adequacy of and adherence to internal credit policies and loan administration procedures and monitors compliance with applicable laws and regulations.
- Evaluates the activities of lending personnel, including their compliance with lending policies and the quality of their loan approval, monitoring, and risk assessment.
- Provides management and the board of directors with an objective, independent, and timely assessment of the overall quality of the loan portfolio.
- Provides management with accurate and timely credit quality information for financial and regulatory reporting purposes, including the determination of appropriate ACL or ALLL, as applicable.

Credit Risk Rating (or Grading) Framework

The foundation for any effective credit risk review system is accurate and timely risk ratings to assess credit quality and identify or confirm problem loans. An effective credit risk rating framework includes the monitoring of individual loans and retail portfolios, or segments thereof, with similar risk characteristics. An effective framework also provides important information on the collectibility of the portfolio for use in the determination of an appropriate ACL or ALLL, as applicable. Further, an effective framework generally places primary reliance on the lending staff to assign accurate and timely risk ratings and identify emerging loan problems. However, given the importance of the credit risk rating framework, the lending personnel's assignment of particular risk ratings is typically subject to review by qualified and independent: (i) Peers, managers, or loan committee(s); (ii) part-time or full-time employee(s); (iii) internal departments staffed with credit review specialists; or (iv) external credit review consultants. A risk rating review that is independent of the lending function and approval process can provide a more objective assessment of credit quality.[6]

An effective credit risk rating framework includes the following attributes:

- A formal credit risk rating system in which the ratings reflect the risk of default and credit losses, and for which a written description of the credit risk framework is maintained, including a

[1] 12 CFR part 30, Appendix A (OCC); 12 CFR part 208 Appendix D–1 (Board); and 12 CFR part 364 Appendix A (FDIC). Part 723 of NCUA Rules and Regulations.

[2] For foreign banking organization branches, agencies, or subsidiaries not operating under single governance in the United States, the U.S. risk committee would serve in the role of the board of directors for purposes of this guidance.

[3] For purposes of this guidance, regulated institutions are those supervised by the following agencies: The Board of Governors of the Federal Reserve System (Board), the Federal Deposit Insurance Corporation (FDIC), the National Credit Union Administration (NCUA), and the Office of the Comptroller of the Currency (OCC) hereafter referred to as the ''agencies.''

[4] The credit risk review function is not intended to be performed by an institutions' internal audit function. However, as discussed in the agencies' March 2003 *Interagency Policy Statement on the Internal Audit Function and its Outsourcing* (2003 policy statement), some institutions coordinate the internal audit function with several risk monitoring functions, such as the credit risk review function. The 2003 policy statement states that coordination of credit risk review with the internal audit function can facilitate the reporting of material risk and control issues to the audit committee, increase the overall effectiveness of these monitoring functions, better utilize available resources, and enhance the institution's ability to comprehensively manage risk. However, an effective internal audit function maintains the ability to independently audit the credit risk review function. (The NCUA was not an issuing agency of the 2003 policy statement.)

[5] Credit risk review may be referred to as loan review, credit review, asset quality review, or another name as chosen by an institution. The role of and expectations for credit risk review as discussed in this document are distinct from the roles and expectations for other groups within an institution that are also responsible for monitoring, managing and reporting credit risk. Examples may be those involved with lending functions, independent risk management, loan work outs, and accounting. Each institution indicates in its own policies and procedures the specific roles and responsibilities of these different groups, including separation of duties. A credit risk review unit, or individuals serving in that role, can rely on information provided by other units in developing its own independent assessment of credit risk in loan portfolios, but should critically evaluate such information to maintain its own view, and not rely exclusively on such information.

[6] Small or rural institutions that have few resources or employees may adopt modified credit risk review procedures and methods to achieve a proper degree of independence. For example, in the review process, such an institution may use qualified members of the staff, including loan officers, other officers, or directors, who are not involved with originating or approving the specific credits being assessed and whose compensation is not influenced by the assigned risk ratings. It is appropriate to employ such modified procedures when more robust procedures and methods are impractical. Institution management should have reasonable confidence that the personnel chosen will be able to conduct reviews with the needed independence despite their position within the loan function.

discussion of the factors used to assign appropriate risk ratings to individual loans and retail portfolios, or segments thereof, with similar risk characteristics.[7]

- Identification or grouping of loans that warrant the special attention of management or other designated ''watch lists'' of loans that management is more closely monitoring.[8]
- Clear explanation of why particular loans warrant the special attention of management or have received an adverse risk rating.
- Evaluation of the effectiveness of approved workout plans.
- A method for communicating direct, periodic, and timely information to the institution's senior management and the board of directors or appropriate board committee on the status of loans identified as warranting special attention or adverse classification, and the actions taken by management to strengthen the credit quality of those loans.
- Information on the institution's historical loss experience for each segment of the loan portfolio.[9]

Elements of an Effective Credit Risk Review System

An effective credit risk review system starts with a written credit risk review policy [10] that is reviewed and approved at least annually by the institution's board of directors or appropriate board committee to evidence its support of, and commitment to, maintaining an effective system. Effective policies include a description of the overall risk rating framework, and establish responsibilities for loan review based on the portfolio being assessed. An effective credit risk review policy addresses the following elements, described in more detail below: The qualifications and independence of credit risk review personnel; the frequency, scope, and depth of reviews; the review of findings and follow-up; and communication and distribution of results.

Qualifications of Credit Risk Review Personnel

An effective credit risk review function is staffed with personnel who are qualified based on their level of education, experience, and extent of formal credit training. Qualified personnel are knowledgeable in both sound lending practices and the institution's lending guidelines for the types of loans offered by the institution. The level of experience and expertise for all personnel involved in the credit risk review process is expected to be commensurate with the nature of the risk and complexity of the portfolios. In addition, qualified credit risk review personnel possess knowledge of relevant laws, regulations, and supervisory guidance.

Independence of Credit Risk Review Personnel

An effective credit risk review system uses both the initial identification of emerging problem loans by loan officers and other line staff, and an assessment of loans by personnel independent of the credit approval process. Placing primary responsibility on loan officers, risk officers, and line staff is important for continuous portfolio analysis and prompt identification and reporting of problem loans. Because of frequent contact with borrowers, loan officers and line staff can usually identify potential problems before they become apparent to others. However, institutions should be careful to avoid over-reliance on loan officers and line staff for identification of problem loans. An independent assessment of risk is achieved when personnel who perform the loan review do not have control over the loan and are not part of, or influenced by individuals associated with, the loan approval process.

While a larger institution may establish a separate department staffed with credit review specialists, cost and volume considerations may not justify such a system in a smaller institution. For example, in the review process, smaller institutions may use an independent committee of outside directors or qualified members of the staff, including loan officers, other officers, or directors, who are not involved with originating or approving the specific credits being assessed and whose compensation is not influenced by the assigned risk ratings. Whether or not the institution has a dedicated credit risk review department, it is prudent for the credit risk review function to report directly to the institution's board of directors or a committee thereof, consistent with safety and soundness standards. Senior management may be responsible for appropriate administrative functions provided such an arrangement does not compromise the independence of the credit risk review function.

The institution's board of directors, or a committee thereof, may outsource the credit risk review function to an independent third party.[11] However, the responsibility for maintaining a sound credit risk review process remains with the institution's board of directors. In any case, institution personnel who are independent from the lending function typically assess risks, develop the credit risk review plan, and verify appropriate follow-up of findings. Outsourcing of the credit risk review function to the institution's external auditor requires additional independence considerations.[12]

Frequency of Reviews

An effective credit risk review system provides for review and evaluation of an institution's significant loans, loan products, or groups of loans at least annually, on renewal, or more frequently when internal or external factors indicate a potential for deteriorating credit quality or the existence of one or more other risk factors. The credit risk review function can also provide useful continual feedback on the effectiveness of the

[7] A bank or savings association may have a credit risk rating framework that differs from the framework for loan classifications used by the federal banking agencies. Such banks and savings associations should maintain documentation that translates their risk ratings into the regulatory classification framework used by the federal banking agencies. This documentation will enable examiners to reconcile the totals for the various loan classifications or risk ratings under the institution's system to the federal banking agencies' categories contained in the Uniform Agreement on the Classification and Appraisal of Securities Held by Depository Institutions Attachment 1—Classification Definitions (OCC: OCC Bulletin 2013–28; Board: SR Letter 13–18; and FDIC: FIL–51–2013). The NCUA does not require credit unions to adopt a uniform regulatory classification system. Risk rating guidance for credit unions is set forth in NCUA letters to credit unions 10–CU–02, ''Current Risks in Business Lending and Sound Risk Management Practices,'' issued January 2010 and 10–CU–03, ''Concentration Risk,'' issued March 2010. *See also* the Commercial and Member Business Loans section of the NCUA *Examiner's Guide* (Commercial and Member Business Loans > Credit Risk Rating Systems).

[8] In addition to loans designated as ''watch list,'' this identification typically includes loans rated special mention, substandard, doubtful or loss.

[9] In particular, institutions with large and complex loan portfolios typically maintain records of their historical loss experience for credits in each of the categories in their risk rating framework. For banks and savings associations, these categories are either those used by, or those that can be translated into those used by, the federal banking agencies.

[10] *See* the Guidelines.

[11] For a discussion of the expectations for institutions that use outside service providers, refer to SR letter 13–19/CA letter 13–21, ''Guidance on Managing Outsourcing Risk,'' issued by the Board on December 5, 2013; FIL–44–2008, ''Guidance for Managing Third-Party Risk,'' issued by the FDIC on June 6, 2008; and OCC Bulletin 2013–29, ''Third-Party Relationships: Risk Management Guidance,'' issued by the OCC on October 30, 2013. For credit unions, refer to NCUA letters to credit unions 01–CU–20 ''Due Diligence over Third Party Service Providers,'' issued November 2001 and 07–CU–13 ''Evaluating Third Party Relationships'' issued December 2007.

[12] For further information with respect to restrictions for external auditors performing internal bank functions, refer to the Interagency Policy Statement on the Internal Audit Function and its Outsourcing, Part III Independence of the Independent Public Accountant.

lending process in order to identify any emerging problems. Ongoing or periodic review of an institution's loan portfolio is particularly important to the estimation of ACLs or the ALLL because loss expectations may change as the credit quality of a loan changes. Use of key risk indicators or performance metrics by credit risk review management can support adjustments to the frequency and scope of reviews.

Scope of Reviews

Comprehensive and effective reviews cover all segments of the loan portfolio that pose significant credit risk or concentrations, and other loans that meet certain institution-specific criteria. A properly designed scope considers the current market conditions or other external factors that may affect a borrower's current or future ability to repay the loan. Establishment of an appropriate review scope also helps ensure that the sample of loans selected for review is representative of the portfolio as a whole and provides reasonable assurance that any credit quality deterioration or unfavorable trends are identified. An effective credit risk review function also considers industry standards for credit risk review coverage consistent with the institution's size, complexity, loan types, risk profile, and risk management practices and helps to verify whether the review scope is appropriate. The institution's board of directors or appropriate board committee typically approves the scope of the credit risk review on an annual basis or whenever significant interim changes are made in order to adequately assess the quality of the current portfolio. An effective scope of credit risk review is generally risk-based and typically includes:

- Loans over a predetermined size.
- A sufficient sample of smaller loans, new loans, and new loan products.
- Loans with higher risk indicators, such as low credit scores, high credit lines, or those credits approved as exceptions to policy.
- Segments of the loan portfolio experiencing rapid growth.
- Exposures from non-lending activities that also pose credit risk.
- Past due, nonaccrual, renewed, and restructured loans.
- Loans previously adversely classified and loans designated as warranting the special attention of the institution's management.[13]
- Loans to insiders or related parties.
- Loans to affiliates.
- Loans constituting concentrations of credit risk and other loans affected by common repayment factors.

Depth of Transaction Reviews

Loans selected for review are typically evaluated for:

- Credit quality, soundness of underwriting and risk identification, borrower performance, and adequacy of the sources of repayment.
- Validity of assumptions.
- Creditworthiness of guarantors or sponsors.
- Sufficiency of credit and collateral documentation.
- Proper lien perfection.
- Proper approvals consistent with internal policies.
- Adherence to any loan agreement covenants.
- Compliance with internal policies and procedures (such as nonaccrual, and classification or risk rating policies), laws, and regulations.
- Quality of the information used in the credit loss estimation process, including the reasonableness of assumptions used and the timeliness of charge-offs.
- The accuracy of risk ratings and the appropriateness and timeliness of the identification of problem loans by loan officers.

Review of Findings and Follow-Up

An important activity of an effective credit risk review system is the discussion of the review findings, including all noted deficiencies, identified weaknesses, and any existing or planned corrective actions (including time frames for correction) with appropriate loan officers, department managers, and senior management. An effective system includes processes for all noted deficiencies and weaknesses that remain unresolved beyond the scheduled time frames for correction to be promptly reported to senior management and the board of directors or appropriate board committee.

It is important to resolve risk rating differences between loan officers and loan review personnel according to a pre-arranged process. That process may include formal appeals procedures and arbitration by an independent party or may require default to the assigned classification or grade that indicates lower credit quality. If credit risk review personnel conclude that a borrower is less creditworthy than is perceived by the institution, the lower credit quality classification or grade typically prevails unless internal parties identify additional information sufficient to obtain the concurrence of the independent reviewer or arbiter on the higher credit quality classification or grade.

Communication and Distribution of Results

Personnel involved in the credit risk review process typically prepare a list of all loans reviewed, the date of review, and a summary analysis that substantiates the risk ratings assigned to the loans reviewed. Effective communication involves providing results of the credit risk reviews to the board of directors or appropriate board committee at least quarterly.[14] Comprehensive reporting includes comparative trends that identify significant changes in the overall quality of the loan portfolio, the adequacy of, and adherence to, internal policies and procedures, the quality of underwriting and risk identification, compliance with laws and regulations, and management's response to substantive criticisms or recommendations. Such comprehensive reporting provides the board of directors or appropriate board committee with insight into the portfolio and the responsiveness of management and facilitates timely corrective action of deficiencies.

Dated: October 1, 2019

Joseph M. Otting,

Comptroller of the Currency.

By order of the Board of Governors of the Federal Reserve System, October 3, 2019.

Ann E. Misback,

Secretary of the Board.

Federal Deposit Insurance Corporation.

Dated at Washington, DC, on September 20, 2019.

Robert E. Feldman,

Executive Secretary.

By the National Credit Union Administration Board on September 20, 2019.

Gerard Poliquin,

Secretary of the Board.

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BILLING CODE 4810–33–P; 6210–01–P; 6714–01–P; 7535–01–P

[13] *See* footnote 8.

[14] A board of directors or appropriate board committee should be informed more frequently than quarterly when material adverse trends are noted. When an institution conducts loan file reviews less frequently than quarterly, the board or appropriate board committee will typically receive results on other credit risk review activities quarterly.

DEPARTMENT OF THE TREASURY

Office of the Comptroller of the Currency

FEDERAL RESERVE SYSTEM

FEDERAL DEPOSIT INSURANCE CORPORATION

Agency Information Collection Activities; Submission for OMB Review; Comment Request

AGENCY: Office of the Comptroller of the Currency (OCC), Treasury; Board of Governors of the Federal Reserve System (Board); and Federal Deposit Insurance Corporation (FDIC).

ACTION: Joint notice and request for comment.

SUMMARY: In accordance with the requirements of the Paperwork Reduction Act of 1995 (PRA), the OCC, the Board, and the FDIC (the agencies) may not conduct or sponsor, and the respondent is not required to respond to, an information collection unless it displays a currently valid Office of Management and Budget (OMB) control number. On June 25, 2019, the agencies, under the auspices of the Federal Financial Institutions Examination Council (FFIEC), requested public comment for 60 days on a proposal to extend for three years without revision the Market Risk Regulatory Report for Institutions Subject to the Market Risk Capital Rule (FFIEC 102), which is currently an approved collection of information for each agency. The comment period for the June 2019 notice ended on August 26, 2019. As described in the **SUPPLEMENTARY INFORMATION** section, no comments were received on the proposal; therefore, the FFIEC and the agencies will proceed with the extension of the FFIEC 102 as proposed. In addition, the agencies are giving notice that they are sending the collections to OMB for review.

DATES: Comments must be submitted on or before November 18, 2019.

ADDRESSES: Interested parties are invited to submit written comments to any or all of the agencies. All comments, which should refer to the OMB control number(s), will be shared among the agencies.

OCC: Commenters are encouraged to submit comments by email, if possible. You may submit comments, which should refer to ''1557–0325'' or ''FFIEC 102,'' by any of the following methods:

- *Email: prainfo@occ.treas.gov.*
- *Mail:* Chief Counsel's Office, Office of the Comptroller of the Currency, Attention: 1557–0100, 400 7th Street SW, Suite 3E–218, Washington, DC 20219.
- *Hand Delivery/Courier:* 400 7th Street SW, Suite 3E–218, Washington, DC 20219.

Instructions: You must include ''OCC'' as the agency name and ''1557–0325'' in your comment. In general, the OCC will publish comments on *www.reginfo.gov* without change, including any business or personal information provided, such as name and address information, email addresses, or phone numbers. Comments received, including attachments and other supporting materials, are part of the public record and subject to public disclosure. Do not include any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure.

You may review comments and other related materials that pertain to this information collection beginning on the date of publication of the second notice for this collection by any of the following methods:

- *Viewing Comments Electronically:* Go to *www.reginfo.gov.* Click on the ''Information Collection Review'' tab. Underneath the ''Currently under Review'' section heading, from the drop-down menu select ''Department of Treasury'' and then click ''submit''. This information collection can be located by searching by OMB control number ''1557–0325'' or ''FFIEC 102''. Upon finding the appropriate information collection, click on the related ''ICR Reference Number.'' On the next screen, select ''View Supporting Statement and Other Documents'' and then click on the link to any comment listed at the bottom of the screen.
- For assistance in navigating *www.reginfo.gov,* please contact the Regulatory Information Service Center at (202) 482–7340.
- *Viewing Comments Personally:* You may personally inspect comments at the OCC, 400 7th Street SW, Washington, DC. For security reasons, the OCC requires that visitors make an appointment to inspect comments. You may do so by calling (202) 649–6700 or, for persons who are deaf or hearing impaired, TTY, (202) 649–5597. Upon arrival, visitors will be required to present valid government-issued photo identification and submit to security screening in order to inspect comments.

Board: You may submit comments, which should refer to ''FFIEC 102,'' by any of the following methods:

- *Agency Website: http://www.federalreserve.gov.* Follow the instructions for submitting comments at: *http://www.federalreserve.gov/generalinfo/foia/ProposedRegs.cfm.*
- *Email: regs.comments@federalreserve.gov.* Include ''FFIEC 102'' in the subject line of the message.
- *Fax:* (202) 452–3819 or (202) 452–3102.
- *Mail:* Ann E. Misback, Secretary, Board of Governors of the Federal Reserve System, 20th Street and Constitution Avenue NW, Washington, DC 20551.

All public comments are available from the Board's website at *www.federalreserve.gov/generalinfo/foia/proposedregs.cfm* as submitted, unless modified for technical reasons. Accordingly, your comments will not be edited to remove any identifying or contact information. Public comments may also be viewed electronically or in paper form in Room N146, 1709 New York Avenue NW, Washington, DC 20006, between 9:00 a.m. and 5:00 p.m. on weekdays. For security reasons, the Board requires that visitors make an appointment to inspect comments. You may do so by calling (202) 452–3684. Upon arrival, visitors will be required to present valid government-issued photo identification and to submit to security screening in order to inspect and photocopy comments.

FDIC: You may submit comments, which should refer to ''FFIEC 102,'' by any of the following methods:

- *Agency Website: https://www.fdic.gov/regulations/laws/federal/.* Follow the instructions for submitting comments on the FDIC's website.
- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments.
- *Email: comments@FDIC.gov.* Include ''FFIEC 102'' in the subject line of the message.
- *Mail:* Manuel E. Cabeza, Counsel, Attn: Comments, Room 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 550 17th Street Building (located on F Street) on business days between 7:00 a.m. and 5:00 p.m.

Public Inspection: All comments received will be posted without change to *https://www.fdic.gov/regulations/laws/federal/* including any personal information provided. Paper copies of public comments may be requested from the FDIC Public Information Center, 3501 North Fairfax Drive, Arlington, VA 22226, or by telephone at (877) 275–3342 or (703) 562–2200.

Additionally, commenters may send a copy of their comments to the OMB desk officers for the agencies by mail to

the Office of Information and Regulatory Affairs, U.S. Office of Management and Budget, New Executive Office Building, Room 10235, 725 17th Street NW, Washington, DC 20503; by fax to (202) 395–6974; or by email to *oira_submission@omb.eop.gov.*

FOR FURTHER INFORMATION CONTACT: For further information about the information collections discussed in this notice, please contact any of the agency staff whose names appear below. In addition, copies of the FFIEC 102 reporting forms and instructions can be obtained at the FFIEC's website (*https://www.ffiec.gov/ffiec_report_forms.htm*).

OCC: Kevin Korzeniewski, Counsel, Chief Counsel's Office, (202) 649–5490, or for persons who are deaf or hearing impaired, TTY, (202) 649–5597.

Board: Nuha Elmaghrabi, Federal Reserve Board Clearance Officer, (202) 452–3884, Office of the Chief Data Officer, Board of Governors of the Federal Reserve System, 20th and C Streets NW, Washington, DC 20551. Telecommunications Device for the Deaf (TDD) users may call (202) 263–4869.

FDIC: Manuel E. Cabeza, Counsel, (202) 898–3767, Legal Division, Federal Deposit Insurance Corporation, 550 17th Street NW, Washington, DC 20429.

SUPPLEMENTARY INFORMATION: On June 25, 2019, the agencies requested public comment on a proposal to extend for three years, without revision, the FFIEC 102. The comment period expired on August 26, 2019 and no comments were received. The FFIEC and the agencies will proceed with the extension of the FFIEC 102 as proposed and the agencies are sending the collections to OMB for review.

Report Titles: Market Risk Regulatory Report for Institutions Subject to the Market Risk Capital Rule.

Form Numbers: FFIEC 102.

Frequency of Response: Quarterly.

Affected Public: Business or other for profit.

OCC

OMB Number: 1557–0325.

Estimated Number of Respondents: 13 national banks and federal savings associations.

Estimated Average Time per Response: 12 hours per quarter.

Estimated Total Annual Burden: 624 hours.

Board

OMB Number: 7100–0365.

Estimated Number of Respondents: 38 state member banks, bank holding companies, savings and loan holding companies, and intermediate holding companies.

Estimated Average Time per Response: 12 hours per quarter.

Estimated Total Annual Burden: 1,824 hours.

FDIC

OMB Number: 3064–0199.

Estimated Number of Respondents: 1 insured state nonmember bank and state savings association.

Estimated Average Time per Response: 12 hours per quarter.

Estimated Total Annual Burden: 48 hours.

General Description of Reports

The Market Risk Regulatory Report for Institutions Subject to the Market Risk Capital Rule (FFIEC 102) is filed quarterly with the agencies and provides information for market risk institutions, defined for this purpose as those institutions that are subject to the market risk capital rule as incorporated into Subpart F of the agencies' regulatory capital rule [1] (market risk institutions). Each market risk institution is required to file the FFIEC 102 for the agencies' use in assessing the reasonableness and accuracy of the institution's calculation of its minimum capital requirements under the market risk capital rule and in evaluating the institution's capital in relation to its risks. Additionally, the market risk information collected in the FFIEC 102: (a) Permits the agencies to monitor the market risk profile of, and evaluate the impact and competitive implications of, the market risk capital rule on individual market risk institutions and the industry as a whole; (b) provides the most current statistical data available to identify areas of market risk on which to focus for onsite and offsite examinations; (c) allows the agencies to assess and monitor the levels and components of each reporting institution's risk-based capital requirements for market risk and the adequacy of the institution's capital under the market risk capital rule; and (d) assists market risk institutions in validating their implementation of the market risk framework.

[1] *12 CFR 3.201* (OCC); *12 CFR 217.201* (Board); and *12 CFR 324.201* (FDIC). The market risk capital rule generally applies to any banking institution with aggregate trading assets and trading liabilities equal to (a) 10 percent or more of quarter-end total assets or (b) $1 billion or more.

Statutory Basis and Confidential Treatment

The quarterly FFIEC 102 information collection is mandatory for market risk institutions: 12 U.S.C. 161 (national banks), 12 U.S.C. 324 (state member banks), 12 U.S.C. 1844(c) (bank holding companies), 12 U.S.C. 1467a (b) (savings and loan holding companies), 12 U.S.C. 5365 (U.S. intermediate holding companies), 12 U.S.C. 1817 (insured state nonmember commercial and savings banks), and 12 U.S.C. 1464 (savings associations). The FFIEC 102 information collections are not given confidential treatment.

Request for Comment

The agencies invite comment on the following topics related to these collections of information:

(a) Whether the information collections are necessary for the proper performance of the agencies' functions, including whether the information has practical utility;

(b) The accuracy of the agencies' 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;

(d) Ways to minimize the burden of information collections on respondents, including through the use of automated collection techniques or other forms of information technology; and

(e) Estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Comments submitted in response to this joint notice will be shared among the agencies. All comments will become a matter of public record.

Dated: October 9, 2019.

Theodore J. Dowd,

Deputy Chief Counsel, Office of the Comptroller of the Currency.

Board of Governors of the Federal Reserve System, October 9, 2019.

Ann Misback,

Secretary of the Board.

Federal Deposit Insurance Corporation.

Dated at Washington, DC, on October 9, 2019.

Annmarie H. Boyd,

Assistant Executive Secretary.

[FR Doc. 2019–22654 Filed 10–16–19; 8:45 am]

BILLING CODE 4810–33–P; 6210–01–P; 6714–01–P

DEPARTMENT OF TREASURY

Office of the Comptroller of the Currency

[Docket ID OCC–2019–0021]

FEDERAL RESERVE SYSTEM

FEDERAL DEPOSIT INSURANCE CORPORATION

Reporting of Data on Loans to Small Businesses and Small Farms

AGENCY: Office of the Comptroller of the Currency (OCC), Treasury; Board of Governors of the Federal Reserve System (Board); and Federal Deposit Insurance Corporation (FDIC).

ACTION: Request for comment.

SUMMARY: The OCC, the Board, and the FDIC (collectively, the agencies) are requesting comment on ways to modify the current requirements for reporting data on loans to small businesses and small farms in the Consolidated Reports of Condition and Income (Call Report) so that the reported data better reflect lending to these sectors of the U.S. economy.

DATES: Comments must be received by the agencies no later than December 16, 2019.

ADDRESSES: Interested parties are invited to submit written comments to any or all of the agencies. All comments, which should refer to ''Loans to Small Businesses and Small Farms,'' will be shared among the agencies.

OCC: Commenters are encouraged to submit comments through the Federal eRulemaking Portal or email, if possible. You may submit comments by any of the following methods:

- *Federal eRulemaking Portal—Regulations.gov Classic or Regulations.gov Beta*

Regulations.gov Classic: Go to *https://www.regulations.gov/.* Enter ''Docket ID OCC–2019–0021'' in the Search Box and click ''Search.'' Click on ''Comment Now'' to submit public comments. For help with submitting effective comments please click on ''View Commenter's Checklist.'' Click on the ''Help'' tab on the *Regulations.gov* home page to get information on using *Regulations.gov*, including instructions for submitting public comments.

Regulations.gov Beta: Go to *https://beta.regulations.gov/* or click ''Visit New Regulations.gov Site'' from the *Regulations.gov* classic homepage. Enter ''Docket ID OCC–2019–0021'' in the Search Box and click ''Search.'' Public comments can be submitted via the ''Comment'' box below the displayed document information or click on the document title and click the ''Comment'' box on the top-left side of the screen. For help with submitting effective comments please click on ''Commenter's Checklist.'' For assistance with the *Regulations.gov* Beta site please call (877) 378–5457 (toll free) or (703) 454–9859 Monday–Friday, 9 a.m.–5 p.m. ET or email to *regulations@erulemakinghelpdesk.com.*

- *Email: regs.comments@occ.treas.gov.*
- *Mail:* Chief Counsel's Office, Attention: Comment Processing, Office of the Comptroller of the Currency, 400 7th Street SW, Suite 3E–218, Washington, DC 20219.
- *Hand Delivery/Courier:* 400 7th Street SW, Suite 3E–218, Washington, DC 20219.

Instructions: You must include ''OCC'' as the agency name and ''Docket ID OCC–2019–0021'' in your comment. In general, the OCC will enter all comments received into the docket and publish the comments on the *Regulations.gov* website without change, including any business or personal information provided such as name and address information, email addresses, or phone numbers. Comments received, including attachments and other supporting materials, are part of the public record and subject to public disclosure. Do not include any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure.

You may review comments and other related materials that pertain to this request for comment by any of the following methods:

- *Viewing Comments Electronically—Regulations.gov Classic or Regulations.gov Beta*

Regulations.gov Classic: Go to *https://www.regulations.gov/.* Enter ''Docket ID OCC–2019–0021'' in the Search box and click ''Search.'' Click on ''Open Docket Folder'' on the right side of the screen. Comments and supporting materials can be viewed and filtered by clicking on ''View all documents and comments in this docket'' and then using the filtering tools on the left side of the screen. Click on the ''Help'' tab on the *Regulations.gov* home page to get information on using *Regulations.gov.* The docket may be viewed after the close of the comment period in the same manner as during the comment period.

Regulations.gov Beta: Go to *https://beta.regulations.gov/* or click ''Visit New Regulations.gov Site'' from the *Regulations.gov* classic homepage. Enter ''Docket ID OCC–2019–0021'' in the Search Box and click ''Search.'' Click on the ''Comments'' tab. Comments can be viewed and filtered by clicking on the ''Sort By'' drop-down on the right side of the screen or the ''Refine Results'' options on the left side of the screen. Supporting Materials can be viewed by clicking on the ''Documents'' tab and filtered by clicking on the ''Sort By'' drop-down on the right side of the screen or the ''Refine Results'' options on the left side of the screen.'' For assistance with the *Regulations.gov* Beta site please call (877) 378–5457 (toll free) or (703) 454–9859 Monday–Friday, 9 a.m.–5 p.m. ET or email to *regulations@erulemakinghelpdesk.com.*

The docket may be viewed after the close of the comment period in the same manner as during the comment period.

- *Viewing Comments Personally:* You may personally inspect comments at the OCC, 400 7th Street SW, Washington, DC 20219. For security reasons, the OCC requires that visitors make an appointment to inspect comments. You may do so by calling (202) 649–6700 or, for persons who are deaf or hearing impaired, TTY, (202) 649–5597. Upon arrival, visitors will be required to present valid government-issued photo identification and submit to security screening in order to inspect comments.

Board: You may submit comments, which should refer to ''Loans to Small Businesses and Small Farms,'' by any of the following methods:

- *Agency Website: http://www.federalreserve.gov.* Follow the instructions for submitting comments at: *http://www.federalreserve.gov/generalinfo/foia/ProposedRegs.cfm.*
- *Email: regs.comments@federalreserve.gov.* Include ''Loans to Small Businesses and Small Farms'' in the subject line of the message.
- *Fax:* (202) 452–3819 or (202) 452–3102.
- *Mail:* Ann E. Misback, Secretary, Board of Governors of the Federal Reserve System, 20th Street and Constitution Avenue NW, Washington, DC 20551.

All public comments are available on the Board's website at *https://www.federalreserve.gov/apps/foia/proposedregs.aspx* as submitted, unless modified for technical reasons. Accordingly, your comments will not be edited to remove any identifying or contact information. Public comments may also be viewed electronically or in paper in Room 146, 1709 New York Avenue NW, Washington, DC 20006, between 9:00 a.m. and 5:00 p.m. on weekdays. For security reasons, the Board requires that visitors make an appointment to inspect comments. You may do so by calling (202) 452–3684. Upon arrival, visitors will be required to

present valid government-issued photo identification and to submit to security screening in order to inspect and photocopy comments.

FDIC: You may submit comments, which should refer to ''Loans to Small Businesses and Small Farms,'' by any of the following methods:

- *Agency Website: https://www.fdic.gov/regulations/laws/federal/.* Follow the instructions for submitting comments on the FDIC's website.
- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments.
- *Email: comments@FDIC.gov.* Include ''Loans to Small Businesses and Small Farms'' in the subject line of the message.
- *Mail:* Manuel E. Cabeza, Counsel, Attn: Comments, Room 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 550 17th Street Building (located on F Street) on business days between 7:00 a.m. and 5:00 p.m.

Public Inspection: All comments received will be posted without change to *https://www.fdic.gov/regulations/laws/federal/* including any personal information provided. Paper copies of public comments may be requested from the FDIC Public Information Center, 3501 North Fairfax Drive, Arlington, VA 22226, or by telephone at (877) 275–3342 or (703) 562–2200.

FOR FURTHER INFORMATION CONTACT:

OCC: Cady Codding, Senior Policy Accountant, Office of the Chief Accountant, (202) 649–5764; Kevin Korzeniewski, Counsel, Chief Counsel's Office, (202) 649–5490; or for persons who are deaf or hearing impaired, TTY, (202) 649–5597.

Board: Douglas Carpenter, Senior Supervisory Financial Analyst, Division of Supervision and Regulation, (202) 452–2205, Board of Governors of the Federal Reserve System, 20th and C Streets NW, Washington, DC 20551.

FDIC: Shannon Beattie, Chief, Accounting and Securities Disclosure Section, Division of Risk Management Supervision, (202) 898–3952, *sbeattie@fdic.gov;* or Michelle Haslett, Examination Specialist, Division of Risk Management Supervision, (202) 898–6923, *mhaslett@fdic.gov.*

SUPPLEMENTARY INFORMATION:

I. Background, Existing Collection, and Use of Data

A. History of the Data Collection

Section 122 of the Federal Deposit Insurance Corporation Improvement Act of 1991 [1] required the agencies to establish an annual data collection from insured depository institutions on lending to small businesses and small farms. The agencies implemented the statute by introducing Schedule RC–C, Part II, to the Call Report [2] effective June 30, 1993.[3] Initially, this schedule was completed annually as of every June 30. However, to improve the agencies' ability to assess the availability of credit to small businesses and small farms in the aftermath of the financial crisis, the agencies changed the reporting frequency for Schedule RC–C, Part II, from annually to quarterly beginning with the March 31, 2010, Call Report.[4] In 2017, as part of the Federal Financial Institutions Examination Council's Call Report burden reduction initiative, the agencies reduced the reporting frequency of Schedule RC–C, Part II, from quarterly to semiannually for institutions that file the FFIEC 051 Call Report.[5] The reporting frequency of Schedule RC–C, Part II, remains quarterly for institutions that file the FFIEC 031 and the FFIEC 041 Call Report.[6]

B. Data Currently Collected

The current data collection in Schedule RC–C, Part II, generally requests information on (i) loans to small businesses, which are defined as loans with original amounts of $1 million or less that are reported as ''Loans secured by nonfarm nonresidential properties'' or ''Commercial and industrial loans'' (in domestic offices) in Call Report Schedule RC–C, Part I, items 1.e and 4; and (ii) loans to small farms, which are defined as loans with original amounts of $500,000 or less that are reported as ''Loans secured by farmland (including farm residential and other improvements)'' and ''Loans to finance agricultural production and other loans to farmers'' (in domestic offices) in Call Report Schedule RC–C, Part I, items 1.b and 3. The agencies currently request the total number and total amount outstanding for each of these four categories of loans, which are stratified into three segments based on the original amounts of the loans. For loans to small businesses, the stratifications are original amounts of $100,000 or less, original amounts of more than $100,000 through $250,000, and original amounts of more than $250,000 through $1 million. For loans to small farms, the stratifications are original amounts of less than $100,000, original amounts of more than $100,000 through $250,000, and original amounts of more than $250,000 through $500,000.

Institutions that do not hold loans that meet the definition of small business or small farm loans do not need to provide data in Schedule RC–C, Part II, for that particular type of loan. Institutions that file the FFIEC 041 or the FFIEC 051 Call Report and hold small business or small farm loans predominantly in original amounts of $100,000 or less report only the total number of the loans in each loan category within that particular type of loan, and do not need to provide the full stratification. Further details about the collection of loans to small businesses and small farms are provided in the applicable Call Report instructions (FFIEC 031, FFIEC 041, or FFIEC 051).[7]

C. Uses of the Data

Among the agencies, the Board is the primary user of the data collected on loans to small businesses and small farms.[8] Collection of these data improves the Board's ability to monitor credit conditions facing small businesses and small farms and significantly contributes to its ability to develop policies intended to address any problems that arise in credit markets. The institution-level Call Report data provide information that cannot be obtained from other indicators of small business and small farm credit conditions. For example, during a period of credit contraction, the Call Report data can be used to identify which types of institutions are reducing the volume of their loans to small businesses and small farms. Having detailed data on the characteristics of affected institutions is crucial to building a sufficiently informative picture of the strength of economic activity.

Monetary policymaking benefits importantly from timely information on

[1] 12 U.S.C. 1817 note.

[2] The ''Call Report'' consists of the Consolidated Reports of Condition and Income for a Bank with Domestic and Foreign Offices (FFIEC 031), the Consolidated Reports of Condition and Income for a Bank with Domestic Offices Only (FFIEC 041), and the Consolidated Reports of Condition and Income for a Bank with Domestic Offices Only and Total Assets Less than $5 Billion (FFIEC 051). U.S. branches and agencies of foreign banks file the Report of Assets and Liabilities of U.S. Branches and Agencies of Foreign Banks (FFIEC 002). The FFIEC 002 includes Schedule C, Part II, Loans to Small Businesses and Small Farms, which is collected only from insured U.S. branches of foreign banks and parallels Call Report Schedule RC–C, Part II.

[3] 57 FR 54235 (November 17, 1992).

[4] 74 FR 68322 (December 23, 2009).

[5] 82 FR 2444 (January 9, 2017).

[6] In the FFIEC 002, Schedule C, Part II, is collected annually as of June 30 from insured U.S. branches of foreign banks.

[7] *https://www.ffiec.gov/ffiec_report_forms.htm.*

[8] *See* 82 FR 2444, 2454 (January 9, 2017).

small business credit conditions and flows. To determine how best to adjust the federal funds rate over time, the Board must continuously assess the prospects for real economic activity and inflation in coming quarters. Credit conditions have an important bearing on the evolution of those prospects over time, and so the Board pays close attention to data from Call Reports. In trying to understand the implications of aggregate credit data for the macroeconomic outlook, it is helpful for the Board to be able to distinguish between conditions facing small firms and those affecting other businesses for several reasons. First, small businesses comprise a substantial portion of the nonfinancial business sector, and so their hiring and investment decisions have an important influence on overall real activity. Second, because small businesses tend to depend more heavily on depository institutions for external financing, they likely experience material swings in their ability to obtain credit relative to larger firms. Third, the relative opacity of small businesses and their consequent need to provide collateral for loans is thought to create a ''credit'' channel for monetary policy to influence real activity. Specifically, changes in monetary policy may alter the value of assets used as collateral for loans, thereby affecting the ability of small businesses to obtain credit, abstracting from the effects of any changes in loan rates. Finally, the credit conditions facing small businesses and small farms differ substantially from those facing large businesses, making it necessary to collect indicators that are specific to these borrowers. Large businesses may access credit from a number of different sources, including the corporate bond market and the commercial paper market. In contrast, small businesses and small farms rely more heavily on credit provided through depository institutions. The dependence of small businesses and small farms on lending by depository institutions—particularly from smaller institutions—highlights the importance of the Call Report data reported in Schedule RC–C, Part II.

II. Current Actions

A. GAO Report

The U.S. Government Accountability Office (GAO) reviewed the data collected on Call Report Schedule RC–C, Part II, Loans to Small Businesses and Small Farms, as part of a study of the effect of regulations on small business lending.[9] In summarizing its findings with respect to the Call Report data on loans to small businesses, the GAO stated that

> [t]he data community banks report to regulators do not accurately capture lending to small businesses because the data exclude some loans to small businesses. Specifically, the definition of small business loans used for banks' reporting excludes loans greater than $1 million and has not been adjusted for inflation since 1992. In addition, the data capture loans by their size rather than the size of the borrowing entity, and therefore could include small loans to large businesses. These limitations hamper regulators' and policymakers' ability to assess actual changes in banks' small business lending, including any effect of regulation.

At the conclusion of this study, which was published in August 2018, the GAO recommended that the agencies should collaborate to reevaluate, and modify as needed, the requirements for the data banks report in the Call Report to better reflect lending to small businesses.

In response to this recommendation, the agencies are reviewing the data currently collected on small business and small farm loans on Schedule RC–C, Part II, in the Call Report to identify options for improving the usefulness of the data reported on these loans so that the data will better reflect lending to small businesses and small farms.

The agencies also recognize that institutions already have processes in place that enable them to report their small business and small farm lending data in the Call Report in accordance with the reporting instructions for Schedule RC–C, Part II, which generally have not been revised since the implementation of Schedule RC–C, Part II, in 1993. Thus, introducing revisions to the reporting requirements and the instructions for Schedule RC–C, Part II, could affect the burden of the collection of small business and small farm lending data on institutions. Certain options for revisions may change burden in differing ways, particularly if the options are not aligned with how institutions currently identify loans to small businesses and small farms and then collect and report data on these loans to their managements or internal purposes. The agencies are interested in learning what data institutions collect and maintain on small business and small farm loans in their loan systems and other automated systems for internal purposes in addition to the data required to be reported on these loans in Call Report Schedule RC–C, Part II, and how institutions are using these data internally, to identify which options may improve the usefulness of the Call Report data collection while considering the burden impact of any adjustments to the current reporting requirements for Schedule RC–C, Part II. The agencies will use the feedback received in response to this request for comment to assess what steps they should take in response to the recommendation from the GAO. After considering the feedback, if the agencies determine that a change to the existing collection of small business and small farm lending data in Schedule RC–C, Part II, is warranted, the agencies would seek further comment on a specific proposal to revise this Call Report schedule in accordance with the Paperwork Reduction Act.[10]

B. Request for Comment

General Questions on Data

1. How do institutions internally report on their small business and small farm loan portfolios? What key indicator(s) do institutions use to define and monitor small business and small farm loan originations each quarter? Do institutions further subcategorize these loan portfolios based on initial loan size or other factors (such as the borrower's gross annual revenue or the borrower's number of employees)? In responding to these questions, commenters from banks and savings associations are encouraged to describe the internal reporting practices, key indicator(s), and any subcategorization at their individual institution.

2. What data do institutions regularly collect from small businesses and small farms related to outstanding loans or commitments (such as gross annual revenues or asset size)? In responding to this question, commenters from banks and savings associations are encouraged to identify the data their institution regularly collects.

Questions Related to the Current Collection

3. As described in Section I.B. above, the agencies' collection classifies and stratifies loans as small business or small farm loans based on the original amounts of the loans. The maximum original amounts used to determine this classification have not changed since Schedule RC–C, Part II, took effect in 1993.

a. Should the agencies consider increasing the maximum original loan amounts for the reporting of loans to small businesses and small farms

[9] *See* Community Banks: Effect of Regulations on Small Business Lending and Institutions Appears Modest, but Lending Data Could Be Improved (GAO–18–312).

[10] 44 U.S.C. chapter 35.

(currently $1 million and $500,000, respectively)? If so, what would be appropriate maximum original amounts for each type of loan?

b. Should the agencies continue to require loan stratification by original loan amount or just collect total amounts for small business and small farm loans without stratification? If the former and the maximum original loan amounts were increased, what would be appropriate original loan amounts for stratification?

c. Should the agencies incorporate an automatic or periodic adjustment for inflation for the maximum original loan amounts going forward?

4. Should the agencies raise the original amount threshold (currently $100,000) for identifying institutions that hold small business or small farm loans with original amounts predominantly below that threshold that would not need to complete the full stratification in Schedule RC–C, Part II?

5. Should the agencies exempt institutions that hold less than a certain number or total amount of small business or small farm loans from reporting data on these loans in Schedule RC–C, Part II? If so, what would be an appropriate threshold for exemption and why?

Questions on Alternate Approaches

6. Should the agencies consider using other business and farm size indicators to identify or stratify loans, *e.g.,* the borrower's gross annual revenues or asset size, or should the agencies combine original loan amounts with one or more of these other indicators to identify or stratify loans?

a. Would other indicators provide a better measure to identify small business and small farm loans than the original loan amount? If so, which indicators?

b. Are such indicator data available back to the origination dates of existing loans? If so, are the data available in your institution's automated loan systems or in manual form, *e.g.,* in individual borrowers' loan files?

c. If only current indicator data are available, would the current data generally be representative of what the indicator data would have been at origination? Are the current indicator data available in your institution's automated loan systems or in manual form?

7. Should the agencies consider referencing other recognized standards for small business classification, such as the U.S. Small Business Administration's size thresholds for small businesses, as a way to identify or stratify loans? [11]

8. Should the agencies consider collecting data only on new loans made during the reporting period (*i.e.,* originations) instead of data on total loans outstanding as of the end of the reporting period regardless of when originated?

9. Are there other approaches the agencies should consider for the identification of, and the collection of information on, small business or small farm loans?

Questions on Potential Challenges and Burden

10. What provisions of the existing Schedule RC–C, Part II, instructions, including the definitions of loans to small businesses and loans to small farms, create difficulties for your institution in reporting in this schedule today? How might the agencies address these issues to reduce reporting burden?

11. What challenges or burden would your institution experience under each of the various options to revise the collection of small business and small farm loan data (*i.e.,* raise existing original amount thresholds; use new indicators to identify small business and small farm loans outstanding as of the end of the reporting period regardless of when the loans were acquired (originated or purchased); use a combination of existing or higher original amount thresholds and new indicators for identifying and stratifying loans outstanding as of the end of the reporting period; collect data only on loan originations during the reporting period rather than total loans outstanding as of the end of the reporting period)?

a. How would burden be affected if a revised method for identifying and reporting small business and small farm loans applies only to loans acquired after the date the revised method takes effect and the collection of data excludes loans held when the revised method takes effect?

b. How would burden be affected if loans acquired after the date the revised method takes effect are reported under a revised method while loans held when the revised method takes effect continue to be reported under the existing Schedule RC–C, Part II, framework, *i.e.,* only by original loan amount?

c. If a revised method were to be used for identifying loans to be reported in Schedule RC–C, Part II, how much lead time would your institution need before you would be prepared to begin reporting under this revised method? How would lead times differ for the various options referenced above in this question?

[11] *See* 13 CFR 121.201.

Dated: October 10, 2019.

Morris R. Morgan,

First Deputy Comptroller, Comptroller of the Currency.

Board of Governors of the Federal Reserve System, October 7, 2019.

Ann Misback,

Secretary of the Board.

Federal Deposit Insurance Corporation.

Dated at Washington, DC, on October 8, 2019.

Annmarie H. Boyd,

Assistant Executive Secretary.

[FR Doc. 2019–22568 Filed 10–16–19; 8:45 am]

BILLING CODE 4810–33–P; 6210–01–P; 6714–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Form Project

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Internal Revenue Service, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on continuing information collections, as required by the Paperwork Reduction Act of 1995. The IRS is soliciting comments concerning gas guzzler tax.

DATES: Written comments should be received on or before December 16, 2019 to be assured of consideration.

ADDRESSES: Direct all written comments to Dr. Philippe Thomas, Internal Revenue Service, Room 6529, 1111 Constitution Avenue NW, Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form should be directed to Kerry Dennis, at (202) 317–5751 or Internal Revenue Service, Room 6529, 1111 Constitution Avenue NW, Washington, DC 20224, or through the internet, at *Kerry.Dennis@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Gas Guzzler Tax.

OMB Number: 1545–0242.

Form Number: Form 6197.

Abstract: Internal Revenue Code section 4064 imposes a gas guzzler tax on the sale, use, or first lease by a manufacturer or first lease by a manufacturer or importer of automobiles whose fuel economy does

not meet certain standards for fuel economy. The tax is computed on Form 6197. The IRS uses the information to verify computation of tax and compliance with the law.

Current Actions: There are no changes being made to the form at this time.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations and individuals or households.

Estimated Number of Respondents: 605.

Estimated Time per Respondent: 7 hours, 42 minutes.

Estimated Total Annual Burden Hours: 4,659 hours.

The following paragraph applies to all of the collections of information covered by this notice.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the 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 collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: October 10, 2019.

Philippe Thomas,

Supervisor Tax Analyst.

[FR Doc. 2019–22575 Filed 10–16–19; 8:45 am]

BILLING CODE 4830–01–P

U.S.-CHINA ECONOMIC AND SECURITY REVIEW COMMISSION

Notice of Open Public Event

AGENCY: U.S.-China Economic and Security Review Commission.

ACTION: Notice of open public event.

SUMMARY: Notice is hereby given of the following open public event of the U.S.-China Economic and Security Review Commission.

The Commission is mandated by Congress to investigate, assess, and report to Congress annually on ''the national security implications of the economic relationship between the United States and the People's Republic of China.'' Pursuant to this mandate, the Commission will hold a public release of its 2019 Annual Report to Congress in Washington, DC on November 14, 2019.

DATES: The release is scheduled for Thursday, November 14, 2019 from 10:00 a.m. to 11:00 a.m.

ADDRESSES: Hart Senate Office Building, Room 902, Washington, DC. Please check the Commission's website at *www.uscc.gov* for possible changes to the event schedule. Reservations are not required to attend.

FOR FURTHER INFORMATION CONTACT: Any member of the public seeking further information concerning the event should contact Leslie Tisdale Reagan, 444 North Capitol Street NW, Suite 602, Washington DC 20001; telephone: 202–624–1496, or via email at *lreagan@uscc.gov*. *Reservations are not required to attend.*

ADA Accessibility: For questions about the accessibility of the event or to request an accommodation, please contact Leslie Tisdale Reagan at 202–624–1496, or via email at *lreagan@uscc.gov*. Requests for an accommodation should be made as soon as possible, and at least five business days prior to the event.

SUPPLEMENTARY INFORMATION:

Topics To Be Discussed: The Commission's 2019 Annual Report to Congress addresses key findings and recommendations for Congressional action based upon the Commission's hearings, research, travel, and review of the areas designated by Congress in its mandate, including focused work this year on: China's internal and external challenges; artificial intelligence, new materials, and new energy; U.S. companies in China and Chinese companies in the United States.; health and pharmaceuticals; China's ambitions to build a ''world-class'' military; China-Russia relations; China's ambitions in space; Taiwan; Hong Kong; changing regional dynamics in Oceania and Singapore; and a review of economics, trade, security, political, and foreign affairs developments in 2019.

Authority: Congress created the U.S.-China Economic and Security Review Commission in 2000 in the National Defense Authorization Act (Pub. L. 106–398), as amended by Division P of the Consolidated Appropriations Resolution, 2003 (Pub. L. 108–7), as amended by Public Law 109–108 (November 22, 2005), as amended by Public Law 113–291 (December 19, 2014).

Dated: October 11, 2019.

Daniel W. Peck,

Executive Director, U.S.-China Economic and Security Review Commission.

[FR Doc. 2019–22653 Filed 10–16–19; 8:45 am]

BILLING CODE 1137–00–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0784]

Agency Information Collection Activity Under OMB Review: Application for Pre-Need Determination of Eligibility for Burial

AGENCY: National Cemetery Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA) of 1995, this notice announces that the National Cemetery Administration (NCA), 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: Comments must be submitted on or before November 18, 2019.

ADDRESSES: Submit written comments on the collection of information through *www.Regulations.gov*, or to Office of Information and Regulatory Affairs, Office of Management and Budget, Attn: VA Desk Officer; 725 17th St. NW, Washington, DC 20503 or sent through electronic mail to *oira_submission@omb.eop.gov.* Please refer to ''OMB Control No. 2900–0784'' in any correspondence.

FOR FURTHER INFORMATION CONTACT: Cynthia Harvey-Pryor at (202) 461–5870 or FAX (202) 501–2240.

SUPPLEMENTARY INFORMATION:

Authority: Public Law 104–13; 44 U.S.C. 3501–21.

Title: Application for Pre-Need Determination of Eligibility for Burial, VA Form 40–10007.

OMB Control Number: 2900–0784.

Type of Review: Revision of an approved collection.

Abstract: VA Form 40–10007 is used to collect information from Veterans and service members who wish to determine their eligibility for burial in a VA national cemetery prior to their time of need for planning purposes. The data will be used for this purpose.

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 Vol. 84, No. 155, Monday, August 12, 2019, pages 39893 and 39894.

Affected Public: Individuals or Households.

Estimated Number of Respondents: 47,400.

Estimated Average Burden per Respondent: 20 minutes.

Frequency of Response: One time.

Estimated Annual Burden: 15,800 hours.

By direction of the Secretary.

Danny S. Green,

Interim Department Clearance Officer, Office of Quality, Privacy and Risk, Department of Veterans Affairs.

[FR Doc. 2019–22687 Filed 10–16–19; 8:45 am]

BILLING CODE 8320–01–P

FEDERAL REGISTER

Vol. 84 Thursday,

No. 201 October 17, 2019

Part II

Department of Health and Human Services

Office of Inspector General

42 CFR Parts 1001 and 1003

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Part 411

Medicare and State Healthcare Programs: Fraud and Abuse; Revisions To Safe Harbors Under the Anti-Kickback Statute, And Civil Monetary Penalty Rules Regarding Beneficiary Inducements; Medicare Program; Modernizing and Clarifying the Physician Self-Referral Regulations; Proposed Rules

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

42 CFR Parts 1001 and 1003

RIN 0936–AA10

Medicare and State Healthcare Programs: Fraud and Abuse; Revisions To Safe Harbors Under the Anti-Kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducements

AGENCY: Office of Inspector General (OIG), Department of Health and Human Services (HHS).

ACTION: Proposed rule.

SUMMARY: This proposed rule is being issued by the Office of Inspector General (OIG) in conjunction with the Department of Health and Human Services' Regulatory Sprint to Coordinated Care. It proposes to add, on a prospective basis only after a final rule is issued, safe harbor protections under the Federal anti-kickback statute for certain coordinated care and associated value-based arrangements between or among clinicians, providers, suppliers, and others that squarely meet all safe harbor conditions. It also would add protections under the anti-kickback statute and civil monetary penalty (CMP) law that prohibits inducements offered to patients for certain patient engagement and support arrangements to improve quality of care, health outcomes, and efficiency of care delivery that squarely meet all safe harbor conditions. The proposed rule would add a new safe harbor for donations of cybersecurity technology and amend the existing safe harbors for electronic health records (EHR) arrangements, warranties, local transportation, and personal services and management contracts. Further, the proposed rule would add a new safe harbor pursuant to a statutory change set forth in the Bipartisan Budget Act of 2018 (Budget Act of 2018) related to beneficiary incentives under the Medicare Shared Savings Program and a new CMP exception for certain telehealth technologies offered to patients receiving in-home dialysis, also pursuant to the Budget Act of 2018.

DATES: To ensure consideration, comments must be delivered to the address provided below by 5 p.m. on December 31, 2019. The 75-day period for public comments being set forth in this proposed rule will serve to protect the public's interest in this rulemaking process by allowing for an opportunity for additional input and recommendations, without unduly delaying any final rulemaking.

ADDRESSES: In commenting, please reference file code OIG–0936–AA10–P. Because of staff and resource limitations, we cannot accept comments by facsimile (fax) transmission. However, you may submit comments using one of three ways (no duplicates, please):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the ''Submit a comment'' instructions.

2. *By regular, express, or overnight mail.* You may send written comments to the following address: Office of Inspector General, Department of Health and Human Services, Attention: OIG–0936–AA10–P, Room 5521, Cohen Building, 330 Independence Avenue SW, Washington, DC 20201.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By hand or courier.* If you prefer, you may deliver your written comments by hand or courier before the close of the comment period to: Office of Inspector General, Department of Health and Human Services, Cohen Building, Room 5521, 330 Independence Avenue SW, Washington, DC 20201.

Because access to the interior of the Cohen Building is not readily available to persons without Federal Government identification, commenters are encouraged to schedule their delivery with one of our staff members at (202) 619–0335.

Inspection of Public Comments: All comments received before the end of the comment period will be posted on *http://www.regulations.gov* for public viewing. Hard copies will also be available for public inspection at the Office of Inspector General, Department of Health and Human Services, Cohen Building, 330 Independence Avenue SW, Washington, DC 20201, Monday through Friday from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone (202) 619–0335.

FOR FURTHER INFORMATION CONTACT: Jillian Sparks or Meredith Williams, (202) 619–0335.

SUPPLEMENTARY INFORMATION:

Social Security Act citation	United States Code citation
1128B, 1128D, 1102, 1128A.	42 U.S.C. 1320a–7b, 42 U.S.C. 1320a–7d, 42 U.S.C. 1302, 42 U.S.C. 1320a.–7a.

I. Executive Summary

A. Purpose and Need for Regulatory Action

The Secretary of Health and Human Services (the Secretary) has identified transforming our healthcare system to one that pays for value as one of the top priorities of the Department of Health and Human Services (the Department or HHS). Unlike the traditional fee-for-service (FFS) payment system, which rewards providers for the volume of care delivered, a value-driven healthcare system is one that pays for health and outcomes. Delivering better value from our healthcare system will require the transformation of established practices and enhanced collaboration among providers and other individuals and entities. The purpose of this proposed rule is to modify existing safe harbors to the anti-kickback statute and add new safe harbors and a new CMP law exception to remove potential barriers to more effective coordination and management of patient care and delivery of value-based care that improves quality of care, health outcomes, and efficiency.

Since the enactment in 1972 of the Federal anti-kickback statute, there have been significant changes in the delivery of, and payment for, healthcare items and services within the Medicare and Medicaid programs and for non-Federal payors and patients. This has included changes to traditional FFS Medicare (*i.e.,* Medicare Parts A and B), Medicare Advantage, and states' Medicaid programs. For some time, the Department has worked to align payment under the Medicare program with the quality of the care provided to Federal health care program beneficiaries. Laws such as the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA),[1] the Deficit Reduction Act of 2005 (DRA),[2] and the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA)[3] are among statutes that guided the Department's efforts to move toward healthcare delivery and payment reform. The Patient Protection and Affordable Care Act (ACA)[4] required or encouraged significant changes to the Medicare program's payment systems and provided the Secretary with broad authority to test and implement models to promote reforms, including through the Center for Medicare and Medicaid

[1] Public Law 108–173, 117 Stat. 2066.

[2] Public Law 109–171, 120 Stat. 4.

[3] Public Law 110–275, 122 Stat. 2494.

[4] Public Law 111–148, 124 Stat. 119, as amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152, 124 Stat. 1029).

Innovation (the Innovation Center) within the Centers for Medicare & Medicaid Services (CMS).[5]

The Department has identified the broad reach of the Federal anti-kickback statute [6] and the CMP law provision prohibiting inducements to beneficiaries, the ''beneficiary inducements CMP,'' [7] as well as the Federal physician self-referral law (sometimes known as the Stark law),[8] as potentially inhibiting beneficial arrangements that would advance the transition to value-based care and improve the coordination of patient care among providers and across care settings in both the Federal health care programs and commercial sectors. Industry stakeholders have informed the Department that, because the consequences of potential noncompliance with the physician self-referral law and the Federal anti-kickback statute could be dire, providers, suppliers, and others may be discouraged from entering into innovative arrangements that would improve quality and health outcomes, produce health system efficiencies, and lower costs (or slow their rate of growth).

To address these concerns and accelerate the transformation of the healthcare system into one that better pays for value and promotes care coordination, HHS launched a Regulatory Sprint to Coordinated Care (Regulatory Sprint), led by the Deputy Secretary. This Regulatory Sprint aims to remove potential regulatory barriers to care coordination and value-based care created by four key healthcare laws and associated regulations: (i) The physician self-referral law, (ii) the Federal anti-kickback statute, (iii) the Health Insurance Portability and Accountability Act of 1996 (HIPAA),[9] and (iv) rules under 42 CFR part 2 related to substance use disorder treatment.

Through the Regulatory Sprint, HHS aims to encourage and improve:

- A patient's ability to understand treatment plans and make empowered decisions;
- providers' alignment on end-to-end treatment (*i.e.,* coordination among providers along the patient's full care journey);
- incentives for providers to coordinate, collaborate, and provide patients tools to be more involved in their own care; and
- information sharing among providers, facilities, and other stakeholders in a manner that facilitates efficient care while preserving and protecting patient access to data.

In connection with the Regulatory Sprint, OIG issued a request for information (OIG RFI) regarding the Federal anti-kickback statute and beneficiary inducements CMP on August 27, 2018.[10] CMS published a Request for Information Regarding the Physician Self-Referral Law in June 2018 (CMS RFI).[11] In the OIG RFI, we sought feedback on ways in which we might modify or add new safe harbors to the Federal anti-kickback statute and exceptions to the beneficiary inducements CMP definition of ''remuneration'' to foster arrangements that would promote care coordination and advance the delivery of value-based care while also protecting patients and taxpayer dollars against harms caused by fraud and abuse. OIG received 359 comments in response to its RFI from a variety of individuals and organizations.

While most commenters strongly asserted the need for regulatory reform to the anti-kickback statute safe harbors and exceptions to the definition of ''remuneration'' under the beneficiary inducements CMP, a number of commenters acknowledged that increased regulatory flexibility could create program integrity vulnerabilities or increase the risk of harms associated with fraud and abuse and urged OIG to exercise caution and include adequate safeguards in any regulatory proposals. Comments supporting regulatory reform encompassed a number of themes, including requests for:

- New safe harbors protecting financial arrangements among parties participating in alternative payment models (APMs), value-based arrangements, and care coordination activities;
- safe harbor protection for financial arrangements with entities not participating in Innovation Center models, including commercial and self-pay APM arrangements;
- additional protection for patient tools and supports, such as in-kind items and services to support patient compliance with discharge and care plans, services and supports to address unmet social needs affecting health, and expanded protections under the local transportation safe harbor;
- enhanced safe harbor protection for transfers of information technology, data, and cybersecurity tools;
- modifications to the current ''patchwork'' fraud and abuse waiver framework for Innovation Center models and the Medicare Shared Savings Program; and
- a variety of protections for pharmaceutical and medical device manufacturer arrangements, including broad protections for drug and medical device manufacturer participation in value-based contracts, pricing arrangements, warranty arrangements, and APMs, as well as protection for coupons and other means of direct copayment assistance to Medicare Part D beneficiaries in certain situations.

B. Summary of OIG's Approach and Proposals

These proposed regulations are informed by comments and other internal and external sources of information, as well as our experience interpreting and applying the safe harbors and beneficiary inducements CMP exceptions to a wide variety of arrangements. In developing this proposed rule, OIG has followed several guiding principles. The first guiding principle has been to design proposed safe harbors that allow for beneficial innovations in healthcare delivery. The second guiding principle has been to avoid promulgating safe harbors and exceptions that drive such innovation to limited channels that may not reflect up-to-date understandings in medicine, science, and technology. The third guiding principle has been to design proposed safe harbors useful for a range of individuals and entities engaged in the coordination and management of patient care, including large and small practices and health systems, rural and urban providers and suppliers, primary care physicians and specialists, providers and suppliers contracting with public and private payors, clinically integrated networks, and looser affiliations of providers and suppliers collaborating to coordinate care for patients across the continuum of care.

[5] The Innovation Center's purpose is to test innovative payment and service delivery models to reduce the cost of care furnished to patients in the Medicare and Medicaid programs while preserving or enhancing the quality of that care. Using its authority in section 1115A of the Social Security Act (the Act), 42 U.S.C. 1315a, the Innovation Center is testing many healthcare delivery and payment models in which providers, suppliers, and individual practitioners participate.

[6] 42 U.S.C. 1320a–7b(b).

[7] 42 U.S.C. 1320a–7a(a)(5).

[8] 42 U.S.C. 1395nn.

[9] Public Law 104–191, 110 Stat. 1936.

[10] Medicare and State Health Care Programs: Fraud and Abuse; Request for Information Regarding the Anti-Kickback Statute and Beneficiary Inducements CMP, 83 FR 43607 (Aug. 27, 2018), *available at https://oig.hhs.gov/authorities/docs/2018/RFI_Regarding_AKS_Beneficiary_Inducements_CMP.pdf.*

[11] Medicare Program; Request for Information Regarding the Physician Self-Referral Law, 83 FR 29524 (June 25, 2018), *available at https://www.gpo.gov/fdsys/pkg/FR-2018-06-25/pdf/2018-13529.pdf.*

Designing proposed safe harbors with these principles in mind is not without challenges and potential pitfalls, particularly with respect to ensuring sufficient safeguards against potential abuses and harms by those who might misuse the safe harbors. In this proposed rule, we have tried to strike the right balance between flexibility for beneficial innovation and safeguards to protect patients and Federal health care programs. No final determination has yet been made that the balance is correct with respect to each proposed safe harbor. Thus, no final determination has been made that the arrangements described in the proposals are, or should be, exempt from liability under the anti-kickback statute. To aid us in making that determination in a final rule, we solicit public comments throughout this proposed rule about whether we have achieved the proper balance such that the arrangements described in the proposed safe harbors should be protected from criminal liability under the anti-kickback statute. To this end, we caution that these proposed safe harbors remain subject to change through the rulemaking process, and that the types of arrangements described in this proposed rule remain subject to case-by-case review under the anti-kickback statute, and if applicable, the beneficiary inducements CMP, including with respect to the requisite intent of the parties. The proposed safe harbors, if finalized, specifically would address barriers to coordinated and value-based care posed by the Federal anti-kickback statute and the beneficiary inducements CMP and would have no application to any other law. In addition, any final safe harbors would provide only prospective protection.

OIG's mission is to protect the integrity of the Federal health care programs as well as the health and welfare of the people they serve. OIG prevents and detects fraud, waste, and abuse, and promotes economy, effectiveness, and efficiency in HHS programs. Stakeholders, including patients, depend upon OIG to be thoughtful, cautious, and deliberate in promulgating safe harbors to ensure that the arrangements the safe harbors protect do not inappropriately increase costs to the Federal health care programs or patients, corrupt practitioners' medical judgment, or result in overutilization, inappropriate patient steering, unfair competition, or poor-quality care. These abuses are sometimes characterized as traditional FFS fraud and abuse risks.

Model design characteristics common to properly structured value-based payment models could curb some traditional FFS risks. However, value-based payment models could present other risks, including stinting on care (underutilization), cherry picking lucrative or adherent patients, lemon dropping costly or noncompliant patients, and incentives to manipulate or falsify data used to verify performance and outcomes for payment purposes. In addition, emerging value-based payment models might present risks not yet identified by OIG or others in the healthcare industry. Many new models combine FFS and value-based payment features, subjecting providers to mixed incentives and potentially posing all or some of the risks raised by volume- and value-based payment. We seek comments on how best to address existing and emerging risks with respect to our proposals below, individually and collectively.

Section C of this Executive Summary and sections III and IV of this preamble summarize our specific proposals. Several proposals address particular types of value-based arrangements designed to promote care coordination and allow for outcomes-based payments. We have included a proposed safe harbor for arrangements that engage patients more actively in preventive care and adhering to treatment and care plans developed between them and their healthcare providers. We also are proposing a new safe harbor related to cybersecurity tools, as well as modifications to the existing safe harbors related to personal services arrangements, electronic health records, warranties, and local transportation.

Our proposals in this rulemaking focus on ensuring protected arrangements: (i) Promote coordinated patient care and foster improved quality, better health outcomes, and improved efficiency; and (ii) would not be misused to perpetrate fraud and abuse, including, for example, schemes in which patients receive unnecessary or substandard care or Federal health care programs are billed for medically unnecessary items or services. We have sought to strike an effective balance among the goals of clarity, objectivity, flexibility, safeguards (including accountability and transparency), and ease of implementation.

OIG and CMS coordinated closely to develop our respective proposed rulemakings in connection with the Regulatory Sprint and strove, where appropriate, to propose consistent terminology for value-based arrangements. In many respects, OIG's proposed rules for value-based arrangements are different or more restrictive than CMS's comparable proposals, in recognition of the differences in statutory structures and penalties. For some arrangements, we believe it is appropriate for the anti-kickback statute, which is a criminal, intent-based statute, to serve as ''backstop'' protection for arrangements that might be protected by a less restrictive exception to the civil, strict liability physician self-referral law. For any final rule, we would examine our rules in combination with any rules CMS may choose to finalize with the goal of creating an overall regulatory landscape that is well-coordinated and serves the intended purpose to allow for beneficial innovation; that is as streamlined as possible, consistent with program integrity considerations; and that provides strong protections for patients and programs, both in terms of promoting value and ensuring that the Government can take action to protect patients and address fraud or abuse. Arrangements that might be protected by a physician self-referral law exception, but might not be explicitly protected by an anti-kickback statute safe harbor, would not necessarily be unlawful under the anti-kickback statute. They would need to be examined on a case-by-case basis, including with respect to the intent of the parties. We note that OIG's proposed new safe harbor for cybersecurity items and services and modifications to the existing safe harbor for electronic health record items and services are closely aligned with CMS' proposals.

C. Summary of the Major Provisions

1. Anti-Kickback Statute and Safe Harbors

As described in more detail below, we propose to amend 42 CFR 1001.952 by modifying certain existing safe harbors to the anti-kickback statute and by adding safe harbors that would provide new protections or codify an existing statutory protection. Subject to definitions and conditions set forth in the proposed regulations, these proposed changes include:

- Three proposed new safe harbors for certain remuneration exchanged between or among participants in a value-based arrangement (as further defined) that fosters better coordinated and managed patient care: (i) Care coordination arrangements to improve quality, health outcomes, and efficiency (1001.952(ee)); (ii) value-based arrangements with substantial downside financial risk (1001.952(ff)); and (iii) value-based arrangements with full financial risk (1001.952(gg)). These proposed safe harbors vary, among other ways, by the types of remuneration protected (in-kind or in-kind and

monetary), the level of financial risk assumed by the parties, and the types of safeguards included as safe harbor conditions;

- a proposed new safe harbor (1001.952(hh)) for certain tools and supports furnished under patient engagement and support arrangements to improve quality, health outcomes, and efficiency;
- a proposed new safe harbor (1001.952(ii)) for certain remuneration provided in connection with a CMS-sponsored model, which should reduce the need for OIG to issue separate and distinct fraud and abuse waivers for new CMS-sponsored models;
- a proposed new safe harbor (1001.952(jj)) for donations of cybersecurity technology and services;
- proposed modifications to the existing safe harbor for electronic health records items and services (1001.952(y)) to add protections for certain cybersecurity technology included as part of an electronic health records arrangement, to update provisions regarding interoperability, and to remove the sunset date;
- proposed modifications to the existing safe harbor for personal services and management contracts (1001.952(d)) to add flexibility with respect to outcomes-based payments and part-time arrangements;
- proposed modifications to the existing safe harbor for warranties (1001.952(g)) to revise the definition of ''warranty'' and provide protection for warranties for one or more items and related services;
- proposed modifications to the existing safe harbor for local transportation (1001.952(bb)) to expand and modify mileage limits for rural areas and for transportation for discharged patients; and
- codification of the statutory exception to the definition of ''remuneration'' at section 1128B(b)(3)(K) of the Act related to ACO Beneficiary Incentive Programs for the Medicare Shared Savings Program (1001.952(kk)).

2. Civil Monetary Penalty Authorities

We propose to amend the definition of ''remuneration'' in the CMP rules at 42 CFR 1003.110 by interpreting and incorporating a new statutory exception to the prohibition on beneficiary inducements for ''telehealth technologies'' furnished to certain in-home dialysis patients, pursuant to section 50302(c) of the Budget Act of 2018.

We further note that, if finalized, the proposed new safe harbor for patient engagement and support arrangements (1001.952(hh)) and the proposed modifications to the local transportation safe harbor (1001.952(bb)) would by operation of law serve as exceptions to the beneficiary inducements CMP prohibition's definition of ''remuneration.''

3. Costs and Benefits

There are no significant costs associated with the proposed regulatory revisions that would impose any mandates on State, local, or Tribal Governments or on the private sector.

II. Background

A. Anti-Kickback Statute and Safe Harbors

Section 1128B(b) of the Act, (42 U.S.C. 1320a–7b(b), the anti-kickback statute), provides for criminal penalties for whoever knowingly and willfully offers, pays, solicits, or receives remuneration to induce or reward the referral of business reimbursable under any of the Federal health care programs, as defined in section 1128B(f) of the Act (42 U.S.C. 1320a–7b(f)). The offense is classified as a felony and is punishable by fines of up to $100,000 and imprisonment for up to 10 years. Violations of the anti-kickback statute also may result in the imposition of CMPs under section 1128A(a)(7) of the Act (42 U.S.C. 1320a–7a(a)(7)), program exclusion under section 1128(b)(7) of the Act (42 U.S.C. 1320a–7(b)(7)), and liability under the False Claims Act (31 U.S.C. 3729–33).

The types of remuneration covered specifically include, without limitation, kickbacks, bribes, and rebates, whether made directly or indirectly, overtly or covertly, in cash or in kind. In addition, prohibited conduct includes not only the payment of remuneration intended to induce or reward referrals of patients but also the payment of remuneration intended to induce or reward the purchasing, leasing, or ordering of, or arranging for or recommending the purchasing, leasing, or ordering of, any good, facility, service, or item reimbursable by any Federal health care program.

Because of the broad reach of the statute, concern was expressed that some relatively innocuous business arrangements were covered by the statute and, therefore, potentially subject to criminal prosecution. In response, Congress enacted section 14 of the Medicare and Medicaid Patient and Program Protection Act of 1987, Public Law 100–93 (section 1128B(b)(3)(E) of the Act; 42 U.S.C. 1320a–7b(b)(3)(E)), which specifically requires the development and promulgation of regulations, the so-called safe harbor provisions, that would specify various payment and business practices that would not be subject to sanctions under the anti-kickback statute, even though they potentially may be capable of inducing referrals of business for which payment may be made under a Federal health care program.

Section 205 of HIPAA established section 1128D of the Act (42 U.S.C. 1320a–7d), which includes criteria for modifying and establishing safe harbors. Specifically, section 1128D(a)(2) of the Act provides that, in modifying and establishing safe harbors, the Secretary may consider whether a specified payment practice may result in:

- An increase or decrease in access to healthcare services;
- an increase or decrease in the quality of healthcare services;
- an increase or decrease in patient freedom of choice among healthcare providers;
- an increase or decrease in competition among healthcare providers;
- an increase or decrease in the ability of healthcare facilities to provide services in medically underserved areas or to medically underserved populations;
- an increase or decrease in the cost to Federal health care programs;
- an increase or decrease in the potential overutilization of healthcare services;
- the existence or nonexistence of any potential financial benefit to a healthcare professional or provider, which benefit may vary depending on whether the healthcare professional or provider decides to order a healthcare item or service or arrange for a referral of healthcare items or services to a particular practitioner or provider; or
- any other factors the Secretary deems appropriate in the interest of preventing fraud and abuse in Federal health care programs.

We have considered these factors in designing our proposals. We are interested in public comments on these factors as they relate to our proposals. Properly structured and operated, we believe that the arrangements we propose to protect have the potential to increase access to care, increase quality of care, aid in the provision of items and services in underserved areas and to underserved populations, decrease costs to Federal health care programs, and decrease the potential for overutilization of healthcare services. We are concerned about reduced patient freedom of choice among providers, potential decreases in competition among health providers, and potential financial benefits to

healthcare professionals or providers that may vary inappropriately based on their ordering decisions. We solicit comments on whether or not our proposals adequately address these or other undesired effects; if commenters believe the proposals would not adequately address these effects, we solicit comments on the degree to which such effects might occur and on additional safeguards to mitigate them.

In giving the Department the authority to protect certain arrangements and payment practices under the anti-kickback statute, Congress intended the safe harbor regulations to be updated periodically to reflect changing business practices and technologies in the healthcare industry.[12] Since July 29, 1991, there have been a series of final regulations published in the **Federal Register** establishing safe harbors in various areas.[13] These safe harbor provisions have been developed ''to limit the reach of the statute somewhat by permitting certain non-abusive arrangements, while encouraging beneficial or innocuous arrangements.'' [14]

Healthcare providers and others may voluntarily seek to comply with final safe harbors so that they have the assurance that their business practices would not be subject to any anti-kickback enforcement action. Compliance with an applicable safe harbor insulates an individual or entity from liability under the anti-kickback statute and the beneficiary inducements CMP only; individuals and entities remain responsible for complying with all other laws, regulations, and guidance that apply to their businesses.

In developing our proposals, we have taken into account information gleaned from a variety of sources: Industry stakeholder input, including through comments to the OIG RFI; learnings from OIG's work (*e.g.,* fraud and abuse waivers for the Medicare Shared Savings Program and Innovation Center models, investigative and oversight work applying the fraud and abuse laws, and audits and evaluations of program effectiveness and efficiency); expertise from CMS and other HHS agencies; and other sources, including literature on care coordination and value-based payments.

B. Civil Monetary Penalty Authorities

1. Overview of OIG Civil Monetary Penalty Authorities

In 1981, Congress enacted the CMP law, section 1128A of the Act, 42 U.S.C. 1320a–7a, as one of several administrative remedies to combat fraud and abuse in Medicare and Medicaid. The law authorized the Secretary to impose penalties and assessments on persons who defrauded Medicare or Medicaid or engaged in certain other wrongful conduct. The CMP law also authorized the Secretary to exclude persons from Federal health care programs (as defined in section 1128B(f) of the Act, 42 U.S.C. 1320a–7b(f)) and to direct the appropriate State agency to exclude the person from participating in any State healthcare programs (as defined in section 1128(h) of the Act, 42 U.S.C. 1320a–7(h)). Congress later expanded the CMP law and the scope of exclusion to apply to all Federal health care programs, but the CMP applicable to beneficiary inducements remains limited to Medicare and State healthcare program beneficiaries. Since 1981, Congress has created various other CMP authorities covering numerous types of fraud and abuse.

2. The Beneficiary Inducements CMP and the Definition of ''Remuneration''

Section 1128A(a)(5) of the Act, 42 U.S.C. 1320a–7a(a)(5), the ''beneficiary inducements CMP,'' provides for the imposition of civil monetary penalties against any person who offers or transfers remuneration to a Medicare or State healthcare program (including Medicaid) beneficiary that the benefactor knows or should know is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier of any item or service for which payment may be made, in whole or in part, by Medicare or a State healthcare program (including Medicaid). Section 1128A(i)(6) of the Act, 42 U.S.C. 1320a–7a(i)(6), defines ''remuneration'' for purposes of the beneficiary inducements CMP as including ''transfers of items or services for free or for other than fair market value.'' Section 1128A(i)(6) of the Act also includes a number of exceptions to the definition of ''remuneration.''

Pursuant to section 1128A(i)(6)(B) of the Act, any practice permissible under the anti-kickback statute, whether through statutory exception or regulations issued by the Secretary, is also excepted from the definition of ''remuneration'' for purposes of the beneficiary inducements CMP. However, no parallel exception exists in the anti-kickback statute. Thus, the exceptions in section 1128A(i)(6) of the Act apply only to the definition of ''remuneration'' applicable to section 1128A.

Relevant to this proposed rulemaking, the Budget Act of 2018 created a new exception to the definition of ''remuneration'' for purposes of the beneficiary inducements CMP. This exception applies to ''telehealth technologies'' provided on or after January 1, 2019, by a provider of services or a renal dialysis facility to an individual with end-stage renal disease (ESRD) who is receiving home dialysis for which payment is being made under Medicare Part B.

III. Provisions of the Proposed Rule: Anti-Kickback Statute Safe Harbors

A. Value-Based Framework

This section provides background on, and an overarching summary of, the framework for value-based arrangements set forth in this proposed rulemaking; explains proposed terminology used in certain proposed safe harbors; and explains the specific safe harbor proposals to protect value-based arrangements (as defined in proposed paragraph 1001.952(ee)) designed to foster better care at lower cost through improved care coordination for patients.

Our proposals endeavor to remove real or perceived regulatory barriers to promote flexible, industry-led innovation in the delivery of more efficient and better coordinated healthcare. Further, consistent with emerging understandings of the benefits of better care coordination and the increasing adoption of value-based care and payment models in the healthcare industry, our proposals may support a more rapid transition from volume (*e.g.,*

[12] H.R. Rep. No. 100–85, Pt. 2, at 27 (1987).

[13] Medicare and State Health Care Programs: Fraud and Abuse; OIG Anti-Kickback Provisions, 56 FR 35952 (July 29, 1991); Medicare and State Health Care Programs: Fraud and Abuse; Safe Harbors for Protecting Health Plans, 61 FR 2122 (Jan. 25, 1996); Federal Health Care Programs: Fraud and Abuse; Statutory Exception to the Anti-Kickback Statute for Shared Risk Arrangements, 64 FR 63504 (Nov. 19, 1999); Medicare and State Health Care Programs: Fraud and Abuse; Clarification of the Initial OIG Safe Harbor Provisions and Establishment of Additional Safe Harbor Provisions Under the Anti-Kickback Statute, 64 FR 63518 (Nov. 19, 1999); 64 FR 63504 (Nov. 19, 1999); Medicare and State Health Care Programs: Fraud and Abuse; Ambulance Replenishing Safe Harbor Under the Anti-Kickback Statute, 66 FR 62979 (Dec. 4, 2001); Medicare and State Health Care Programs: Fraud and Abuse; Safe Harbors for Certain Electronic Prescribing and Electronic Health Records Arrangements Under the Anti-Kickback Statute, 71 FR 45109 (Aug. 8, 2006); Medicare and State Health Care Programs: Fraud and Abuse; Safe Harbor for Federally Qualified Health Centers Arrangements Under the Anti-Kickback Statute, 72 FR 56632 (Oct. 4, 2007); Medicare and State Health Care Programs: Fraud and Abuse; Electronic Health Records Safe Harbor Under the Anti-Kickback Statute, 78 FR 79202 (Dec. 27, 2013); and Medicare and State Health Care Programs: Fraud and Abuse; Revisions to the Safe Harbors Under the Anti-Kickback Statute and Civil Monetary Penalty Rules Regarding Beneficiary Inducements, 81 FR 88368 (Dec. 7, 2016).

[14] Medicare and State Health Care Programs: Fraud and Abuse; OIG Anti-Kickback Provisions, 56 FR at 35958.

FFS reimbursement for office visits, tests, or procedures) toward value (*e.g.,* paying for patient or population outcomes).

1. Anti-Kickback Statute Implications of Care Coordination and the Value-Based Framework

Better care coordination—including more effective transitions for patients across the care continuum, less duplication of items and services, and open sharing of health data (consistent with privacy and security rules)—is integrally connected to advancing the transition to a value-based healthcare system. Care coordination arrangements, especially when linked to appropriate clinical or other value-driven outcomes, can help improve health and the patient experience of care; enable providers to participate successfully in value-based care and payment models; and advance the goals of value-based care: Delivering better health outcomes and maximizing desirable efficiency in healthcare delivery. For example, OIG's recent report entitled, ''ACOs' Strategies for Transitioning to Value-Based Care: Lessons From the Medicare Shared Savings Program,'' [15] highlights the tools—including care coordination arrangements—that certain accountable care organizations (ACOs) under the Medicare Shared Savings Program have deployed successfully to reduce costs and improve quality. Many of the strategies discussed in this report involve care coordination, care management, and patient engagement, including: engaging beneficiaries to improve their own health, managing beneficiaries with costly or complex care needs to improve their health outcomes, addressing behavioral health needs and social determinants of health, and using technology to increase information sharing among providers.[16]

Because care coordination often involves arrangements between providers that refer Federal health care program patients to one another and an exchange of remuneration, the anti-kickback statute may be implicated. Moreover, providing patients with remuneration to engage and support them in achieving better health outcomes may implicate both the anti-kickback statute and the beneficiary inducements CMP.

[15] OIG, *ACOs' Strategies for Transitioning to Value-Based Care: Lessons From the Medicare Shared Savings Program* (July 2019), *available at https://oig.hhs.gov/oei/reports/oei-02-15-00451.pdf.*

[16] *Id.*

2. Balancing Innovation With Protection Against Fraud and Abuse Risks

To remove regulatory barriers to care coordination and support value-based arrangements, we are faced with the challenge of designing safe harbor protections for emerging healthcare arrangements. The optimal form, design, and efficacy of such emerging arrangements remain unknown or unproven. This is a key challenge of regulating during a period of innovation and experimentation. The challenge of designing appropriate safe harbors is exacerbated by: The substantial variation in care coordination and value-based arrangements contemplated by the healthcare industry (meaning that one-size-fits-all safe harbor designs may be less than optimal), variation among patient populations and provider characteristics, emerging health technologies and data capabilities, the still-developing science of quality and performance measurement, and our desire not to chill beneficial innovation.

It is sometimes difficult to gauge fraud and abuse risk in a rapidly evolving environment of substantial innovation, experimentation, and deployment of technology and digital data. In some cases, innovations and the availability of more actionable, transparent data may enhance program integrity and protect against fraud and abuse. There is a compelling concern that uncertainty and regulatory barriers—real or perceived—could prevent the best and most efficacious innovations from emerging and being tested in the marketplace. Our goal is to craft safe harbors that, if finalized, would protect arrangements that promote value, while also protecting against fraud, abuse and associated harms. Over time, we expect that best practices in care coordination and value-based payment will emerge.

3. Overview of Proposed Safe Harbors

We are proposing safe harbors for value-based arrangements, with greater flexibilities available to parties as they assume more downside financial risk for the cost and quality of care. This ''tiered'' structure is intended to support the transformation of industry payment systems and takes into account that arrangements involving higher levels of downside risk curb, at least to some degree, FFS incentives to order medically unnecessary or overly costly items and services. We propose these safe harbors, recognizing that the transition from an FFS to a value-based care and payment system will take time. Where parties may have both FFS and value-based payment incentives, we believe assuming downside financial risk from a payor for items and services furnished to patients helps mitigate incentives that often drive fraud and abuse present in traditional FFS.

For the purposes of this rule, the proposed safe harbors that require assumption of risk focus on value-based arrangements with substantial downside financial risk (1001.952(ff)) and value-based arrangements at full financial risk (1001.952(gg)). While these proposed safe harbors largely focus on the assumption of downside financial risk, we understand that participants in value-based arrangements may assume certain types of risk other than downside financial risk for items and services furnished to a target patient population (*e.g.,* upside risk, clinical risk, operational risk, contractual risk, or investment risk).

We believe that our focus on downside financial risk is appropriate because the assumption of downside financial risk may shift the incentives that serve to influence those making the referring and ordering decisions, the conduct at the center of the anti-kickback statute. We solicit comments on whether, for purposes of a final rule, other types of risk would have a comparable effect. We are particularly interested in fact patterns that illustrate how other types of risk would operate to change ordering or referring behaviors of providers and suppliers that might still be paid on an FFS basis or otherwise help ensure that safe-harbored arrangements would serve appropriate value-based purposes.

Remuneration has at least two dimensions relevant to this proposed rulemaking: (i) Payments by payors; and (ii) remuneration exchanged between clinicians, providers, suppliers, and others. Payor payments that drive toward value include capitated payments and global budgets at one end of the ''value-based payments'' spectrum; shared savings and bundled payment mechanisms in the middle; and bonuses and reductions applied to FFS payments at the other end of the spectrum. Examples of remuneration exchanged among clinicians, providers, suppliers, and others include sharing staff, such as care coordinators, or technology, such as data analytics tools, to improve quality or efficiency or to achieve other performance or outcomes targets, whether set by payors or among themselves. In some cases, these parties also may have value-based payment arrangements among themselves, such as gainsharing or shared savings agreements.

We are proposing a suite of safe harbors that, if finalized, would address a variety of scenarios. Collectively, we

believe these proposed safe harbors, in combination with existing safe harbors, would provide pathways for protection for most beneficial care coordination and value-based care and payment arrangements. In crafting these safe harbors, we have endeavored to be agnostic with respect to the composition of the value-based enterprise (VBE), a concept and defined term described further below, and scope of protected value-based arrangements to allow for innovation and experimentation in the healthcare marketplace and to foster a level playing field for those seeking safe harbor protection, whether they are large health systems or individual practitioners. The proposed safe harbors would cover value-based arrangements involving both publicly and privately insured patients.

The first proposed safe harbor, at 1001.952(ee), covers care coordination arrangements to improve quality, health outcomes, and efficiency (''care coordination arrangements'' safe harbor). It covers certain in-kind remuneration, including services and infrastructure. The second proposed safe harbor, at 1001.952(ff), with greater flexibility, covers certain in-kind and monetary arrangements where the VBE is at substantial downside financial risk from a payor (as defined). The third proposed safe harbor, at 1001.952(gg), is for in-kind and monetary arrangements where the VBE is at full downside financial risk from a payor and allows for even more flexibility. In addition, we propose to protect certain outcomes-based compensation (regardless of whether it meets the criteria for substantial downside financial risk) under the rubric of ''outcomes-based payments'' through proposed modifications to the personal services and management contracts safe harbor at 1001.952(d), as discussed in the section III.J. below.

We are mindful of the role patient engagement can play in improved coordination of patient care and health outcomes. Thus, we are proposing a safe harbor at 1001.952(hh) for arrangements for patient engagement and support to improve quality, health outcomes, and efficiency (the ''patient engagement and support'' safe harbor). We are further proposing a separate safe harbor at 1001.952(ii) for care delivery and payment arrangements as well as beneficiary incentives pursuant to certain CMS-sponsored models, including Innovation Center models. This proposed safe harbor would largely, if not entirely, replace OIG's current model-by-model fraud and abuse waiver process for CMS-sponsored models. The requirements of each proposed safe harbor are discussed in detail below.

As always, all safe harbor conditions would need to be precisely met for safe harbor protections to apply. Many value-based arrangements and activities may qualify for existing safe harbor protections, including under the employees safe harbor (1001.952(i)), the EHR items and services safe harbor (1001.952(y)), the personal services and management contracts safe harbor (1001.952(d)), the local transportation safe harbor (1001.952(bb)), and the several safe harbors pertaining to health plans and managed care organizations set forth at 1001.952(l), (m), (t), and (u). Many others may not raise anti-kickback issues at all if they do not relate to Federal health care program beneficiaries or are not tied in any way to the volume or value of Federal health care program business. (Likewise, with respect to compliance with the beneficiary inducements CMP, patient engagement and support arrangements and activities may fit in existing exceptions to the CMP law, may be within applicable nominal value limits, or may not raise concerns under that statute if they do not relate to Medicare or Medicaid patients or are not likely to influence the selection of providers, practitioners, or suppliers.)

In the next section, we describe the proposed definitions for several key terms used in the proposed safe harbors for value-based arrangements at proposed paragraphs 1001.952(ee), (ff), and (gg) for care coordination arrangements, value-based arrangements with substantial downside financial risk, and value-based arrangements at full financial risk, respectively. We then describe each proposed safe harbor in detail. Related proposed modifications to the personal services and management contracts safe harbor (1001.952(d)) for outcomes-based payments (where there is no substantial downside financial risk) are described at section III.J. The patient engagement and support safe harbor is described at section III.F. The proposed safe harbor for CMS-sponsored models, including Innovation Center models, is described at section III.G.

B. Proposed Value-Based Terminology (1001.952(ee))

We propose definitions for key terms in paragraph 1001.952(ee). These terms are used consistently in several proposed safe harbors. The proposed defined terms are intended to work in conjunction with one another to describe the universe of value-based arrangements potentially eligible for proposed safe harbor protection and of individuals and entities that can engage in protected arrangements, provided all conditions of a specific safe harbor are squarely met.

Generally speaking, when read together, the proposed terminology and safe harbors are intended to protect care coordination and support value-based arrangements where, as a threshold matter, the arrangements are under the auspices of a VBE (of any size, and as further defined in proposed paragraph 1001.952(ee)) that is essentially a network of participants (such as clinicians, providers, or suppliers) that has agreed to collaborate to, for example: (i) Put the patient at the center of care through improved care coordination, (ii) increase efficiencies in the delivery of care, and (iii) improve quality of care and health outcomes for patients or populations. The VBE has value-based purposes and its participants enter into value-based arrangements for value-based activities to further those purposes.

Wherever possible and appropriate, it is our intent to align our proposed value-based terminology with those that CMS proposes in its notice of proposed rulemaking regarding the physician self-referral law, ''Modernizing and Clarifying the Physician Self-Referral Regulations.'' Because of the close nexus between the value-based terminology in our proposed rule and CMS's proposed terminology, we may also consider for purposes of making determinations for a final rule comments submitted about value-based terminology in response to CMS's proposed rule.

We use the term ''value-based'' in our proposed terminology in a non-technical way to signal value produced through improved care coordination, improved health outcomes, lower costs or reduced growth of costs for patients and payors, and improved efficiencies in the delivery of care. We recognize that our use of the words ''value'' and ''value-based'' here do not necessarily capture all dimensions of value in healthcare. We solicit comments on our approach, as well as comments on whether we should define ''value'' specifically in the final rule, and if so, how best to define ''value'' as it pertains to care coordination and value-based payment. For example, we are considering for the final rule whether ''value'' should be defined with reference to financial arrangements under advanced APMs (whether HHS or other payor models).

1. Value-Based Enterprise (VBE)

We propose to use the term ''value-based enterprise'' to describe the

network of individuals and entities that collaborate together to achieve one or more value-based purposes (as defined in proposed paragraph 1001.952(ee)). As defined in this rulemaking, and as a general matter, the VBE would delineate the universe of individuals and entities participating in arrangements eligible for safe harbor protection, if all safe harbor conditions are fully met. The VBE also would be accountable for ensuring that such protected arrangements are conducted under the auspices of the VBE.

a. Two or More VBE Participants

First, we propose that VBE would mean two or more VBE participants (as defined in proposed paragraph 1001.952(ee)) that are collaborating to achieve at least one value-based purpose. VBEs may take many different forms, and we intend for the definition of ''VBE'' to be flexible. For example, a VBE could be as small as two individual physician practices collaborating to coordinate care for shared patients. The same term also could cover a formal or informal network of hospital systems, post-acute care providers, and physician practices. An accountable care organization or health system comprised of hospitals and physician practices, for example, could also constitute a VBE.

b. Party to a Value-Based Arrangement

Second, we propose that each VBE participant in the VBE must be a party to a value-based arrangement (as defined below) with at least one other VBE participant from the same VBE. In the case of a VBE comprised of two VBE participants, the two VBE participants would need to be engaged in a value-based arrangement with each other. We intend for this criterion to ensure that parties qualifying as part of a VBE are contributing to a value-based arrangement. Consistent with our intention to provide flexibility for innovation, VBE participants could engage in one or multiple value-based arrangements, so long as all of the value-based arrangements further the value-based purpose(s) of the VBE.

c. Accountable Body

Third, we propose that the VBE must have an accountable body (such as a board of directors or other governing body) or person (which, depending on the size and scope of the VBE, may be an entity, such as a hospital or physician practice that is among the VBE participants, or an individual) responsible for financial and operational oversight of the VBE. As part of its oversight role, we expect that the accountable body or responsible person would serve as the ''gatekeeper'' to the VBE, with a process and criteria to ensure that those admitted to the VBE after its formation as VBE participants have a legitimate role in the VBE and in VBE arrangements and that VBE participants are not participants in name only. In addition to ensuring operational and financial oversight, we believe the accountable body or responsible person would be positioned to identify program integrity issues and to initiate action to address them, as necessary and appropriate. We are considering for the final rule, and solicit comment on, whether the VBE or its participants should be required to have a compliance program that covers at least those value-based arrangements for which safe harbor protection is sought and whether the accountable body or person should have responsibility for the compliance program.

The arrangements that would be protected by these proposed safe harbors would not have the benefit of programmatic oversight comparable to CMS-sponsored models. Accordingly, we view this accountability criterion as important to ensure that arrangements operate for their designated value-based purpose(s) and as a key safeguard to ensure that value-based arrangements are aligned with at least one value-based purpose and not misused for purposes that raise program integrity concerns (*e.g.,* arrangements that encourage providers to steer patients in ways that are not in the patients' best interests or stint on medically necessary care).

The oversight role may include, depending on the applicable proposed safe harbor at 42 CFR 1001.952(ee), (ff), and (gg) and how the applicable VBE effectuates safe harbor requirements, monitoring whether VBE participants are performing under their value-based arrangements in a manner that furthers the coordination and management of care for the target patient population. We are considering for the final rule a requirement that all VBE participants affirmatively recognize the oversight role of the accountable body or responsible person and explicitly agree to cooperate with its oversight efforts (*e.g.,* by requiring the inclusion of a statement to this effect in the applicable written agreement).

We also are considering for the final rule whether the accountable body or responsible person (or some other party or parties to value-based arrangements addressed by the proposed safe harbors) should have more specific oversight responsibilities, such as oversight related to utilization of items and services, cost, quality of care, patient experience, adoption of technology, and the quality, integrity, privacy, and security of data related to the arrangement (such as outcomes, quality, and payment data). To facilitate effective oversight, we are considering for the final rule whether VBEs should be required to implement reporting requirements for their VBE participants or mechanisms for obtaining access to, and verifying, VBE participant data concerning performance under any value-based arrangement.

We welcome comments on this approach or any different or additional actions that may help ensure effective ongoing oversight.

We intend for VBEs to implement the criterion regarding the accountable body or responsible person in a manner that is tailored to the complexity and sophistication of the VBE. For example, a VBE involving two physician practices with a single value-based arrangement could designate one of the physician practices (or its compliance professional) as the individual responsible for this oversight. Where the VBE is larger and involves numerous sophisticated entities, it might be advisable and a best practice to create a separate governing body to serve as the accountable body, overseeing the VBE.

The proposed definition of ''VBE'' does not require the VBE's accountable body or responsible person to be independent of the interests of individual VBE participants (which would preclude a VBE participant from acting as the accountable body or responsible person) or to have a distinct duty of loyalty to the VBE. However, to provide further assurances that a VBE's accountable body or responsible person is acting in furtherance of the VBE's value-based purpose(s) and not any one VBE participant's individual interests, we are considering for the final rule imposing a standard requiring either independence or a duty of loyalty as a criterion of this definition or as a safe harbor requirement. We solicit comments on the benefits, burdens, and challenges of this approach.

d. Governing Document

Fourth, we propose that each VBE must have a governing document that describes the VBE and how the VBE participants intend to achieve its value-based purpose(s). The intent of this requirement is to provide transparency regarding the structure of the VBE, the VBE's value-based purpose(s), and the VBE participants' roadmap for achieving such purpose(s). This document may include any other terms the VBE participants deem important. The governing document need not be formal bylaws or in another specific format.

Written documentation recording the terms of a value-based arrangement may serve as the required VBE governing document, provided it describes the enterprise and how the parties intend to achieve its value-based purpose(s).

e. VBE's Assumption of Downside Financial Risk

Lastly, we note that two of our proposed safe harbors require that a VBE has assumed downside financial risk from a payor. We anticipate that VBEs could contract with payors and other entities in a variety of ways. For example, a VBE comprised of a large number of VBE participants across a range of healthcare settings might create a standalone legal entity that enters into contracts directly with payors on the VBE participants' behalf. Alternatively, one VBE participant might contract with payors on behalf of other VBE participants within the VBE. In the latter example, the VBE would still be required to be at risk, but it would be through one of its VBE participants rather than through a contract directly with the payor.

2. Value-Based Arrangement

The proposed safe harbors at 42 CFR 1001.952(ee), (ff), and (gg) would protect remuneration paid or exchanged pursuant to a ''value-based arrangement'' if all conditions are met. We propose to define a value-based arrangement as ''an arrangement for the provision of at least one value-based activity for a target patient population between or among: (A) The value-based enterprise and one or more of its VBE participants; or (B) VBE participants in the same value-based enterprise.'' We intend for these requirements to ensure that each value-based arrangement is aligned with the VBE's value-based purpose(s) and subject to its financial and operational oversight. Our proposed definition is intended to capture arrangements for care coordination and certain other value-based activities among VBE participants within the same VBE.

Addressing each requirement of the definition in turn, we first propose to require that the value-based arrangement include at least one value-based activity (as defined in proposed paragraph 1001.952(ee)) to be undertaken by the parties. We would expect that many value-based arrangements would be comprised of multiple value-based activities.

Second, we propose that the value-based arrangement's value-based activities must be undertaken with respect to a target patient population (as defined in proposed paragraph 1001.952(ee)). That is, the value-based arrangement, and its value-based activities, must be tailored to meet the needs of a defined patient population. This element further ties the value-based arrangement to care coordination of patients and value-based goals. We note that the definition of ''value-based arrangement'' is broad enough to cover commercial and private insurer arrangements.

3. Target Patient Population

We propose to define ''target patient population'' as ''an identified patient population selected by the VBE or its VBE participants using legitimate and verifiable criteria that: (A) Are set out in writing in advance of the commencement of the value-based arrangement; and (B) further the value-based enterprise's value-based purpose(s).'' Our intent in defining this term is to protect value-based arrangements that serve an identifiable patient population for whom the value-based activities likely would improve health outcomes or lower costs (or both). By using the terms ''legitimate and verifiable,'' we seek to ensure the target patient population selection process is transparent and that VBE participants select their target patient population in an objective manner based on criteria that further the applicable value-based arrangement's value-based purpose(s). If VBE participants selectively include patients in a target patient population for purposes inconsistent with the objectives of a properly structured value-based arrangement (*e.g.,* cherry picking or lemon dropping patients), we would not consider such a selection process to be based on ''legitimate and verifiable criteria that further the value-based enterprise's value-based purpose(s).''

This proposed definition is not limited to Federal health care program beneficiaries. For example, VBE participants seeking to enhance access to, and usage of, primary care services for patients concentrated in a certain geographic region might base the target patient population on ZIP Code or county of residence. If a value-based arrangement is focused on enhancing care coordination for patients with a chronic disease, the target patient population might be patients with that disease (*e.g.,* congestive heart failure). VBE participants might also, for example, use data to identify a target patient population at increased risk of developing a chronic disease for improved care coordination under a value-based arrangement.

We are considering for the final rule and solicit comments on limiting the definition of ''target patient population'' to patients with a chronic condition, or alternatively, limiting any or all of the proposed safe harbors that use the target patient population definition to value-based arrangements for patients with a chronic condition. We might effectuate this approach through changes to the scope of the target patient population definition or other definitions, including value-based activity, value-based arrangement, and value-based purpose.

This alternative proposal is in recognition that patients with chronic conditions may be more susceptible to comorbidities, requiring care across the health spectrum, and thus most likely to benefit from the care coordination central to this proposed rule. To the extent we include such a limitation in the final rule, either by definition or through a safe harbor requirement, we are considering how to define ''chronic condition,'' and whether OIG should cross-reference other Medicare or Medicaid program guidelines or rules related to chronic conditions. In particular, we are considering and seek comment on defining ''chronic condition'' as the list of 15 Special Needs Plans (SNP)-specific chronic conditions developed by the SNP Chronic Condition Panel, as may be modified from time to time.[17] As new chronic conditions are identified, and as existing conditions benefit from life-prolonging technological advances, we are mindful that any definition of ''chronic condition'' might need flexibility to expand to remain appropriately inclusive and consistent with clinical understandings.

As an additional alternative, we are considering for purposes of the final rule, and solicit comments on, limiting the definition of ''target patient population'' to patients with a shared disease state that would benefit from care coordination.

We seek comment on how best to address the need for flexibility in any final rule, especially should we limit a final safe harbor to patients with a chronic condition or shared disease state. Moreover, we are interested in feedback on impacts of such limitations on the ability of VBE participants to provide better coordinated care for other categories of patients, including patients discharged from hospitals following acute care, patients requiring maternal

[17] CMS, Chronic Condition Special Need Plans (C–SNP), List of Chronic Conditions, *https://www.cms.gov/Medicare/Health-Plans/SpecialNeedsPlans/Chronic-Condition-Special-Need-Plans-C-SNP.html#s1.*

care, patients needing preventive care, and patients with mental health conditions.

Additionally, we solicit comments on whether we should replace ''legitimate and verifiable'' in this proposed definition with language that would require VBE participants to have more parameters and structure with respect to their selection of the target patient population and are considering whether use of the term ''evidence-based'' would achieve this goal. (Our proposed interpretation of ''evidence-based'' is addressed below in our discussion of the proposed safe harbor for care coordination arrangements.)

Last, we are considering for the final rule, and seek comments on, whether and if so how, parties other than VBE participants should or could be involved in selecting the target patient population. For example, we are considering for the final rule the role of payors in identifying or selecting the target patient population or establishing outcome measures with respect to a value-based arrangement. While payors might not be parties to a value-based arrangement, we believe many care coordination and other value-based arrangements may be entered into in order to achieve performance or outcome goals set by payors. We seek feedback on the potential benefit, including any reduced program integrity risks, of allowing or requiring payors to select either or both the target patient population and relevant outcome measures and targets (for purposes of the definitions, safe harbors, or both). If there would be benefit in doing so, we seek feedback on how best to implement such a permission or requirement. We also seek feedback on whether, for purposes of the final rule, we should treat as a favorable factor that a value-based arrangement (or outcomes-based payment arrangement) aligns its target patient population or its outcome measures and targets with payor-driven incentives.

4. Value-Based Activity

For purposes of these safe harbors, we propose that the term ''value-based activity'' would mean ''any of the following activities, provided that the activity is reasonably designed to achieve at least one value-based purpose of the value-based enterprise: (A) the provision of an item or service; (B) the taking of an action; or (C) the refraining from taking an action.'' ''Value-based activity'' does not include the making of a referral.

We are considering for the final rule whether to interpret ''reasonably designed'' to mean that the value-based activities set forth in the value-based arrangement are expected to further the value-based purpose of the arrangement. While this standard would not require that the value-based purpose actually be achieved, we are considering whether to require in the final rule that the VBE participants entering into the value-based arrangement engage in an evidence-based process to design value-based activities that they believe will reach such a goal. Our proposed interpretation of ''evidence-based'' for purposes of this proposed rule is addressed below in our discussion of the proposed care coordination arrangements safe harbor.

With this definition, we acknowledge that a ''value-based activity'' may encompass not only affirmative actions taken by VBE participants (*e.g.,* providing care coordinators to help patients with complex needs navigate the transition from a hospital to their homes) but also instances of inaction (*e.g.,* refraining from ordering certain items or services in accordance with a medically appropriate care protocol that reduces the number of required steps in a given procedure). Under no circumstances would simply making a referral constitute a ''value-based activity.''

Lastly, we are considering for the final rule expressly excluding from the definition of ''value-based activity'' any activity that results in information blocking. Similar to the concerns articulated in the section detailing our proposed modifications to the electronic health records safe harbor, we seek to preclude from protection under our proposed safe harbors at 42 CFR 1001.952(ee), (ff), and (gg) any arrangement that may, on its face, meet our definition of ''value-based activity'' but that ultimately is used to engage in practices of information blocking (*e.g.,* the donation of health information technology that may facilitate care coordination across providers participating in the VBE, but also prevents or unreasonably interferes with the exchange of electronic health information with other providers in order to lock-in referrals between such providers). Information blocking practices that may affect value-based activities include, but are not limited to, (i) locking electronic health information into the VBE or keeping it only between VBE participants, or (ii) preventing referrals or other electronic health information from leaving the VBE or being transmitted from a VBE participant to another healthcare provider. This exclusion would be based on the definition and exceptions for ''information blocking'' in the 21st Century Cures Act and the Office of the National Coordinator for Health Information Technology (ONC), HHS Notice of Proposed Rulemaking ''21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program,'' to the extent such definition and exceptions are finalized.

5. VBE Participant

We propose to define ''VBE participant'' as ''an individual or entity that engages in at least one value-based activity as part of a value-based enterprise.'' Depending upon the terms and requirements of the value-based arrangement (and the conditions of the relevant safe harbor), ''engaging in'' a value-based activity may be, for example, (i) performing an action to achieve certain quality or outcome metrics and the providing or receiving of payment for such achievement, or (ii) coordinating care to achieve better outcomes or efficiencies (*e.g.,* sharing staff or infrastructure to improve the discharge planning and care follow-up process between two VBE participants). Subject to the limitations proposed below, such term would broadly include clinicians, providers, and suppliers, as well as other individuals and entities. Potential VBE participants could be, by way of example only, physician practices, hospitals, payors, post-acute providers, pharmacies, chronic care and disease management companies, and social services organizations. Given that our proposed definition may encompass non-traditional healthcare entities, and our experience with respect to financial arrangements between such entities and providers and suppliers is limited, we are considering for the final rule, and solicit comments on, any fraud and abuse risks that financial arrangements with these entities may present and what, if any, additional safeguards we may need to place around these entities' participation in value-based arrangements under the proposed safe harbors.

a. Entities Not Included as VBE Participants

The ''VBE participant'' definition expressly excludes pharmaceutical manufacturers; manufacturers, distributors, or suppliers of durable medical equipment, prosthetics, orthotics or supplies (DMEPOS); and laboratories. On the basis of our historical enforcement and oversight experience, we are concerned that some companies within these types of entities, which are heavily dependent upon practitioner prescriptions and referrals, might misuse the proposed

safe harbors primarily as a means of offering remuneration to practitioners and patients to market their products, rather than as a means to create value for patients and payors by improving the coordination and management of patient care, reducing inefficiencies, or lowering health care costs. For example, we are concerned that these entities might create arrangements styled as value-based arrangements that serve to tether clinicians or patients to the use of a particular product (*e.g.,* a drug or implantable device, such as a device with a mechanical or physical effect on the body) when a different product could be more clinically effective for the patient. Moreover, pharmaceutical manufacturers, and manufacturers, distributors, and suppliers of DMEPOS, and laboratories are less likely to be on the front line of care coordination and treatment decisions in the same way as other types of proposed VBE entities, such as hospitals, physicians, and remote monitoring companies that provide care coordination and management tools and services directly to patients. We solicit comments on whether this assumption is correct, along with examples of the specific roles played by these entities in coordinating and managing care for patients.

We note that we received comments in response to the OIG RFI from pharmaceutical manufacturers seeking safe harbor protection for a variety of emerging outcomes-based and value-based contracting practices for their pharmaceutical products, as well as related patient medication adherence and similar programs. We also acknowledge that some pharmaceutical manufacturers may help facilitate care coordination and management of care through, for example, data analytics associated with their pharmaceutical products furnished to purchasers of their products. These kinds of manufacturer arrangements raise different program integrity issues from those addressed in this rulemaking and would likely require different safeguards. We are considering pharmaceutical manufacturers' role in coordination and management of care and may address it in future rulemaking. We may also consider specifically tailored safe harbor protection for value-based contracting and outcomes-based contracting for the purchase of pharmaceutical products (and potentially other types of products) in future rulemaking.

We are considering for the final rule whether some or all of the entities we propose to exclude from the definition of a ''VBE participant'' and from the proposed safe harbor for outcomes-based compensation under the personal services and management contracts safe harbor should be included in the definition of ''VBE participant'' and potentially protected by the applicable safe harbors. We are interested in comments with examples of how and the extent to which the entities we propose to exclude participate in the coordination and management of care for patients and whether and how they may be involved in providing beneficial health technology, including digital technology, used to coordinate and manage care and improve health outcomes. We also are considering and are interested in comments on additional safeguards we could include in the safe harbors to: (i) Prevent abusive marketing practices with respect to the items and services these entities (or other entities, not excluded from the proposed definition of ''VBE participant'') sell to patients, payors, and providers (*e.g.,* practices that include payments to physicians, hospitals, or patients to reward them for ordering the entity's products); (ii) protect clinical decision-making about products that are in the patient's best medical interests and patient freedom of choice; and (iii) reduce the risk of inappropriate cost-shifting to Federal health care programs and inappropriate increased costs to Federal health care programs. We are considering whether to include a safeguard, in the applicable proposed safe harbors, that would preclude protection for value-based arrangements and outcomes-based payments that include exclusivity requirements, such as a requirement that the VBE participant is the exclusive provider of care coordination items or services or the exclusive provider of a reimbursable item or service. We are further considering whether to impose certain heightened standards and conditions on certain entities that would receive safe harbor protection, such as enhanced monitoring, reporting, or data submission requirements or some or all of the conditions presented in the discussion of proposed 1001.952(ee) below.

While pharmaceutical manufacturers and other listed entities would not be eligible for protection under the proposed safe harbors for value-based arrangements, patient engagement and support, and revisions related to outcomes-based payments included in the personal services and management contracts safe harbor, other elements of this proposed rule would be available to them. As explained below, we propose certain other modifications to the personal services and management contracts safe harbor that would be available, including greater flexibility for part-time arrangements and arrangements in which the aggregate compensation is not known in advance. These entities also would be eligible under the proposed safe harbors for cybersecurity items and services and for CMS-sponsored models, as well as for the proposed modifications to the warranties safe harbor. Further, we solicit comments on potential revisions to the reporting requirements in the warranties safe harbor that could accommodate outcomes-based warranty arrangements that excluded manufacturers and suppliers may want to undertake. Lastly, we note that pharmaceutical manufacturers or other entities we propose to exclude from the definition of ''VBE participant'' may use the OIG's advisory opinion process for value-based or other arrangements they may want to undertake.

We are considering for the final rule, and seek comments on, whether we should exclude other entities from the definition of ''VBE participant.'' For example, we are considering excluding pharmacies (including compounding pharmacies) from the definition of ''VBE participant.'' We acknowledge that some pharmacies (and pharmacists) have the potential to contribute to the type of beneficial value-based arrangements this rulemaking is designed to foster (*e.g.,* through medication adherence programs or educational services for patients with diabetes). However, pharmacies, like the entities we propose to exclude from the definition of ''VBE participant,'' primarily provide items, and we are concerned that their participation in value-based arrangements may not further the care coordination purposes of this rulemaking. We seek comments on beneficial arrangements pharmacies may want to undertake under the new value-based framework and any safeguards we could implement in the final rule if we were to allow such entities to participate in value-based arrangements eligible for safe harbor protection. We are further considering for the final rule whether specific types of pharmacies, such as compounding pharmacies, should be excluded as VBE participants even if others, such as retail and community pharmacies, are included. In particular, we are concerned that pharmacies that specialize in compounding pharmaceuticals may pose a heightened risk of fraud and abuse, as evidenced by our enforcement experience, and would not play a direct role in patient care coordination.

We also are considering for the final rule excluding pharmacy benefits managers (PBMs), wholesalers, and distributors from the definition of ''VBE participant'' for reasons comparable to those for excluding pharmaceutical manufacturers.[18] We may further consider the role of these entities in care coordination and management in future rulemaking. We are aware that PBMs are increasingly providing services related to the coordination of care for patients. We are interested in comments with examples demonstrating how PBMs engage in care coordination and management with healthcare providers and suppliers, as well as insights into the risks and benefits of including PBMs as VBE participants eligible to enter into value-based arrangements that could qualify for safe harbor protection if all conditions are satisfied.

b. Health Technology Companies

We are mindful that a growing number of companies are providing mobile health and digital technologies to physicians, hospitals, patients, and others for the coordination and management of patients and their healthcare, and such companies are eligible to be VBE participants under the proposed definition. These companies provide a range of services such as remote monitoring, predictive analytics, data analytics, care consultations, patient portals, and telehealth and other communications that may be used by providers, clinicians, payors, patients, and others to coordinate and manage care, improve the quality and safety of care, and increase efficiency. These companies also furnish a variety of devices, technologies, software, and applications that support their services, are used by customers to coordinate and monitor patient care and health outcomes (for individuals and populations), or are used directly by patients and their caregivers to monitor their health, manage treatment, and communicate and access patient medical information. For example, we are aware of companies that provide diabetes management services, leveraging devices that can be worn or attached to the body to monitor blood sugar levels and transmit that data, through an application to a cloud storage service, for review by patients and the clinicians managing the patients' diabetes care.

We are further aware that mobile health and digital health technology companies may be newer entrants to the healthcare marketplace or they may be existing companies. In some cases, they are existing healthcare companies that have developed new lines of business in digital health technology. For example, in some cases, they are companies that have historically manufactured medical devices reimbursed by Federal health care programs and have developed digital technologies that are used in conjunction with medical devices, such as pacemakers. It is our understanding that, depending on the company's business model, what is included as part of the Food and Drug Administration (FDA)-approved device, and payor coverage determinations, the digital technologies and associated functionalities may be included as part of the customer's cost of the medical device, or they may be part of a separate services arrangement.

These technologies hold promise for improving care coordination and health outcomes through monitoring of real-time patient data and detection and prevention of health problems. We are concerned, however, and solicit public comments, about the risk that some companies that manufacture medical devices covered by Federal health care programs, particularly implantable devices used in a hospital or ambulatory surgical center setting, might misuse value-based arrangements to disguise improper payments for care coordination intended as kickbacks to purchase the medical devices they manufacture. This concern arises from historical law enforcement experience, including large False Claims Act settlements involving kickbacks paid to physicians, hospitals, and ambulatory surgery centers to market various medical devices, such as devices used for invasive procedures; in some cases, these schemes resulted in patients getting medically unnecessary surgeries. OIG also has longstanding anti-kickback concerns about physician-owned distributorships because the financial incentives physician-owned distributorships offer to their physician-owners may induce the physicians both to perform more procedures (or more extensive procedures) than are medically necessary and to use the devices the physician-owned distributorships sell in lieu of other, potentially more clinically appropriate, devices.[19]

To address these concerns, we are considering for the final rule the exclusion of some or all device manufacturers under the definition of ''VBE participant'' and from protection under the various proposed safe harbors, including the exclusion from participation in outcomes-based payment arrangements under proposed 1001.952(d)(2) and (3). As with pharmaceutical manufacturers, it is not clear that all device manufacturers play a comparable role in the coordination and management of patient care as those entities proposed to come within the definition of a VBE participant. We solicit comments about this assumption and the roles that traditional device manufacturers play in care coordination and management. Also, as with issues raised by arrangements involving pharmaceutical manufacturers, we are considering future safe harbor rulemaking to address specifically tailored protection for value-based and outcomes-based contracting for device manufacturers. This proposed rule focuses primarily on arrangements to coordinate and manage the care of patients, and does not, for example, address purchase and sale arrangements for covered items and services. We may take up the issue of purchase and sale arrangements, including consideration of modifications to the discount safe harbor or additional modifications to the warranties safe harbor, in future rulemaking.

We recognize that defining a universe of device manufacturers that would be excluded would present difficulties, and we are interested in public feedback on the following issues. First, there is no specific definition of a device manufacturer or medical device manufacturer in the Medicare program. As explained below, in the absence of a Medicare definition, we are considering several other approaches. Second, any definition of the term ''device manufacturer'' may be so broad as to sweep in virtually any kind of device or health technology, including the kinds of digital and remote monitoring technology that may support and improve care coordination. Relatedly, given that many companies pursue multiple lines of business and that digital technologies are being integrated into traditional medical devices, it may not be possible to distinguish clearly a traditional medical device manufacturer from a health technology company.

OIG is considering for the final rule, and seeks comments regarding, whether to define medical device manufacturers using CMS's definition of ''applicable manufacturer'' in 42 CFR 403.902,

[18] Note that, should we adopt, as discussed below, the definition of ''applicable manufacturer'' set forth in 42 CFR 403.902, such definition would include distributors and wholesalers (which include re-packagers, re-labelers, and kit assemblers) that hold title to a covered drug, device, biological, or medical supply.

[19] OIG, Special Fraud Alert: Physician-Owned Entities (Mar. 26, 2013), *available at https://oig.hhs.gov/fraud/docs/alertsandbulletins/2013/POD_Special_Fraud_Alert.pdf.*

which relates to the ''Sunshine'' provisions of the ACA (section 6002 of the ACA, which added section 1128G to the Act). We also are considering, and seek comment on, whether any definition of ''device manufacturer'' should include an entity that manufacturers any item that requires premarket approval by, or premarket notification to, the FDA or that is classified by the FDA as a medical device. We are further considering whether we could define a device manufacturer, in whole or in part, with respect to whether the item it manufactures is eligible for separate or bundled payment from a Federal health care program or other payor or is used in a test that is eligible for separate or bundled payment from a Federal health care program or other payor. We are considering whether the definition of a device manufacturer should include distributors or wholesalers when they are distributing or selling devices manufactured by a device manufacturer. With respect to these proposed definitional approaches, we solicit public comments on whether the proposals would be too broad or too narrow, including whether they would have the effect of excluding from the safe harbors companies that develop and provide digital or other health technologies for care coordination and patient engagement. We are interested in other recommended definitions that would exclude medical device manufacturers without limiting beneficial digital technologies, or recommended factors that we should consider if we were to craft a definition of ''device manufacturer'' or ''medical device manufacturer.''

Finally, apart from excluding device manufacturers, we are considering, and solicit comments on, whether to include additional safeguards in the final safe harbors to mitigate risks of abuse. These safeguards might apply specifically to arrangements involving VBE participants that are health technology companies or device manufacturers or more broadly to all VBE participants. Specifically, as stated above, we are considering and are interested in comments on safeguards that (i) prevent abusive marketing practices with respect to the items and services these the companies sell to patients, payors, and providers (*e.g.,* practices that include payments to physicians, hospitals, or patients to reward them for ordering the company's products); (ii) protect independent clinical decision making about products that are in the patient's best medical interests and patient freedom of choice; and (iii) reduce the risk of inappropriate cost-shifting or inappropriately increasing costs to Federal health care programs. We are considering whether to include a safeguard in the final rule that would preclude protection for value-based arrangements that include exclusivity requirements, such as a requirement that the VBE participant is the exclusive provider of care coordination items or services or the exclusive provider of a reimbursable item or service. We are furthering considering whether heightened standards and conditions could include enhanced monitoring, reporting, or data submission requirements or some or all of the conditions presented in the proposed rule's discussion of proposed 1001.952(ee).

c. Alternatives to ''VBE Participant'' Exclusion List

We are interested in comments on whether, instead of excluding broad categories of entities from the definition of ''VBE participant,'' we should distinguish among entities that would be included or excluded from the definition on the basis of factors such as product type, company structure, heightened fraud risk, or other features. We solicit similar input with respect to exclusions from the proposed revisions to the personal services and management contracts safe harbor related to outcomes-based payments.

Making distinctions by product or arrangement type might alleviate some of the difficulty presented by the increasing integration of healthcare company business lines and the movement of traditional healthcare companies into digital health technology. In this regard, we are considering for the final rule whether to address program integrity concerns regarding potentially abusive drug, device, DMEPOS, and laboratory arrangements by regulating the type of items, goods, or services that can be included in an arrangement eligible for safe harbor protection (under any of the proposed safe harbors) rather than regulating the types of entities included and excluded. For example, we might include arrangements involving the use of mobile or digital technology to coordinate care or achieve outcomes-based payments but exclude arrangements for the sale or distribution of implantable medical devices (*e.g.,* devices with a mechanical or physical effect on the body) or durable medical equipment. In determining for a final rule which products or arrangements would be included and excluded from safe harbor protection, we would take into account any heightened fraud risk based on enforcement experience, CMS's experience administering provider enrollment, claims analysis, and other data sources. We are interested in feedback on which kinds of products or arrangements, if any, should be excluded from safe harbor protection based on heightened fraud risk and examples of such arrangements.

As another alternative to finalizing specific exclusions in the definition of ''VBE participant,'' we are considering excluding entities under the proposed paragraphs (ee), (ff), (gg), and (hh). These paragraphs could each include a condition excluding certain specified entities from protection under the safe harbor. Specifically, we would consider excluding from each of these safe harbors one or more of the following entities: Pharmaceutical manufacturers; manufacturers, distributors, or suppliers of DMEPOS; laboratories; pharmacies (including compounding pharmacies or only compounding pharmacies); device manufacturers; PBMs; pharmaceutical wholesalers; and pharmaceutical distributors. If we include safe harbor-specific conditions excluding certain specified entities from protection under each of (ee), (ff), (gg), and (hh), the entities excluded from each safe harbor could differ.

We also solicit public comment on how best to treat hospitals, health systems, and other types of entities that we have not proposed to exclude under the definition of ''VBE participant'' when they own or operate an entity that we propose to exclude, such as a DMEPOS supplier or laboratory. For example, we are considering for the final rule whether the exclusion should apply only to independent or free-standing DMEPOS suppliers and laboratories and to DMEPOS suppliers and laboratories owned or operated in whole or part by another entity excluded as a VBE participant. For the final rule, we are considering, and solicit comments on, how best to treat health systems and others that may be entering into the device or technology development arenas.

6. Value-Based Purpose

We propose to define a ''value-based purpose'' as: (i) Coordinating and managing the care of a target patient population; (ii) improving the quality of care for a target patient population; (iii) appropriately reducing the costs to, or growth in expenditures of, payors without reducing the quality of care for a target patient population; or (iv) transitioning from healthcare delivery and payment mechanisms based on the volume of items and services provided to mechanisms based on the quality of

care and control of costs of care for a target patient population. With respect to purpose (iii), we are considering whether appropriately reducing the costs to, or growth in expenditures of, payors should be a value-based purpose only when there is improvement in patient quality of care or the parties are maintaining an improved level of care.

We intend for this definition to include infrastructure investment and operations necessary to redesign care delivery to better coordinate care for patients across settings, including technology, data analytics, and training. For example, this could include investing in application programming interface (API) technology that facilitates the exchange of data between VBE participants regarding the target patient population.

Each of our proposed safe harbors at 1001.952(ee), (ff), and (gg) requires that the protected arrangement include value-based activities that directly further the first of the four value-based purposes: The coordination and management of care for the target patient population. We are considering for the final rule, and seek comments on, whether we should include other objectives in the definition of ''value-based purpose'' to reflect our goal of promoting care coordination and the shift toward value-based care and whether any other or different objectives should be prerequisites to protection under our proposed safe harbors. We also are considering for the final rule, and solicit comments on, whether, instead of requiring that some value-based activities directly further the coordination and management of care, we require only that value-based activities be directly connected to, or be reasonably designed to achieve, any of the value-based purposes.

We propose that the first value-based purpose in the definition is the coordination and management of care for a target patient population. This purpose may include taking significant steps to prepare or position oneself to coordinate and manage the care of patients effectively. We propose to define ''coordination and management of care'' and ''coordinating and managing care'' synonymously to mean, for purposes of the anti-kickback statute safe harbors, the deliberate organization of patient care activities and sharing of information between two or more VBE participants or VBE participants and patients, tailored to improving the health outcomes of the target patient population, in order to achieve safer and more effective care for the target patient population.'' [20] For example, such coordination might occur between hospitals and post-acute care providers, between specialists and primary care physicians, or between hospitals or physician practices and patients. Coordinating and managing care could include using care managers, providing care or medication management, creating a patient-centered medical home, helping with transitions of care, sharing and using health data to improve outcomes, or sharing accountability for the care of a patient across a continuum of care.[21] Importantly, our proposed definition of ''coordination and management of care'' relates only to the application of the proposed safe harbor regulations. Although other laws and regulations, including the physician self-referral law and associated regulations, may utilize the same or similar terminology, the definition and interpretations proposed here would not affect CMS's (or any other governmental agency's) interpretation or ability to interpret such term.

Through the proposed definition of ''coordination and management of care,'' we seek to distinguish between referral arrangements, which would not be protected, and legitimate care coordination arrangements, which naturally involve referrals across provider settings but include beneficial activities beyond the mere referral of a patient or ordering of an item or service. We are particularly concerned about distinguishing between coordinating and managing patient care transitions for the purpose of improving the quality of patient care or appropriately reducing costs, on one hand, and churning patients through care settings to capitalize on a reimbursement scheme or otherwise generate revenue, on the other. For example, the coordination and management of care of a target patient population would not include cycling patients through skilled nursing facilities (SNFs) and assisted living facilities for the purpose of maximizing revenue under any applicable Federal health care program reimbursement payment systems.

We are considering for the final rule, and solicit comments on, ways in which we could revise the definition of the ''coordination and management of care'' or additional elements we could include in the definition to protect against fraudulent and abusive practices that parties attempt to characterize as the coordination and management of patient care.

One approach we are considering for the final rule to address these concerns would be to preclude some or all protection under the proposed safe harbors for arrangements between entities that have common ownership. We might do this through refinements to the definition of ''value-based arrangement'' or by adding restrictions to one or more of the proposed safe harbors at paragraphs (ee), (ff), (gg), or (hh). We recognize that while this approach might protect against abusive cycling of patients for financial gain among entities with common ownership, it might also preclude protection for care coordination arrangements among entities in integrated health systems that could otherwise qualify for proposed safe harbor protection. We solicit comments on this potential exclusion, and specifically, how best to (i) define ''common ownership''; and (ii) appropriately demarcate beneficial versus problematic financial arrangements between commonly owned entities. We are interested in feedback on the extent to which integrated health systems believe they need new safe harbor protection for care coordination arrangements in light of currently available protections.

We would not consider the provision of billing or administrative services to be the management of patient care for purposes of this proposed rulemaking; we would consider the sharing or use of health information technology and data to identify a target patient population, coordinate care, or measure outcomes to fit our definition.

We solicit comments on the unique intersection between cybersecurity and the coordination and management of care, and specifically, whether remuneration in the form of cybersecurity items or services could ever meet definition of the ''coordination and management of care'' for a target patient population. For example, we solicit feedback on whether we should consider cybersecurity items or services to only meet this defined term when such remuneration is donated and used in conjunction with health information

[20] *See, e.g.,* Agency for Healthcare Research and Quality, *Care Coordination Measures Atlas* 6 (2014) (citing K. McDonald et al., *Closing the Quality Gap: A Critical Analysis of Quality Improvement Strategies* (2007)), *https://www.ahrq.gov/sites/default/files/publications/files/ccm_atlas.pdf.*

[21] *See, e.g.,* NEJM Catalyst, *What is Care Coordination?* (Jan. 1, 2018), *https://catalyst.nejm.org/what-is-care-coordination/* (providing examples and noting that ''[c]are coordination synchronizes the delivery of a patient's health care from multiple providers and specialists. The goals of coordinated care are to improve health outcomes by ensuring that care from disparate providers is not delivered in silos, and to help reduce health care costs by eliminating redundant tests and procedures.'').

technology that meets this definition of ''coordination and management of care.'' As entities engage in care coordination, increased connectivity and information exchanges may further the need for donating or sharing cybersecurity technology or services to ensure that appropriate cybersecurity safeguards are used to address the cybersecurity risks arising from connections among the entities engaged in care coordination. We recognize the patient safety risks and risk of harm attributed to cybersecurity vulnerabilities and threats.[22] We also solicit comments on whether parties should simply seek protection for cybersecurity items or services under the proposed cybersecurity safe harbor at 1001.952(jj) explained below.

In addition to undertaking value-based activities that are directly connected to the coordination and management of care for the target patient population, our proposed definition of ''value-based purpose'' recognizes that a VBE could have additional value-based purposes and qualify under the value-based framework, namely to: (i) Improve the quality of care for a target patient population; (ii) appropriately reduce the costs to, or growth in expenditures of, payors without reducing the quality of care for a target patient population; and (iii) transition from healthcare delivery and payment mechanisms based on the volume of items and services provided to mechanisms based on the quality of care and control of costs.

C. Care Coordination Arrangements to Improve Quality, Health Outcomes, and Efficiency Safe Harbor (42 CFR 1001.952(ee))

The first proposed safe harbor for value-based arrangements would protect certain care coordination arrangements. Numerous commenters to the OIG RFI noted that individuals and entities may promote value-based care and facilitate care coordination even when assuming no financial risk. We agree. This proposed safe harbor would protect in-kind remuneration exchanged between qualifying VBE participants with value-based arrangements that squarely satisfy all of the proposed safe harbor's requirements. (Certain monetary remuneration associated with care coordination or other value-based activities may be protected under other proposed safe harbors, including those at proposed 42 CFR 1001.952(ff), (gg), (ii), as well as the proposed modifications to the personal services and management safe harbor at 1001.952(d) for outcomes-based payment arrangements.)

Under this proposal, each offer of remuneration must be analyzed separately for compliance with the safe harbor. For example, in a value-based arrangement between a hospital and a SNF, the hospital might provide a behavioral health nurse to follow designated inpatients with mental health disorders in the event of discharge to the SNF. In turn, the SNF might provide certain staff to assist the hospital in coordinating designated patients' care through the discharge planning process or might provide office space for the behavioral health nurse. The hospital's offer of the behavioral health nurse to the SNF must be analyzed separately from the SNF's offer of certain staff members or office space to the hospital.

This proposed safe harbor does not require parties to bear or assume downside financial risk. We are concerned that the offer or provision of remuneration under value-based arrangements could present opportunities for the types of fraud and abuse traditionally seen in the FFS system, particularly where the parties offering or receiving the remuneration have not assumed downside financial risk for the care of the target patient population. For this reason and to ensure that the safe harbored arrangements operate to achieve their value-based purposes, we propose the conditions and safeguards described below.

1. Outcome Measures

We propose to require that parties to a value-based arrangement establish one or more specific evidence-based, valid outcome measures against which the recipient of remuneration will be measured, and which the parties reasonably anticipate will advance the coordination and management of care of the target patient population. We intend for the outcome measures to serve as benchmarks for assessing the recipient's performance under the value-based arrangement and advancement toward achieving the coordination and management of care for the target patient population. Accordingly, we expect such outcome measures to have a close nexus to the value-based activities undertaken by the parties to the value-based arrangement and to the needs of the target patient population.

For purposes of this proposed rule, we would consider ''evidence-based'' to mean the selected outcome measures must be grounded in legitimate, verifiable data or other information, whether the information is internal to one or more of the VBE participants or from a credible external source, such as a medical journal, social sciences journal, scientific study, an established industry quality standards organization, or results of a payor- or a CMS-sponsored model or quality program. For example, a specific evidence-based, valid outcome measure in the context of a hospital's provision of a care coordinator to a SNF could be an increase in the target patient population's average mobility functional score by a certain percentage over the course of a year, contributing to earlier, medically appropriate discharges of patients to their homes and fewer readmissions to acute care. We do not consider measures related to patient satisfaction or convenience (*e.g.,* timeliness of appointments) to be valid outcome measures for purposes of this proposed requirement because we are concerned that such measures may not reflect actual improvement in the quality of patient care, health outcomes, or efficiency in the delivery of care. We solicit comments on whether there are categories of evidence-based outcomes measures in the areas of patient satisfaction or convenience that we should permit in the final rule because they reflect quality or efficiency of care.

Any identified evidence-based, valid outcome measures against which the recipient of remuneration will be measured should not simply reflect the status quo. Consequently, we are considering for the final rule an express requirement that outcome measures be designed to drive meaningful improvements in quality, health outcomes, or efficiencies in care delivery. We intend to provide flexibility given the range of arrangements that may be covered by the proposed safe harbor. For example, an outcome measure may drive meaningful improvements if it drives improvements that are measurable or that are more than nominal in nature. Additionally, we are considering for the final rule, and solicit comment on, whether the outcome measures requirement should be broader or narrower than the standard we are proposing.

We also are considering for the final rule, and solicit comments on, whether to require parties to rebase the outcome measures (*i.e.,* reset the benchmark used to determine whether the outcome measure was achieved) where rebasing is feasible. We are considering whether parties should rebase measures (or determine whether rebasing is feasible)

[22] *See, e.g.,* Health Care Industry Cybersecurity Task Force Report, *available at https://www.phe.gov/preparedness/planning/cybertf/documents/report2017.pdf.*

periodically or pursuant to a specified timeframe, such as at least every 1 year, 3 years, or other time period. We are interested in comments addressing whether and, if so, why the appropriate time frame for rebasing should depend on the type of outcome measure or nature of the arrangement, and what rebasing time periods would be best for different types of measures or arrangements. We are interested in feedback on whether rebasing should be tied to any relevant requirements set by payors. We further solicit comments on whether we should specify a particular party that should be responsible for implementing the rebasing and which party would be best positioned to do so (*e.g.,* the VBE or the offeror of the remuneration). We would anticipate any rebasing requirement would align with the rebasing proposal set forth in our proposed modifications to the personal services and management contracts safe harbor related to outcomes-based payments.

If parties to a value-based arrangement revise the evidence-based, valid outcome measure(s) through an amendment during the term of the arrangement, the revised outcome measure(s) would need to continue to incentivize the recipient of the remuneration to make meaningful improvements. Were parties retrospectively to revise their outcome measures (*e.g.,* modify the outcome measures and make such modifications effective 6 months prior), such revisions would raise questions regarding whether the modified measures were designed to obscure a lack of meaningful improvement by the recipient of the remuneration. For purposes of the final rule, we are considering whether to incorporate the CMS Quality Payment Program measures into the requirement to establish outcome measures.

As described below, the parties to the arrangement also must include a description of the outcome measure(s) in a signed writing, and the VBE, the VBE's accountable body or responsible person, or a VBE participant in the value-based arrangement acting on the VBE's behalf must monitor and assess the recipient's progress toward achieving the outcome measure(s). In addition, as described below, should the VBE's accountable body or responsible person determine through monitoring or otherwise that the value-based arrangement is (i) unlikely to achieve the evidence-based, valid outcome measure(s) or further the coordination and management of care for the target patient population or (ii) has resulted in material deficiencies in quality of care, the parties must terminate the arrangement within 60 days of such a determination or lose safe harbor protection thereafter.

We recognize that it may be difficult for parties giving information technology pursuant to a value-based arrangement to establish an outcome measure upon which to assess the recipient's performance that is ''evidence-based'' as we propose to interpret the term. For this reason, we are considering for the final rule imposing a requirement that information technology meet a different standard than the proposed specific evidence-based, valid outcome measures standard. Specifically, we may require an adoption and use standard (*i.e.,* has the technology been adopted and used in a meaningful way for the intended purposes, such that it advances the coordination and management of care for the target patient population), a performance standard (*i.e.,* has the technology been used to achieve a certain result, such as efficiencies), or a similar standard that serves as a benchmark for assessing a recipient's use of remuneration without requiring the parties to establish evidence-based outcome measures to measure performance. As part of this adoption and use, performance, or similar standard, we are considering requiring parties to a value-based arrangement for the provision of information technology to set forth, in a signed writing, the specific reasons for which the technology is being provided, which would be required to directly relate to health outcomes, patient care quality improvements, or the appropriate reduction in costs to, or growth in expenditures of, payors or patients. For example, parties giving information technology, such as accessibility to a patient portal or data analytics platform, would be required to have health-outcome, quality-related, or efficiency-related reasons, such as improving efficiencies by increasing patient access to health information.

In addition, under an adoption and use, performance, or similar standard, we may require that the parties set forth specific, meaningful measures that relate to the remuneration's intended purpose against which the recipient will be measured. For example, under an adoption and use standard, parties to a value-based arrangement may set a percentage adoption and use measure for a patient portal platform, pursuant to which the recipient would be measured by its adoption and use of the patient portal for a specified percentage of the target patient population.

Lastly, we are considering for the final rule adding the following safeguards for the exchange of information technology: (i) The requirements set forth in paragraph (4) of the current electronic health records items and services safe harbor (1001.952(y)), prohibiting making the receipt of items or services a condition of doing business with the offeror); (ii) a requirement limiting the time frame during which a recipient can receive information technology to, for example, 1, 3, or 5 years, after which time the recipient would be required to pay fair market value for the continued use of the information technology; and (iii) a remedy for the failure to achieve the applicable standard, such as discontinued use of the information technology.

2. Commercial Reasonableness

We propose to require that the value-based arrangement is commercially reasonable, considering both the arrangement itself and all value-based arrangements within the VBE. By way of example with respect to the first prong of the commercial reasonableness requirement, if VBE participants enter into a value-based arrangement to facilitate the sharing of patient-outcome data, it may be commercially reasonable for a hospital VBE participant to donate technology to a group practice VBE participant to facilitate this process. However, it may not be commercially reasonable for that same hospital VBE participant to donate technology substantially more sophisticated, or with enhanced functionality, beyond that necessary for communicating data on shared patients between the two parties. (We note that nothing would prevent the donation of technology with enhanced functionality when a value-based arrangement requires that capability or when technology without that functionality is not practicable.) With respect to the second prong of the commercial reasonableness assessment, again by way of example, a single value-based arrangement in which a hospital VBE participant provides a necessary number of care coordinators for the target patient population to a SNF VBE participant may be commercially reasonable. However, if a VBE includes multiple similar value-based arrangements, each of which involves the same hospital VBE participant furnishing care coordinators to the same SNF VBE participant for the same or a similar target patient population, the commercial reasonableness of the remuneration exchanged within the value-based arrangements in the aggregate may be suspect if it lacks a legitimate business purpose.

We are considering for the final rule whether to define ''commercially reasonable arrangement'' as an arrangement that would make commercial sense if entered into by reasonable entities of a similar type and size, even without the potential for referrals. We solicit comments on the need for a definition of ''commercially reasonable arrangement,'' and if we incorporate a definition, whether we should select this particular definition or an alternative definition.

3. Writing

To promote transparency and accountability, we propose a requirement that the value-based arrangement be set forth in a writing. We propose that the writing be signed by the parties and established in advance of, or contemporaneous with, the commencement of the value-based arrangement or any material change to the value-based arrangement. We propose that the writing state, at a minimum: (i) The value-based activities to be undertaken by the parties to the value-based arrangement; (ii) the term of the value-based arrangement; (iii) the target patient population; (iv) a description of the remuneration; (v) the offeror's cost for the remuneration; (vi) the percentage of the offeror's costs contributed by the recipient; (vii) if applicable, the frequency with which the recipient will make payments for ongoing costs; and (viii) the specific evidence-based, valid outcome measures against which the recipient would be measured. In the final rule, we would align the writing requirements in (v) and (vi) with the requirements for the contribution requirement described below; in other words, if we were to change the contribution requirements, we would correspondingly change the writing requirement.

We believe that a writing, setting forth the above terms in advance of, or contemporaneous with the commencement of or any material change to the value-based arrangement, constitutes a key safeguard to ensure that VBE participants are not using the value-based arrangement merely to incentivize and reward referrals of business. We are interested in comments regarding whether a requirement to have a single writing signed by all parties may be burdensome, especially for large-scale arrangements, and whether we should instead permit a collection of writings provided that every party to the arrangement has signed a writing acknowledging consent to the arrangement.

4. Limitations on Remuneration

a. In-Kind Remuneration

We propose to protect only in-kind, non-monetary remuneration, provided all other conditions of the safe harbor are met. (While monetary remuneration is not protected by this proposed safe harbor, certain outcomes-based payment arrangements may be protected by proposed modifications to the personal services and management contracts safe harbor, as subsequently addressed.) We further propose that this safe harbor would exclude protection for gift cards, regardless of whether they may be considered cash equivalents. By way of example, we intend for this safe harbor to allow a VBE participant to share a care coordinator with another VBE participant if the conditions of this safe harbor are met (including the proposed contribution requirement). However, this safe harbor would not protect cash provided from one VBE participant to another to hire a care coordinator. Lastly, we note that by virtue of our exclusion of monetary remuneration, the proposed safe harbor would not protect an ownership or investment interest in the VBE or any distributions related to an ownership or investment interest. In addition to our long-standing view that the exchange of monetary remuneration poses heightened and different fraud and abuse risks and thus should be subject to safeguards such as a fair market value requirement, we do not view the offer or receipt of ownership or investment interests as integral to the coordination and management of care for a target patient population.

b. Primarily Engaged in Value-Based Activities

We propose to require that the remuneration provided by, or shared among, VBE participants be used primarily to engage in value-based activities that are directly connected to the coordination and management of care of the target patient population. As set forth in proposed paragraph 1001.952(ee), we propose to define a ''value-based activity'' as ''any of the following activities, provided that the activity is reasonably designed to achieve at least one value-based purpose of the value-based enterprise: (i) the provision of an item or service; (ii) the taking of an action; or (iii) the refraining from taking an action.'' In the definition of ''value-based activity'', we specify that it does not include the making of a referral. We also propose to require that the value-based arrangement be set forth in a signed writing stating the value-based activities to be undertaken by the parties in the value-based arrangement.

We recognize that in-kind remuneration exchanged for value-based activities may indirectly benefit patients outside of the scope of the value-based arrangement, and furthermore, that parties may find it difficult to anticipate or project the scope or extent of such ''spillover'' benefits. This, in and of itself, would not result in the loss of safe harbor protection, provided the parties primarily use the remuneration for its intended purposes (*i.e.,* the specific value-based activities for which the remuneration is being provided, as set forth in the parties' signed writing). We are mindful of the need to provide parties with sufficient flexibility, while also minimizing the risks of potentially abusive arrangements that disguise remuneration unrelated to the coordination and management of care for the target patient population.

For purposes of the final rule, as an alternative to the requirement that remuneration exchanged between VBE participants be used primarily to engage in value-based activities, we are considering requiring that the remuneration exchanged be limited to value-based activities that only benefit the target patient population. Under this approach, arrangements with ''spillover'' benefits would not be protected by the safe harbor. We solicit comments on this alternative approach.

c. No Furnishing of Medically Unnecessary Items or Services or Reduction in Medically Necessary Items or Services

We propose to require that the remuneration exchanged not induce the parties to furnish medically unnecessary items or services or reduce or limit medically necessary items or services furnished to any patient. Remuneration that induces a provider to order or furnish unnecessary care is inherently suspect. In addition, a reduction in medically necessary services would be contrary to the goals of this rulemaking and, in some instances involving hospitals and physicians, could be a violation of the CMP law provision relating to gainsharing arrangements at sections 1128A(b)(1) and (2) of the Act (42 U.S.C. 1320a–7a(b)(1) and (2)).

d. No Remuneration From Individuals or Entities Outside the Applicable VBE

We propose that this safe harbor would not protect any remuneration funded by, or otherwise resulting from the contributions of, an individual or entity outside of the applicable VBE. This proposal is intended to ensure that protected arrangements are closely

related to the VBE, that VBE participants are committed to the VBE and striving to achieve the coordination and management of care of the target patient population, and that non-VBE participants cannot indirectly use the safe harbor to protect arrangements that are designed to influence the referrals or decision making of VBE participants. For example, a pharmaceutical manufacturer could not circumvent the proposed exclusion of pharmaceutical manufacturers from the definition of ''VBE participant'' by providing funds to a third-party entity and then directing or otherwise controlling any aspect of the third-party entity's participation as a VBE or a VBE participant. We solicit comments on this approach and whether there may be defined, limited circumstances in which non-VBE participants should be able to contribute to a value-based arrangement eligible for safe harbor protection.

As a corollary to this requirement, we are considering for the final rule whether to require that remuneration be provided directly from the offeror to the recipient. This requirement would prohibit the involvement of individuals or entities other than the VBE or a VBE participant in the exchange of remuneration under a value-based arrangement, including, potentially, third-party vendors and contractors. We solicit comments on any practical impediments such as restriction would create.

5. The Offeror Does Not Take Into Account the Volume or Value of, or Condition Remuneration on, Business or Patients Not Covered Under the Value-Based Arrangement

We propose a requirement that prohibits the offeror of the remuneration from taking into account the volume or value of, or conditioning an offer of remuneration on: (i) Referrals of patients that are not part of the value-based arrangement's target patient population, or (ii) business not covered under the value-based arrangement. This proposal is modeled on a similar safeguard contained in the existing safe harbor at paragraph 1001.952(t)(1)(ii)(B), which provides that ''neither party gives or receives remuneration in return for or to induce the provision or acceptance of business (other than business covered by the agreement) for which payment may be made in whole or in part by a Federal health care program on a fee-for-service or cost basis.'' Our purpose in proposing this requirement is to prohibit protection for remuneration offered under the guise of a value-based arrangement when that remuneration actually is intended to induce referrals of patients or business not covered under the value-based arrangement (sometimes called ''swapping'' arrangements).

This requirement would exclude safe harbor protection for any remuneration that is explicitly or implicitly offered, paid, solicited, or received in return for, or to induce or reward, any referrals or other business generated outside of the value-based arrangement. Under our proposal, VBE participants could encourage referrals of the target patient population as part of value-based activities (*e.g.,* a hospital could develop a ''preferred network'' of post-acute care providers that meet certain quality criteria). However, VBE participants could not offer remuneration in connection with the preferred network to induce business or the referral of patients that fall outside the scope of the value-based arrangement.

In lieu of the proposed requirement that prohibits the offeror of the remuneration from taking into account the volume or value of, or conditioning an offer of remuneration on: (i) Referrals of patients that are not part of the value-based arrangement's target patient population, or (ii) business not covered under the value-based arrangement, we are considering for the final rule, and solicit comments on, an alternative requirement that would require that the aggregate compensation paid by the offeror is not determined in a manner that takes into account the volume or value of referrals or business generated between the parties for which payment may be made by a Federal health program. While we believe that this condition could potentially better protect against bad actors who may seek to use the care coordination arrangements safe harbor as an affirmative defense for an unlawful referral arrangement or to disguise arrangements that result in unnecessary increases in utilization and expenditures, we seek comments on whether and to what extent this requirement might impede to goal of this rulemaking, namely to remove barriers for beneficial care coordination and value-based arrangements. We are interested in specific examples of arrangements that would be unable to use this safe harbor were we to adopt this requirement.

6. Contribution Requirement

The goal of this proposed rulemaking is to remove barriers to improved care coordination and to promote efficient, value-driven care. To this end, it is important that protected remuneration be used to facilitate the coordination and management of care for the target patient population. We are proposing a recipient contribution requirement as a safeguard to help ensure that the use of any remuneration exchanged pursuant to this safe harbor would be for the coordination and management of the target patient population's care.

Specifically, the proposed rule would condition safe harbor protection on the recipient's payment of at least 15 percent of the offeror's cost for the in-kind remuneration. This requirement is intended to mirror that set forth in the current electronic health records items and services safe harbor, 1001.952(y). We are considering for the final rule, and solicit comments on, whether we should require a more specific methodology for determining value, such as either the fair market value of the remuneration to the recipient or the reasonable value of the remuneration to the recipient. If we were to require that parties assess the fair market value of the remuneration to the recipient in order to determine the required contribution amount(s), we would not require parties to obtain an independent fair market valuation. We are interested in feedback on whether the method for determining the contribution requirement should be different for services than for goods.

We believe that requiring financial participation by a recipient should: Increase the likelihood that the recipient actually would use the care coordination items and services, ensure that the remuneration is well-tailored to the recipient, and promote the recipient's vested interest in achieving the intended purpose of the value-based arrangement, namely, furthering the coordination and management of care of the target patient population.

In proposing this contribution requirement, we solicit feedback on the proposed contribution amount, whether certain recipients, such as rural providers, small providers, Tribal providers, providers who serve underserved populations, or critical access hospitals should be exempted from the contribution requirement or pay a lower contribution percentage and if so, why. We are considering for the final rule alternative contribution amounts ranging from 5 percent to 35 percent and solicit comments on an appropriate amount (or amounts) that would invest recipients in using the remuneration they receive to advance the coordination and management of care of the target patient population, while still allowing flexibility for parties with fewer financial resources to engage in value-based arrangements. We are considering whether we should require different contribution amounts for

different types of remuneration (*e.g.,* a higher or lower contribution amount for technology and a higher or lower contribution amount for care coordinators or other services arrangements).

We also are considering whether in the final rule we should impose different contribution requirements for different recipients. Because a contribution requirement may impose a significant financial burden on certain recipients, we are considering for the final rule, and solicit comments on, whether a lower contribution amount, or no contribution amount, would be appropriate for arrangements involving certain providers with financial constraints, such as providers in rural or underserved areas, providers serving underserved populations, small providers, Tribal providers, and critical access hospitals.

For consideration of this potential contribution requirement condition, and whether a lower contribution amount, or no contribution amount, is appropriate for arrangements involving such providers, we cross-reference the proposals discussed more fully in relation to the electronic health records arrangements safe harbor's 15 percent contribution requirement. We will review and consider comments received about those proposals in relation to our consideration of this potential condition. Based on feedback on the contribution requirement in our existing electronic health records safe harbor, we are mindful of the potential administrative burdens of a contribution requirement and seek comments on this issue.

We also solicit comments on how to apply the contribution requirement for ongoing costs and unexpected ''add-ons'' (*e.g.,* updates or upgrades to software that trigger additional costs). Under the proposed contribution requirement, if the remuneration represents a one-time cost, the recipient would be required to make a contribution in advance of receiving the remuneration. However, for any ongoing costs, the proposed rule would require that the recipient make any contributions on reasonable, regular intervals, with the frequency of such payments documented in writing. We are considering for the final rule, and seek comment on, an alternative requirement for the recipient to make a contribution with respect to the initial provision of remuneration but not with respect to any update, upgrade, or patch of the remuneration already provided. This is similar to an option being considering for the electronic health records arrangements safe harbor, 1001.952(y). We recognize that this alternative option may affect contribution requirements only for technology-based remuneration that is most likely to need upgrades, updates, and patches to continue operating as intended.

7. Requirements of a Value-Based Arrangement

a. Direct Connection to the Coordination and Management of Care

We propose that the value-based arrangement has a direct connection to the coordination and management of care for the target patient population. We interpret this requirement to mean that any remuneration offered pursuant to a value-based arrangement has a close nexus to the coordination and management of care for the target patient population, as opposed to the VBE participants' referral patterns and business generated. By way of example only, arrangements where VBE participants offer, or are required to provide, remuneration to receive referrals or to be included in a ''preferred provider network'' (*i.e.,* ''pay-to-play'' arrangements) would not have a direct connection to the coordination and management of care. We are considering for purposes of the final rule, and solicit comments on, whether we should use alternative language to ''direct connection'' (*e.g.,* ''reasonably related and directly tied'') in order to better convey the close nexus that this safe harbor requires between each value-based arrangement and the coordination and management of care of a target patient population.

b. No Limitation on Decision Making; Restrictions on Directing or Restricting Referrals

We propose that the value-based arrangement must not limit parties' ability to make decisions in the best interests of their patients. That is, VBEs and VBE participants to a value-based arrangement must maintain their independent, medical, or other professional judgment. Additionally, we are aware that some payors and others, such as employers, direct or restrict where their networks or employees refer patients; moreover, we are aware that under some value-based arrangements, referrals would be directed within a network or continuum of preferred providers (based on quality and other legitimate considerations). We propose that, in addition to not limiting parties' ability to make referral decisions in the patients' best medical interests, value-based arrangements cannot direct or restrict referrals if: (i) A patient expresses a preference for a different practitioner, provider, or supplier; (ii) the patient's payor determines the provider, practitioner, or supplier; or (iii) such direction or restriction is contrary to applicable law or regulations under titles XVIII and XIX of the Act. This provision is intended, in part, to preserve patient freedom of choice among healthcare providers and ensure the VBE's and VBE participants' independent medical or professional judgment is not unduly restricted. That being said, we do not intend for this criterion to bar VBEs or VBE participants from communicating the benefits of receiving care from other VBE participants in the VBE.

c. No Marketing of Items or Services or Patient Recruitment Activities

We propose to exclude safe harbor protection for value-based arrangements that include marketing items or services to patients or patient recruitment activities. Our enforcement experience demonstrates that fraud schemes often involve the purchase of beneficiaries' medical identity or other inducements to lure beneficiaries to obtain unnecessary care. This proposed safe harbor condition would protect beneficiaries and make clear that such coercive arrangements are not value-based arrangements protected by the proposed safe harbor. Accordingly, the proposed safe harbor would offer flexibility to improve quality of care, health outcomes, and efficiency while limiting the risk of the value-based arrangement being used as a marketing or recruiting tool to generate federally payable business for a VBE participant. Specifically, this requirement would restrict any party to a value-based arrangement, or such party's agent, from marketing, or engaging in patient recruitment activities related to, any items or services offered or provided to patients in the target patient population under a value-based arrangement.

We do not intend for this limitation to prohibit a VBE participant that is a party to a value-based arrangement from educating patients in the target patient population regarding permissible value-based activities. For example, if a SNF or home health agency placed a staff member at a hospital to assist patients in the discharge planning process, and in doing so, the staff member educated patients regarding care management processes used by the SNF or home health agency, this would not constitute marketing of items and services (provided the staff member only worked with patients that had already selected the SNF or home health agency and SNF or home-health agency care was

medically appropriate for such patient). However, if the SNF or home health agency placed a staff member at a hospital to market its services to hospital patients, the arrangement would not comply with this proposed requirement. We solicit comments on this approach.

8. Monitoring and Assessment

We propose a requirement that the VBE, a VBE participant in the value-based arrangement acting on the VBE's behalf, or the VBE's accountable body or responsible person monitors and assesses, no less frequently than annually, or once during the term of the value-based arrangement for arrangements with terms of less than 1 year: (i) The coordination and management of care for the target population in the value-based arrangement, (ii) any deficiencies in the delivery of quality care under the value-based arrangement, and (iii) progress toward achieving the evidence-based, valid outcome measure(s) in the value-based arrangement. We further propose to require that the party conducting such monitoring and assessment reports such monitoring and assessment to the VBE's accountable body or responsible person (if the VBE's accountable body or responsible person is not itself conducting the monitoring and assessment). Through this proposal, we seek to ensure that the VBE's accountable body or responsible person periodically assesses the parties' performance of certain key metrics under each value-based arrangement. We note that this proposal does not mandate how this monitoring should be performed. We intend for the monitoring to be tailored based on the complexity and sophistication of the VBE participants, the VBE, and the value-based arrangement and available resources. We are considering for the final rule, and solicit comments on, whether to require that both the party offering the remuneration and its recipient jointly conduct monitoring and assessment responsibilities. We further solicit comments on the role monitoring of utilization, referral patterns, and expenditure data could play in ensuring that the potential for abuses or gaming is reduced.

The proposed rule would further require that if the VBE's accountable body or responsible person determines, through reports of monitoring and assessment, that the value-based arrangement (i) is unlikely to further the coordination and management of care for the target patient population, (ii) has resulted in material deficiencies in quality of care, or (iii) is unlikely to achieve the evidence-based, valid outcome measure(s), the parties terminate the arrangement within 60 days of such a determination. To the extent the parties do not terminate an arrangement within 60 days of such determination, the parties would lose safe harbor protection under this proposal. We solicit comments on whether to adopt a longer or shorter timeframe for termination; our goal is a reasonable but also prompt termination of arrangements that are no longer serving the goals for which safe harbor protection is offered. In addition, we are considering for the final rule and seek comment regarding whether, in lieu of the proposed termination requirement for the above subsections (i) through (iii), the safe harbor should instead allow for remediation—within a reasonable timeframe—before any required termination.

We are not proposing to define ''material deficiency in quality of care.'' We believe that such ''material deficiency'' may vary depending on the nature of the VBE and the value-based arrangements of its VBE participants. Examples of a ''material deficiency in quality of care'' may include, but are not limited to, identified instances of potential patient harm or a pattern of diminished quality of care.

Our proposals with respect to monitoring and assessment stem from a recognition that most arrangements protected by this proposed care coordination arrangements safe harbor would not be subject to governmental programmatic requirements, oversight, or monitoring comparable to CMS-sponsored models. Accordingly, to aid in protecting against abusive arrangements, to further facilitate the government's understanding and awareness of value-based arrangements and their impacts on Federal health care program beneficiaries and expenditures, and to create incentives for VBEs to exercise due diligence when establishing them, we are considering for the final rule requiring VBEs to submit certain data to the Department that would identify the VBE, VBE participants, and value-based arrangements, as a requirement for safe harbor protection. We solicit comments on whether such a requirement would present compliance or operational burdens for VBEs seeking the protection of this safe harbor.

Were such a proposal finalized, required data might include the National Provider Identifier (NPI) number or other identifying information of each VBE participant in the VBE, each party participating in the value-based arrangement, as well as information regarding the arrangement, such as its duration. This data could be used, for example, by the government for data analysis to understand whether value-based arrangements are associated with increased or decreased utilization or outlier levels of utilization (taking into account that in some value-based arrangements one would expect to see increased utilization of some types of items and services and decreases in others). Should we adopt this approach, information would be submitted in a form and manner and at times specified by the Secretary in guidance. We solicit comments on the types of data that the parties availing themselves of safe harbor protection should be required to submit to the Department, potential reporting and compliance burdens for small and large value-based enterprises, and any different or additional actions that may help ensure appropriate oversight.

9. No Diversion, Resell, or Use for Unlawful Purposes

We propose that the exchange of remuneration under this safe harbor would not be protected if the offeror knows or should know that the remuneration is likely to be diverted, resold, or used by the recipient for an unlawful purpose. Here, we state expressly what is otherwise implicit in the design of a value-based arrangement under this proposed safe harbor: The exchange of remuneration that the offeror knows or should know is likely to be diverted, resold, or used by the recipient for purposes other than the coordination and management of care of a target patient population would not be protected.

10. Materials and Records

To ensure transparency, we propose a requirement that VBE participants or the VBE make available to the Secretary, upon request, all materials and records sufficient to establish compliance with the conditions of this safe harbor. We are not proposing parameters regarding the creation or maintenance of documentation to allow VBE participants the flexibility to determine what constitutes best documentation practices, but welcome comments on whether such parameters may be needed. In particular, we seek comment regarding whether we should require, in the final rule, a requirement that parties maintain materials and records sufficient to establish compliance with the conditions of this safe harbor for a set period of time (*e.g.,* at least 6 years or 10 years).

11. Possible Additional Safeguards

a. Bona Fide Determination

We are considering for the final rule a condition that would require that, in advance of, or contemporaneous with, the commencement of the applicable value-based arrangement, the VBE's accountable body or responsible person make two *bona fide* determinations with respect to the value-based arrangement. First, we are considering a condition requiring that the accountable body or responsible person make a *bona fide* determination that the value-based arrangement is directly connected to the coordination and management of care for the target patient population. Second, we are considering a condition requiring that the accountable body or responsible person make a *bona fide* determination that the value-based arrangement is commercially reasonable, considering both the arrangement and all value-based arrangements within the VBE.

b. Cost-Shifting Prohibition

We are considering for the final rule, and seek comment on, a condition prohibiting VBEs or VBE participants from billing Federal health care programs, other payors, or individuals for the remuneration; claiming the value of the remuneration as a bad debt for payment purposes under a Federal health care program; or otherwise shifting costs to a Federal health care program, other payors, or individuals.

This proposal would not exclude arrangements from safe harbor protection that involve legitimate shifting of some costs that result from achieving care coordination goals or other value-based purposes. For example, depending on the arrangement, one might expect to see increases in primary care costs or costs for care furnished in home and community settings paired with reductions in unnecessary hospitalizations, duplicative testing, and emergency room visits; one also might see increases in remote monitoring or care management services.

c. Fair Market Value Requirement and Restriction on Remuneration Tied to the Volume or Value of Referrals

Commenters to the OIG RFI pointed to fair market value requirements and restrictions on remuneration based on the volume or value of business in existing safe harbors as barriers to arrangements that facilitate coordinated and value-based care, so we have crafted this proposed safe harbor without them, relying instead upon other program integrity safeguards. However, fair market value requirements and restrictions that prohibit paying remuneration based on the volume or value of referrals help ensure that protected payments are for legitimate purposes and are not kickbacks. We have endeavored to draft this safe harbor to distinguish between beneficial care coordination arrangements and payment-for-referral schemes that do not serve, and may be contrary to, the goals of coordinated care and the shift to value. We solicit comments from stakeholders for safeguards that may help distinguish payments to reward or induce referrals from remuneration provided to promote or support legitimate care coordination activities.

To this end, we are considering as an alternate proposal for the final rule's care coordination arrangements safe harbor: (i) Whether we should include a fair market value requirement on any remuneration exchanged pursuant to a value-based arrangement, and (ii) whether we should include a further or alternate requirement prohibiting VBE participants from determining the amount or nature of the remuneration they offer, or the VBE participants to whom they offer such remuneration, in a manner that takes into account the volume or value of referrals or other business generated, including both business or patients that are part of the value-based arrangement and those that are not. To the extent these requirements would impede value-based and care coordination arrangements, we are interested in feedback on potential, alternative safe harbor conditions that might mitigate such effects.

We are further considering for the final rule whether we could best achieve the goals of this rulemaking through a safe harbor design that requires value-based arrangements to be fair market value but that does not prohibit determining the amount or nature of the remuneration on the volume or value of referrals or other business generated. This approach would recognize the anti-kickback statute compliance challenge that the restriction on the volume or value of referrals or other business generated poses for arrangements that inherently reflect the volume of patients for whom care is coordinated or the value of services offered under a value-based arrangement. In addition, or as an alternative, we are considering a restriction that would prohibit remuneration based *directly* on the volume or value of business generated between the parties (thus permitting remuneration based indirectly on the volume or value of referrals or other business generated between the parties).

d. Additional Requirements for Dialysis Providers

Dialysis providers furnish vital services to patients with critical and extensive care needs. Patients with end stage renal disease (ESRD) stand to benefit substantially from better coordinated, more efficient care as envisioned by this proposed rule. Dialysis providers play a central role in coordinating the care of individuals with ESRD. However, the dialysis industry has unique attributes—in particular, market dominance by a limited number of dialysis providers—that may increase fraud and abuse risks attendant to financial relationships between dialysis providers and others. We are concerned that present levels of market consolidation could impact access to dialysis care, quality of care, and associated health outcomes.[23] In addition, we are concerned that, because of the aforementioned market dominance of a limited number of providers, the conduct that would be protected by this proposed safe harbor could lead to a decrease in competition among dialysis providers. We seek comment on whether and how the potential protection of financial arrangements between dialysis providers and others under this proposed safe harbor could affect the concentration of the dialysis market, access to care, quality of care, and associated health outcomes. We are considering whether to include in the final rule certain conditions specific to dialysis providers to further ensure that their care coordination arrangements operate to improve the management and care of patients and are not pay-for-referral schemes. These conditions could include enhanced monitoring, reporting, or data submission requirements or some of the conditions discussed in sections a., b., and c. directly above, including fair market value requirements and restrictions that prohibit paying remuneration based on the volume or value of referrals.

12. Example of a Value-Based Arrangement Analyzed Under the Proposed Care Coordination Arrangements Safe Harbor

The following example demonstrates how parties might analyze the proposed care coordination arrangements safe harbor's various requirements with

[23] *See* Kevin F. Erickson et al., *Consolidation in the Dialysis Industry, Patient Choice, and Local Market Competition,* 28 Clinical J. of the American Society of Nephrology 3 (Mar. 7, 2017).

respect to the following fact pattern: To coordinate care between an acute care hospital and a SNF for mental health patients, the hospital and SNF enter into a care coordination arrangement under which the hospital engages in the value-based activity of providing a behavioral health nurse for to the SNF to follow designated inpatients with certain mental health disorders for a 1-year time period, who comprise the target patient population, following discharge from the hospital and during admission to and while receiving care at the SNF. In this example, both the hospital and the SNF stand to benefit from this arrangement because they participate in a value-based payment arrangement that offers them shared savings payments for improved quality and patient outcomes and reduced emergency room visits. The hospital and SNF are the only VBE participants in a VBE that is designed to accomplish the value-based purpose of coordinating and managing the care of patients with mental health disorders (namely, by improving the quality of care they receive during the care transition process from acute care to skilled nursing care and during their SNF stay).

This proposed arrangement would implicate the anti-kickback statute, because the hospital would be providing the SNF with remuneration (the behavioral health nurse services) and the SNF could refer Medicare, Medicaid, or other Federal health care program patients to the hospital. Safe harbor protection is afforded only to those arrangements that precisely meet all of a safe harbor's conditions. Consequently, the hospital and SNF might engage in the following analysis to determine whether their proposed arrangement satisfies the proposed care coordination arrangements safe harbor's requirements.

First, the hospital and SNF must establish specific evidence-based, valid outcome measures against which the SNF will be measured throughout the arrangement, and which the parties reasonably anticipate will advance the coordination and management of care for the target patient population.

Second, the parties must ensure that devoting one full-time nurse to oversee these patients would be commercially reasonable, considering both the arrangement itself and all value-based arrangements in the VBE.

Third, the hospital and SNF must execute a signed writing documenting the terms of the value-based arrangement prior to, or contemporaneous with, its commencement or any material changes to the arrangement. The writing must include: (i) The term of the value-based arrangement; (ii) the value-based activities to be undertaken; (iii) the target patient population; (iv) a description of the remuneration (*e.g.,* the assignment of a full-time nurse to the SNF and the cost of the nurse's services to the offeror); (v) the offeror's cost of the remuneration; (vi) the percentage of the offeror's cost contributed by the recipient; (vii) if applicable, the frequency of the recipient's contribution payments for ongoing costs; and (viii) set forth the specific, evidence-based valid outcome measure(s) against which the SNF would be measured.

Fourth, the remuneration must: (i) Be in-kind; (ii) be used primarily to engage in one or more value-based activities that have a direct connection to the coordination and management of care for the target patient population; and (iii) not induce VBE participants to furnish medically unnecessary items or services or reduce or limit medically necessary items and services furnished to any patient. In addition, the hospital could not provide the nurse to the SNF if any part of the cost of the nurse would be funded by, or otherwise result from the contributions of, an individual or entity outside of the VBE, such as a pharmaceutical or medical device manufacturer.

Fifth, the hospital's provision of the nurse to the SNF must not take into account the volume or value of, or condition the remuneration on, referrals of patients who are not part of the target patient population and business not covered under the value-based arrangement.

Sixth, the SNF must pay for at least 15 percent of the hospital's cost of the care coordination services provided by the nurse over the arrangement's one-year term. Assuming the nurse provides periodic services throughout the year, the SNF must pay its required contribution amount at reasonable, regular intervals, such as on a monthly basis.

Seventh, the value-based arrangement must be directly connected to the coordination and management of care of the target patient population. In addition, the value-based arrangement must not place any limitation on the VBE participants' ability to make decisions in the best interest of their patients. Further, if the value-based arrangement restricts or directs referrals, the value-based arrangement may not require referrals to a particular provider, practitioner, or supplier: (i) If a patient expresses a preference for a different practitioner, provider, or supplier; (ii) if the patient's payor determines the provider, practitioner, or supplier; or (iii) such direction or restriction is contrary to applicable law or regulations under titles XVIII and XIX of the Act. For example, the hospital could not require physicians on its medical staff to refer patients in the target patient population to the SNF if a patient expresses a preference for a different facility or if the patient's payor does not cover services at the SNF.

Eighth, the arrangement must not include marketing to patients of items or services or engaging in patient recruitment activities.

Ninth, the VBE (or alternatively, the SNF or hospital acting on the VBE's behalf), or the VBE's accountable body or responsible person must monitor and assess at least annually (or once during the agreement's term if the agreement is for less than a year): (i) The coordination and management of care of the target patient population; (ii) any deficiencies in the delivery of quality care under the value-based arrangement; and (iii) progress toward achieving the evidence-based, valid outcome measure(s) in the value-based arrangement. If, through monitoring and assessment, the VBE's accountable body or responsible person determines that the value-based arrangement is: (i) Is unlikely to further the coordination and management of care for the target patient population, (ii) has resulted in material deficiencies in quality of care, or (iii) is unlikely to achieve the evidence-based, valid outcome measure(s), the parties terminate the arrangement within 60 days of such a determination.

Tenth, the hospital does not, and should not, know that the behavioral nurse's services are likely to be ''diverted'' by the SNF (*e.g.,* used by the SNF to perform tasks unrelated to the care coordination and management of the target patient population) or used for an unlawful purpose (*e.g.,* the provision of medically unnecessary services).

Finally, the VBE participants must provide documentation, such as the signed writing, to the Secretary, upon request, showing that the parties complied with the safe harbor provisions.

13. Alternative Regulatory Structure

This proposed rule provides protections for certain care coordination and value-based arrangements through a combination of proposed revisions to the personal services and management contracts safe harbor at 1001.952(d), the proposed care coordination arrangements safe harbor at 1001.952(ee), the proposed substantial downside financial risk safe harbor at

1001.952(ff), and the full downside financial risk safe harbor at 1001.952(gg). As an alternative to this suite of protections, we are considering for the final rule a different regulatory structure and approach to protect care coordination and other value-based arrangements that are not at full financial risk (as defined at proposed 1001.952(gg)) and are not part of a CMS-sponsored model (as defined at proposed 1001.952(ii)). For this alternate approach, we would rely solely on the personal services and management contracts safe harbor at paragraph 1001.952(d) as a platform to create tiered protection for value-based arrangements, each step of which would remove additional conditions of paragraph 1001.952(d) to allow greater flexibility for innovation as the arrangements become more closely aligned with value-based purposes (as defined in proposed paragraph 1001.952(ee)) and the parties take on more downside financial risk.

First, as proposed and described in our proposed modifications to the personal services and management contracts safe harbor, we would remove the requirement that aggregate compensation under service arrangements be set forth in advance, substituting a requirement that the methodology for determining the compensation be set in advance. This would offer broader protection for certain outcomes-based payment arrangements that are fair market value and do not take into account the volume or value of referrals or other business. Protected arrangements would not be required to meet the proposed definition of ''value-based arrangement.''

Second, for value-based arrangements that meet applicable requirements of the VBE framework previously outlined (*e.g.,* the parties to the arrangement are VBE participants in a VBE), we would provide additional flexibility under the personal services and management contracts safe harbor by removing the requirements that the aggregate compensation: (i) Be set in advance (but requiring that the compensation methodology be set in advance); and (ii) not be determined in a manner that takes into account the volume or value of referrals. We may also incorporate safeguards from our proposed care coordination arrangements safe harbor (*e.g.,* the monitoring requirement). To ensure that protected arrangements meet their value-based purposes, we might incorporate additional accountability and transparency requirements, such as those proposed for new safe harbor 1001.952(ee). We envision this framework would be similar to our current proposal to add new protections for outcomes-based payments at proposed new paragraph 1001.952(d)(2).

Third, for parties that meet the requirements of the value-based framework and also assume substantial downside financial risk (as defined in proposed 1001.952(ff)), we would provide increased flexibility under the personal services and management contracts safe harbor for their arrangements by removing the requirements that the aggregate compensation: (i) Be set in advance (but requiring that the compensation methodology be set in advance); (ii) not be determined in a manner that takes into account the volume or value of any referrals; and (iii) be consistent with fair market value in arm's-length transactions. This additional flexibility would be afforded in recognition of the parties' assumption of downside financial risk.

With respect to the volume or value requirement, we are considering for the final rule several alternative ways we might remove it in the second and third steps of this approach. We might remove it entirely or remove it in part by retaining a requirement that the compensation not relate *directly* to the volume or value of referrals or other business generated between the parties (allowing for indirect correlations). With respect to a fair market value requirement, we might remove it entirely; remove it only for monetary remuneration or only for in-kind remuneration; or remove it where the non-fair market value arrangement primarily benefits the offeror of the remuneration, with such benefit independent of any increase in the volume or value of referrals (*e.g.,* a hospital offering care managers to a post-acute care facility to better coordinate care and prevent avoidable readmissions for which the hospital might be penalized). We might also permit a broader set of free or below fair market value arrangements for providers coordinating care in rural or underserved areas or providers serving underserved populations.

We are cognizant that this alternative approach may present operational challenges for parties, particularly with respect to determining fair market value for value-based arrangements. Moreover, we solicit comments on this approach as a whole and, in particular, on the following: (i) How to include in any safe harbor finalized consistent with this approach protection for the exchange of information technology and infrastructure that might not be part of a personal services or management contract, with a scope of protection equivalent to the protection collectively proposed under paragraphs 1001.952(ee) and (ff); and (ii) how parties would determine that a payment for quality outcomes is consistent with fair market value. As with the second tier described above, to ensure that protected arrangements meet their value-based purposes, we might incorporate additional accountability and transparency requirements, such as those proposed for new safe harbor 1001.952(ee).

We are also interested in comments regarding any special problems a fair market value requirement would pose for providers in rural or underserved areas, providers serving underserved populations, or others. With respect to other proposed safe harbors where we have indicated that we are considering including in the final rule a restriction related to the volume or value of referrals and other business generated or a requirement for fair market value, we will consider comments to this alternative regulatory structure addressing how these criteria would operate in connection with value-based arrangements.

D. Value-Based Arrangements With Substantial Downside Financial Risk (1001.952(ff))

We are proposing a new safe harbor for certain value-based arrangements involving VBEs that assume substantial downside financial risk (as defined in the proposed regulation) from a payor. We propose to incorporate the definitions of ''coordination and management of care,'' ''target patient population,'' ''value-based activity,'' ''value-based arrangement,'' ''value-based enterprise,'' ''value-based purpose,'' and ''VBE participant'' found in proposed paragraph 1001.952(ee).

This safe harbor, which would protect both monetary and in-kind remuneration, would offer greater flexibility than the safe harbor for care coordination arrangements in recognition of the VBE's assumption of substantial downside financial risk. It could apply, for example, to an arrangement between an accountable care organization that is a VBE and a network provider to share savings and losses earned or owed by the accountable care organization, or between a VBE that has contracted with a payor for an episodic payment and a hospital and post-acute care provider that would be coordinating care for patients under the episodic payment. However, as proposed, this safe harbor would apply only to the exchange of remuneration between VBEs that have assumed substantial downside financial

risk and VBE participants that meaningfully share in the VBE's downside financial risk (as further described below).

In other words, where a VBE participant agrees to spread the VBE's financial risk and coordinate care, additional safe harbor flexibility would be available. For the same reasons articulated in our discussion of the care coordination arrangements safe harbor, we propose that this safe harbor would not protect an ownership or investment interest in the VBE or any distributions related to an ownership or investment interest. We solicit comments on this approach and, in particular, whether this proposal presents any operational challenges with respect to the creation of a VBE as a separate legal entity. We are considering for the final rule whether this safe harbor should protect ownership or investment interests with respect to VBEs that must contract with a payor on behalf of VBE participants for purposes of value-based arrangements with substantial downside financial risk.

Additionally, for the same reasons articulated in our discussion of the care coordination arrangements safe harbor, we propose that this safe harbor would not protect any remuneration funded by, or otherwise resulting from contributions by, an individual or entity outside of the applicable VBE.

We are considering for the final rule whether, and if so, how, to extend this safe harbor to remuneration that passes from one VBE participant to another (without the risk-bearing VBE being party to the arrangement) when the VBE has assumed substantial downside financial risk from a payor. We are concerned that under many such downstream arrangements, the VBE participant receiving the remuneration may have assumed little or no financial risk and may be billing for his or her services on an FFS basis, thus retaining FFS incentives with respect to ordering or arranging for items and services for patients. We note the proposed care coordination arrangements safe harbor, with its additional safeguards, may be available for such arrangements, where they involve only in-kind remuneration, and the personal services and management safe harbor's proposed modifications for outcomes-based payments may be available for monetary remuneration.

This proposed safe harbor would protect remuneration exchanged between a VBE and a VBE participant pursuant to a value-based arrangement if several standards are met. First, the VBE must have assumed, or be contractually obligated to assume, substantial downside financial risk from a payor for providing or arranging for the provision of items and services for a target patient population. The VBE can assume this risk directly if the VBE is an entity or through a VBE participant acting as an agent of, and accountable to, the VBE. (We note, to the extent a VBE participant wholly assumes risk on behalf of the VBE, it may act in both its capacity as a VBE participant and an agent of the VBE.)

To balance the need to protect start-up arrangements while also limiting potential program integrity risks, this safe harbor would protect arrangements between the VBE and the VBE participant during the 6 months prior to the date by which the VBE must assume substantial downside financial risk (as defined below). We solicit comments on whether 6 months is a sufficient timeframe, and if not, what longer or shorter timeframe would be appropriate.

For purposes of this safe harbor, we are proposing specific methodologies that would qualify as substantial downside financial risk. Under any of our proposed methodologies, the VBE would assume risk from a payor for the provision of items and services to a target patient population for the entire term of the value-based arrangement. Our intent is for such risk to be of a degree likely to ensure that the value-based arrangements of the VBE are designed to appropriately reduce (or slow the growth of) costs, improve efficiencies, or improve health outcomes for the target patient population (and are not likely to increase over- or under-utilization or costs to payors or patients). We propose that a VBE would be at substantial downside financial risk if it is subject to risk pursuant to one of the following methods, drawn from the Department's experience: [24]

(i) Shared savings with a repayment obligation to the payor of at least 40 percent of any shared losses, where loss is determined based upon a comparison of costs to historical expenditures, or to the extent such data is unavailable, evidence-based, comparable expenditures;

(ii) A repayment obligation to the payor under an episodic or bundled payment arrangement of at least 20 percent of any total loss, where loss is determined based upon a comparison of costs to historical expenditures, or to the extent such data is unavailable, evidence-based, comparable expenditures;

(iii) A prospectively paid population-based payment for a defined subset of the total cost of care of a target patient population, where such payment is determined based upon a review of historical expenditures, or to the extent such data is unavailable, evidence-based, comparable expenditures; or

(iv) A partial capitated payment from the payor for a set of items and services for the target patient population where such capitated payment reflects a discount equal to at least 60 percent of the total expected FFS payments based on historical expenditures, or to the extent such data is unavailable, evidence-based, comparable expenditures of the VBE participants to the value-based arrangements.[25]

We are soliciting comments on this proposed definition of ''substantial downside financial risk,'' including whether: (i) These benchmarks should be higher or lower to ensure appropriate incentives; (ii) there are other methodologies not captured by this list that should qualify as substantial downside financial risk, such as those listed under 42 CFR 1001.952(u)(1)(i)(C); and (iii) some or all of these benchmarks should be omitted from this rule or modified to better capture true assumption of substantial downside financial risk for items and services furnished to patients. With respect to (i) through (iii), we are considering and solicit comments on whether the requirement to compare losses to, or determine payments based on, historical expenditures or evidence-based, comparable expenditures and whether additional means to establish a baseline against which to measure losses or payments is feasible for new or small VBEs or whether new or small VBEs should be allowed additional means to establish a baseline, such as allowing new or small VBEs to establish such baselines after a reasonable period of operation, such as 1 year. We also solicit comments on whether the assumption of substantial downside financial risk by the VBE as contemplated here, in combination with the safeguards proposed for this safe harbor, results in meaningful protections that will ensure that the

[24] For clarity, we note that we would not consider a prospective payment system for acute inpatient hospitals, home health agencies, hospice, outpatient hospitals, inpatient psychiatric facilities, inpatient rehabilitation facilities, long-term-care hospitals, and SNFs, or other like payment methodologies to meet any of the prongs of our proposed definition of ''substantial downside financial risk.''

[25] To afford VBE participants flexibility, we are not prescribing how parties may determine the basis for shared savings, shared losses, population-based payments, or partial capitation payments. However, we expect any such approach will reflect a legitimate compensation methodology, not one that simply manipulates numbers to artificially inflate savings or decrease losses, as may be applicable.

benefits of the arrangements that would be protected by this safe harbor outweigh any risk of misuse of the safe harbor to protect fraudulent or abusive arrangements.

Lastly, we are considering for the final rule, and seek comment regarding, whether we should include advanced APMs and other payor advanced APMs, as both terms are defined at 42 CFR 414.1305, in the definition of ''substantial downside financial risk.'' Specifically, we seek comment on the following: (i) If advanced APM participants would likely rely on this safe harbor versus the CMS-sponsored model arrangements safe harbor; and if so, what barriers, if any, our proposed definition of ''substantial financial risk'' and ''meaningfully share'' (as outlined in further detail below) may pose; and (ii) whether our current definition of ''substantial financial risk'' is too narrow, such that we have excluded advanced APMs or other payor advanced APMs that encourage participants to meaningfully assume downside financial risk.

This safe harbor proposes to protect remuneration from a VBE to a VBE participant pursuant to a value-based arrangement. As a condition of this safe harbor, the terms of the value-based arrangement require the VBE participant to meaningfully share in the VBE's substantial downside financial risk for providing or arranging for items and services for the target patient population. This condition is intended to ensure that VBE participants ordering or arranging for items and services for patients (in other words, those making care decisions) closely share the VBE's goals and share in accountability if those goals are not achieved.

For purposes of this condition, we propose that a VBE participant ''meaningfully shares'' in the VBE's substantial downside financial risk if the value-based arrangement contains one of the following: (i) A risk-sharing payment pursuant to which the VBE participant is at risk for 8 percent of the amount for which the VBE is at risk under its agreement with the applicable payor (*e.g.,* an 8-percent withhold, recoupment payment, or shared losses payment); (ii) a partial or full capitated payment or similar payment methodology (excluding the prospective payment systems for acute inpatient hospitals, home health agencies, hospice, outpatient hospitals, inpatient psychiatric facilities, inpatient rehabilitation facilities, long-term care hospitals, and SNFs or other like payment methodologies); or (iii) in the case of a VBE participant that is a physician, a payment that meets the requirements of the physician self-referral law's regulatory exception for value-based arrangements with meaningful downside financial risk at section 411.357(aa)(2).

Under (i), the proposed percentage of the VBE's substantial downside financial risk in which the VBE participant must share is based on the 8-percent nominal risk standard under the CMS regulation governing advanced APM and other payor advanced APM criteria at 42 CFR 414.1415 and 414.1420, respectively. We solicit comments on additional or alternative, specific thresholds we could include in the final rule to help ensure that the VBE participant is meaningfully engaged with the VBE in delivering value through its ordering and referring decisions, as well as data to support suggestions.

To protect against risks of stinting on care, we further propose that the remuneration must not induce limitations on, or reductions of, medically necessary items or services furnished to any patient. We are considering for the final rule additional conditions to safeguard against risks of cherry picking or lemon dropping of patients, which could affect the quality of care patients receive. In addition, we are considering and solicit comments on whether to include a length-of-time requirement (*e.g.,* 1 year) for the VBE to be at substantial downside financial risk to avoid gaming (as highlighted in our subsequent discussion of this issue in the full financial risk safe harbor).

We are proposing to include the following conditions similar to certain conditions we are proposing for the care coordination arrangements safe harbor and would interpret these conditions, where applicable, as described previously in the discussion of the care coordination arrangements safe harbor:

(i) The value-based arrangement must be set forth in a writing that contains, among other information, a description of the nature and extent of the VBE's substantial downside financial risk for the target patient population and a description of the manner in which the recipient meaningfully shares in the VBE's substantial downside financial risk;

(ii) the VBE or VBE participant offering the remuneration does not take into account the volume or value of, or condition the remuneration on, referrals of patients outside of the target patient population or business not covered under the value-based arrangement;

(iii) the value-based arrangement does not: (1) Place any limitation on VBE participants' ability to make decisions in the best interest of their patients, or (2) direct or restrict referrals to a particular provider, practitioner, or supplier if:

(A) A patient expresses a preference for a different practitioner, provider, or supplier;

(B) the patient's payor determines the provider, practitioner, or supplier; or

(C) such direction or restriction is contrary to applicable law or regulations under titles XVIII and XIX of the Act;

(iv) the value-based arrangement does not include marketing to patients of items or services or engaging in patient recruitment activities; and

(v) the VBE or its VBE participants maintain documentation sufficient to demonstrate compliance with the safe harbor's conditions and make such records available to the Secretary upon request.

Note that we are considering, and seek comment regarding whether we should include in the final rule, a condition regarding the maintenance of materials and records sufficient to establish compliance with the conditions of this safe harbor for a set period of time (*e.g.,* at least 6 years or 10 years).

In addition to the foregoing standard, under this proposed safe harbor, the remuneration must be used primarily to engage in value-based activities that are directly connected to the items and services for which the VBE is at substantial downside financial risk. For example, a VBE is at substantial downside financial risk through an agreement with a payor to assume a percentage of shared losses for items and services provided in connection with hip replacements to the target patient population. Remuneration provided by the VBE to a VBE participant would be protected under this proposed safe harbor only if the VBE participant primarily uses the remuneration to engage in value-based activities that have a direct connection to the items and services provided to patients in the target patient population undergoing hip replacement surgery (*i.e.,* the items and services for which the VBE is at substantial downside financial risk). Thus, while the VBE could give the VBE participant money that it uses to hire a staff member who primarily coordinates patients' transitions between care settings after undergoing hip replacement surgery, the VBE could not give the VBE participant money that it uses to hire a staff member who coordinates transitions between care settings for patient undergoing an array of surgical procedures. In addition, we propose that the remuneration exchanged must be directly connected to one or more of the

VBE's value-based purposes, at least one of which must be the coordination and management of care for the target patient population.

We believe these safeguards are necessary to ensure transparency and accountability, as well as to reduce the potential for protected arrangements to be used to pay for referrals unrelated to coordinating care and improving health outcomes and value for programs and patients. For example, as with other safe harbors proposed in this rulemaking, we do not intend to protect arrangements nominally characterized as a care coordination or value-based arrangement but that in reality are schemes intended merely to buy or sell referrals. To further protect against such arrangements, we are considering including in the final rule a commercial reasonableness requirement and a monitoring standard, each of which would be similar to those included in our proposed care coordination arrangements safe harbor at 1001.952(ee). In addition, to heighten transparency of any value-based arrangements and to ensure that the value-based arrangement is known by and closely related to the VBE itself, we are considering for the final rule whether to require that, in advance of, or contemporaneous with, the commencement of the applicable value-based arrangement, the VBE's accountable body or responsible person make a *bona fide* determination that the value-based arrangement is directly connected to a value-based purpose, at least one of which must be the coordination and management of care for the target patient population.

As discussed previously, we remain aware that the arrangements protected by the proposed substantial downside financial risk safe harbor would not be subject to programmatic requirements, oversight, or monitoring comparable to CMS-sponsored models. Accordingly, we are considering for the final rule including a requirement to submit information to the Department about the VBE, VBE participants, and the value-based arrangement similar to the requirement we are considering for the care coordination safe harbor at 1001.952(ee). As discussed in the care coordination arrangements safe harbor section, we also are considering for the final rule a condition prohibiting VBEs or VBE participants from billing Federal health care programs, other payors, or individuals for remuneration exchanged pursuant to the safe harbor; claiming the value of the remuneration as a bad debt for payment purposes under a Federal health care program; or otherwise shifting costs to a Federal health care program, other payors, or individuals.

Through the substantial downside financial risk safe harbor, we seek to provide more flexibility for entities that assume a substantial amount of financial risk such that the risk incentivizes a shift from volume-based decision making to value-based decision making. By allowing parties this enhanced flexibility in exchange for assuming risk with respect to only a subset of items and services furnished to a target patient population, we are mindful of the potential for parties to assume financial risk for such a narrow subset of items and services that the offeror's risk does not equate to *substantial* downside financial risk. We solicit comments on safeguards against this risk and the overall approach we have taken with respect to the substantial downside financial risk safe harbor.

E. Value-Based Arrangements With Full Financial Risk (1001.952(gg))

We propose to protect certain arrangements (including in-kind and monetary remuneration) involving VBEs that have assumed ''full financial risk,'' as that term is defined in the proposed regulation, for a target patient population. Because we recognize that VBEs that have assumed full financial risk present fewer traditional FFS fraud and abuse risks, this proposed safe harbor would include more flexible conditions than the proposed care coordination arrangements and substantial downside financial risk safe harbors, which we believe would reduce burden for the VBE and its VBE participants. We intend for the safe harbor to offer this category of VBEs the greatest ability to innovate with respect to coordinated care arrangements in light of their assumption of the highest level of risk contemplated in this proposed rulemaking. We propose to incorporate the definitions of ''coordination and management of care,'' ''target patient population,'' ''value-based activity,'' ''value-based arrangement,'' ''value-based enterprise,'' ''value-based purpose,'' and ''VBE participant'' found in proposed paragraph 1001.952(ee). For the same reasons discussed previously with respect to the care coordination arrangements safe harbor, we propose that this safe harbor would not protect an ownership or investment interest in the VBE or any distributions related to an ownership or investment interest. We solicit comments on this approach and, in particular, whether this proposal presents any operational challenges with respect to the creation of a VBE as a separate legal entity. We are considering for the final rule whether we should protect ownership or investment interests with respect to VBEs that must contract with a payor on behalf of VBE participants for purposes of value-based arrangements with full financial risk.

We also propose, for the same reasons discussed previously with respect to the care coordination arrangements safe harbor, that this safe harbor would not protect any remuneration funded by, or otherwise resulting from contributions by, an individual or entity outside of the applicable VBE.

We propose that a VBE would be at ''full financial risk'' for the cost of care of a target patient population if the VBE is financially responsible for the cost of all items and services covered by the applicable payor for each patient in the target patient population and is prospectively paid by the applicable payor. By ''prospective,'' we mean the anticipated cost of all items and services covered by the applicable payor for the target patient population, has been determined and paid in advance (as opposed to billing under the otherwise applicable payment systems and undergoing a retrospective reconciliation after items and services have been furnished).

By way of example, a VBE would be at ''full financial risk'' if it received a prospective, capitated payment for all items and services covered by Medicare Parts A and B for a target patient population. Similarly, we would consider a VBE that contracts with a Medicaid managed care organization and receives a fixed per-patient per-month amount to be at full financial risk if the fixed amount covered the cost of all Medicaid-covered items and services furnished to the target patient population.

In contrast, our proposal would not protect an entity that receives a partial capitated payment, be it either: (i) A capitated payment that covers a limited set of items or services or (ii) a payment arrangement where an entity receives a combination of reduced FFS and capitation payments for a defined set of items or services. For example, a hospital that participates in a bundled payment program for patients who receive knee replacements, and that receives an episodic payment to cover all costs associated with the knee replacement surgeries and follow-up care for 90 days, would not be eligible for protection under this safe harbor. The hospital is at full financial risk for the knee surgeries and related services but not for the patients' total cost of care. We note that other proposals in

this rulemaking may be available for such arrangements.

We note that our proposed definition of ''full financial risk'' would not prohibit a VBE from entering into arrangements—like global risk adjustments, risk corridors, reinsurance, or stop loss agreements—to protect against catastrophic losses. We emphasize that it is our intent for such arrangements to be limited to *catastrophic* losses; a VBE may not use risk corridors or other like arrangements as a mechanism to shift an amount of financial risk that does not meet the spirit of this safe harbor. Similarly, we note that our proposed definition of ''full financial risk'' would not prohibit a VBE from conducting a ''back-end'' reconciliation, with resulting payment adjustments due to quality or financial performance metrics, provided again, that the reconciliation is not used as a mechanism to shift material financial risk back to the contracting payor.

We also are considering other ways to define ''full financial risk'' in the final rule. For example, we are considering for purposes of the final rule including an actuarial equivalence standard similar to that used in the Medicare Part D context, and we request comments on the use of this potential standard. In addition, we seek comments about other situations that stakeholders believe should qualify as a VBE assuming ''full financial risk.'' We request that commenters provide specific examples of arrangements that they believe constitute ''full financial risk'' but that would not be covered by the definition proposed above.

We propose to require that the VBE assume full financial risk either directly, or through a VBE participant with the legal authority to obligate the VBE. We note, to the extent a VBE participant wholly assumes risk on behalf of the VBE, it may act in both its capacity as a VBE participant and an agent of the VBE.

In addition, we propose that this safe harbor would cover both value-based arrangements between a VBE and a VBE participant where the VBE has assumed full financial risk as of the date the VBE and VBE participant enter into the value-based arrangement, as well as value-based arrangements between a VBE and a VBE participant where the VBE is contractually obligated to assume such risk but has not yet done so. We are mindful that a VBE that is contractually obligated to take on full financial risk may need lead time to develop and implement arrangements in anticipation of taking on full financial risk. However, we also are concerned about providing safe harbor protection for arrangements involving parties that have not yet assumed the risk that operates as a prerequisite and key safeguard for this safe harbor. To balance the need to protect start-up arrangements with our program integrity concerns, the safe harbor would protect arrangements between the VBE and the VBE participant only during the 6 months prior to the date by which the VBE must assume full financial risk. We solicit comments on whether 6 months is a sufficient timeframe, and if not, what an appropriate timeframe might be. We could include a longer or shorter timeframe in the final rule.

We propose writing requirements in this safe harbor that are designed to promote transparency and accountability. First, we propose that the VBE have a signed writing with a payor that specifies the target patient population and contains terms sufficient to demonstrate that the VBE is at full financial risk for the target patient population for at least 1 year. Our intent in proposing a length-of-time requirement is to minimize gaming opportunities that could arise if the VBE assumes full financial risk for a short time period in order to take advantage of the proposed safe harbor's flexibility but without meaningfully committing to the transition to full financial risk. Second, we propose that the parties set forth the material terms of the value-based arrangement in a signed writing, including the value-based activities to be undertaken by the parties, and that the arrangement must be for a period of at least 1 year.

We propose that the term of the value-based arrangement must be for a period of at least 1 year to ensure that the VBE participant is committed to coordinating care for the target patient population of the VBE that has taken on full financial risk.

We propose that the VBE participant cannot claim additional or separate payment in any form directly or indirectly from a payor for items or services covered under the value-based arrangement. For purposes of this safe harbor, we propose that the phrase ''items or services'' would have the meaning set forth in paragraph 1001.952(t)(2)(iv), which defines ''items and services'' as: ''Health care items, devices, supplies or services or those services reasonably related to the provision of health care items, devices, supplies or services including, but not limited to, non-emergency transportation, patient education, attendant services, social services (*e.g.,* case management), utilization review and quality assurance. Marketing and other pre-enrollment activities are not 'items or services' for purposes of this section.''

If the VBE participant is permitted to seek additional payment for items or services furnished to the target patient population from a payor, the safe harbor would not protect the value-based arrangement. For example, protection under the safe harbor would not extend to payment made by a VBE to a VBE participant for telehealth services furnished to the target patient population if the VBE participant could also claim separate payment for such services from a payor. Value-based arrangements that permit VBE participants to claim separate payment from a payor are not ''full risk.'' Such arrangements potentially involve mixed financial incentives for providers, and parties would need to seek protection for such arrangements under one of the other proposed safe harbors. This requirement would permit VBE participants to bill a payor but not claim payment (*e.g.,* through a ''no-pay claim'') if required by a payor, including Medicare.

We also propose requirements related to the remuneration. First, we propose that remuneration exchanged must: (i) Be used primarily to engage in the value-based activities set forth in the parties' signed writing; (ii) is directly connected to one or more of the VBE's value-based purpose(s), at least one of which must be the coordination and management of care for the target patient population; and (iii) not induce the VBE or VBE participants to reduce or limit medically necessary items or services furnished to any patient. We propose to interpret these conditions consistent with the similar conditions in the proposed care coordination arrangements safe harbor at 1001.952(ee).

Second, we propose to require that the VBE and VBE participant must not take into account the volume or value of, or condition the remuneration exchanged on: (i) Referrals of patients who are not part of the target patient population or (ii) business not covered under the value-based arrangement. This requirement would preclude protection under the safe harbor for remuneration that is part of a broader ''swapping'' arrangement to steer patients outside of the target patient population to the party offering the remuneration. We solicit comments on this condition and any additional safeguards that we should include in this safe harbor to mitigate the risk of problematic swapping arrangements in order to prevent the safe harbor from being used to protect payments for referrals that are not part of the value-

based arrangement. We would have significant concerns with a VBE participant entering into a purported value-based arrangement in which it offers the VBE a reduced rate for patients in the target patient population in exchange for gaining access to that VBE's other patients.

We propose to require that the VBE provide or arrange for: (i) An operational utilization review program and (ii) a quality assurance program that protect against underutilization and specify patient goals, including measurable outcomes, where appropriate. These conditions mirror those found in the existing safe harbor at paragraph 1001.952(u), which were derived from the then-current regulatory requirements for plans operating under section 1876 of the Act. We are considering for the final rule whether there may be other ways to frame this requirement that meet the spirit of the conditions in paragraph 1001.952(u) but are updated to reflect the utilization review and quality assurance mechanisms in place today.

Like the proposed care coordination arrangements and substantial downside financial risk safe harbors and for the reasons explained in connection with those proposals, we are considering for the final rule requiring the submission to the Department of information about VBEs, VBE participants, and value-based arrangements for safe harbor protection. We welcome comments on this. As discussed in the care coordination arrangements safe harbor section, we also are considering for the final rule a condition prohibiting VBEs or VBE participants from billing Federal health care programs, other payors, or individuals for remuneration exchanged pursuant to the safe harbor; claiming the value of the remuneration as a bad debt for payment purposes under a Federal health care program; or otherwise shifting costs to a Federal health care program, other payors, or individuals.

We also propose requirements that (i) the value-based arrangement does not include marketing to patients of items or services or engaging in patient recruitment activities; and (ii) the VBE or its VBE participants maintain documentation sufficient to demonstrate compliance with the safe harbor's conditions and make such records available to the Secretary upon request. We are considering for the final rule and seek comment regarding whether we should include, in the final rule, a condition regarding the maintenance of materials and records sufficient to establish compliance with the conditions of this safe harbor for a set period of time (*e.g.,* at least 6 years or 10 years). We would interpret these requirements as described with respect to the care coordination arrangements safe harbor and would include them in this safe harbor for the reasons articulated there.

In addition, we note that, as proposed, this safe harbor would apply only to remuneration exchanged between a VBE and a VBE participant pursuant to a value-based arrangement. The proposed full financial risk safe harbor would not protect remuneration exchanged between or among VBE participants that are part of the same VBE, remuneration exchanged between a VBE participant and a downstream contractor, or remuneration between two downstream contractors. However, nothing prevents these parties from turning to other available safe harbors for protection.

We are considering for the final rule and solicit comments on whether to extend this safe harbor to remuneration that passes from a VBE participant to a downstream contractor (which also could be, but may not be required to be, a VBE participant). While we recognize that increased flexibility at the VBE participant level may foster innovation, we are concerned that these downstream arrangements present higher risks of fraud and abuse because the VBE participants and downstream contractors exchanging the remuneration may have assumed little or no financial risk. As such, they may continue to be subject to the potential risks inherent in any FFS financial arrangements, namely, incentives to order medically unnecessary or overly costly items and services. For these reasons, we are considering for the final rule, and solicit comments on, the following:

- In addition to the safeguards proposed in paragraph 1001.952(gg), whether additional safeguards could be implemented under the full financial risk safe harbor (or a different proposed safe harbor) to ensure that legitimate arrangements between VBE participants and downstream contractors that advance the value-based purpose(s) of the VBE are protected.
- For purposes of protecting downstream arrangements, whether we should incorporate some of the safeguards proposed in the safe harbor for care coordination arrangements or the safe harbor for parties at substantial downside financial risk. If so, whether certain safeguards would best capture our need to protect against fraud and abuse risks with the recognition that we do not want to impose undue burden on parties to these arrangements.
- If we were to protect certain downstream arrangements, whether we should limit protection to arrangements between VBE participants that are part of the same VBE, or we should extend protection to arrangements between: (i) A VBE participant and a downstream contractor, (ii) arrangements between two downstream contractors, or (iii) both. We request that any comments include specific examples of downstream arrangements that may not be protected under existing safe harbors or any of the safe harbors proposed under this rulemaking but warrant protection under this proposed safe harbor because of the level of risk assumed by the VBE.

F. Arrangements for Patient Engagement and Support To Improve Quality, Health Outcomes, and Efficiency (1001.952(hh))

We propose to establish a new safe harbor at proposed paragraph 1001.952(hh) to protect certain arrangements for patient engagement tools and supports to improve quality, health outcomes, and efficiency furnished by VBE participants, as defined in proposed paragraph 1001.952(ee), to specified patients. This safe harbor, hereinafter the ''patient engagement and support safe harbor,'' is intended to remove barriers presented by the anti-kickback statute and the beneficiary inducements CMP [26] to providers offering patients beneficial tools and supports to improve quality, health outcomes, and efficiency, by promoting patient engagement with their care and adherence to care protocols. Commenters to the OIG RFI overwhelmingly supported such a safe harbor, with appropriate safeguards.

Achieving well-coordinated care and improving value require patients to actively participate and engage in their preventive care, treatment, and general health. To prevent illness or disease or to manage a disease or condition effectively, patients must be involved in their healthcare and be empowered to make informed healthcare-related decisions. Appropriate patient engagement tools and supports can foster successful behavior modifications that improve health, ensure that patients receive the medically necessary care and other nonclinical, but health-related, items and services they need, and improve adherence to an appropriate treatment regimen.

In some cases, improved care coordination may be facilitated through various supports, including, for

[26] A practice permissible under the anti-kickback statute, whether through statutory exception or regulations issued by the Secretary, is also excepted from the beneficiary inducements CMP. Section 1128A(i)(6)(B) of the Act.

example, providing supports that aim to improve patients' safety at home or during care transitions (including discharge from facility care to the community) or that allow providers to communicate more efficiently and effectively with patients and their families and to monitor their patients' care. However, we also are cognizant of the potential for improper patient engagement tools and supports to result in inappropriate utilization, the steering of patients to particular providers, suppliers, or products that might not be in their best interests, increased costs to payors and patients, and anti-competitive effects.

Depending on the facts and circumstances, providing patient engagement tools and supports may implicate the Federal anti-kickback statute and the beneficiary inducements CMP. Some tools and supports may be protected under existing safe harbors or exceptions to the definition of ''remuneration'' under the beneficiary inducements CMP (*e.g.,* the local transportation safe harbor, 42 CFR 1001.952(bb); the exception for remuneration that promotes access to care and poses a low risk of harm to patients and Federal health care programs, 42 CFR 1003.110; and the exception for incentives given to individuals to promote the delivery of preventive care, 42 CFR 1003.110). In addition, for CMS-sponsored models, some patient engagement tools and supports may qualify for protection under the Medicare Shared Savings Program's waiver for patient incentives [27] or a waiver available for beneficiary incentives offered under an applicable Innovation Center model.[28] However, under certain facts and circumstances, no safe harbor, exception, or waiver may be available to protect beneficial patient engagement tools and supports that implicate the anti-kickback statute, beneficiary inducements CMP, or both. These arrangements must be evaluated on a case-by-case basis for compliance with the statutes.

Under the proposed patient engagement and support safe harbor at paragraph 1001.952(hh), ''remuneration'' under the Federal anti-kickback statute would not include in-kind patient engagement tools or supports (as specified in proposed paragraph 1001.952(hh)) furnished directly by a VBE participant (as defined in proposed paragraph 1001.952(ee)) to a patient in a target patient population (as defined in proposed paragraph 1001.952(ee)), that are directly connected to the coordination and management of care (as defined in proposed paragraph 1001.952(ee)), provided that all of the conditions of proposed paragraph 1001.952(hh) are satisfied.

1. Limitations on Offerors

Under this proposal, only patient engagement tools and supports furnished by a VBE participant, as defined in proposed paragraph 1001.952(ee), would receive protection. Our intent in proposing to limit safe harbor protection to VBE participants is to align the safe harbor with the value-based framework set forth in this proposed rulemaking. We are mindful that this approach would require the offeror of the remuneration to be part of a VBE (of any size) as defined at proposed paragraph 1001.952(ee). We are soliciting comments, including illustrative fact patterns, about potential patient engagement tools and supports that would improve care coordination and health outcomes where the offeror does not meet the proposed definition of a VBE participant because the offeror is not part of a VBE.

For example, we are considering for the final rule safe harbor protection for, and seek comments regarding, a hospital's or physician group practice's provision of patient engagement tools and supports that would advance coordination and management of care for a patient and otherwise satisfy conditions similar to those set forth in the proposed safe harbor, but where such hospital or physician group practice is not part of a VBE. We seek comments on the fraud and abuse risks associated with removing the requirement that the offeror is a VBE participant and what additional safeguards would be appropriate to offset those risks.

Pharmaceutical manufacturers, distributors, and suppliers of DMEPOS, and laboratories are not included in the proposed definition of ''VBE participant'' in paragraph 1001.952(ee) for the reasons described earlier in this preamble. In addition to the reasons for exclusion of pharmaceutical manufacturers in the definition of ''VBE participant'' previously articulated, we believe that offers of remuneration by such manufacturers to patients could improperly influence the patient, as well the patient's clinician's decision to prescribe one drug over another. Such remuneration could influence a patient to request a particular drug that is more expensive or less clinically efficacious than other clinically equivalent drugs. This could both improperly influence patient choice and increase costs to Federal health care programs—two factors cited by Congress to consider when developing safe harbors—without necessarily increasing quality.

As noted above, we also are excluding manufacturers, distributors, and suppliers of DMEPOS and laboratories from the definition of a VBE participant. Based on long-standing enforcement and oversight experience, we are concerned that manufacturers, distributors, and suppliers of DMEPOS and laboratories may inappropriately use patient engagement tools and supports to market their products or divert patients from a more clinically appropriate item or service, provider, or supplier without regard to the best interests of the patient or to induce medically unnecessary demand for items and services.

We are interested in comments on the impact of any such exclusions, if included in the final rule, for the patient engagement and support safe harbor in particular and any negative impact on the provision of potentially beneficial tools and supports. We seek comments regarding whether the proposed exclusion of these entities from the definition of ''VBE participant,'' and the proposed condition at (hh)(2), limiting funding by and other contributions from non-VBE participants, might negatively impact patients' ability to receive beneficial items and services, including new technologies that may foster better access to care and improve health outcomes.

As noted above, we also are considering whether to exclude other categories of suppliers and other entities, including pharmacies, PBMs, wholesalers, and distributors from the definition of ''VBE participant.'' [29] We solicit comments on the potential impact of our considered exclusion of pharmacies, PBMs, wholesalers, and distributors, if included in the final rule, for the patient engagement and support safe harbor in particular.

We also are considering, and seek comment on, whether this proposed safe harbor should protect only in-kind tools and supports furnished by VBE participants that assume at least some

[27] Medicare Program; Final Waivers in Connection With the Shared Savings Program, 80 FR 66726, 66743 (Oct. 29, 2015).

[28] *See, e.g.,* Notice of Waivers of Certain Fraud and Abuse Laws in Connection with the Bundled Payments for Care Improvement Advanced Model (May 25, 2018), *available at https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Downloads/BPCI-Advanced-Model-Waivers.pdf.*

[29] Note that, should we adopt the definition of ''applicable manufacturer'' as set forth in in 42 CFR 403.902, such definition would include distributors and wholesalers (which include re-packagers, re-labelers, and kit assemblers) that hold title to a covered drug, device, biological or medical supply.

financial risk, so as to better align protected remuneration with value-based purposes. In particular, if we were to limit safe harbor protection to only VBE participants that assume financial risk, we are considering, and seek comments regarding, the appropriate level of financial risk to require of such VBE participants (*e.g.,* VBE participants that assume at least some downside financial risk or VBE participants that assume substantial downside financial risk).

2. Limitations on Recipients

This proposed safe harbor would protect patient engagement tools and supports furnished to patients in a target patient population (as defined in proposed paragraph 1001.952(ee)). We note that the scope of this proposed safe harbor would not be limited to Federal health care program beneficiaries in recognition that the VBE or VBE participants may define the target patient population without regard to payor type. We solicit comments on whether we should instead provide safe harbor protection for tools and supports VBE participants furnish to a broader universe of patients by, for example, protecting patient engagement tools and supports furnished by VBE participants to any patient, so long as the tools and supports predominantly address needs of the target patient population and the tools and supports have a direct connection to the coordination and management of care for the patient.

We recognize that some VBEs may not be able to prospectively identify the individual patients in the target patient population. For example, in some accountable care organization (ACO) arrangements under CMS-sponsored models, beneficiaries are assigned to the ACO, which could be a VBE, retrospectively or on a preliminary prospective basis (*e.g.,* for agreement periods beginning on July 1, 2019, ACOs participating in the Medicare Shared Savings Program may select preliminary prospective assignment with retrospective reconciliation).[30] We are interested in stakeholder comments on the challenges, if any, presented by the safe harbor's protection of only patient engagement tools and supports furnished to patients in the target patient population when the VBE's assigned beneficiaries are identified retrospectively or on a preliminary prospective basis.

3. Limitations on Type of Remuneration

The proposed safe harbor would protect only tools or supports, as specified in proposed 1001.952(hh), furnished by a VBE participant to a patient in the target patient population. As proposed in 1001.952(hh)(3)(i), (ii) and (iii), we would limit a patient engagement ''tool or support'' to in-kind, preventive items, goods, or services, or items, goods, or services such as health-related technology, patient health-related monitoring tools and services, or supports and services designed to identify and address a patient's social determinants of health, that have a direct connection to the coordination and management of care of the target patient population. This limitation on tools or supports would exclude gift cards, cash, and any cash equivalent (*e.g.,* a check or pre-paid debit card).

We do not propose a specific definition of ''preventive care item or service'' to provide flexibility for VBE participants that seek to furnish preventive care items and services as a means to improve patient outcomes and better overall patient health.[31] OIG is mindful of the evolving nature of clinical practice guidelines and recommendations for practices that are categorized as ''preventive care,'' and we intend to allow this proposed safe harbor to protect the provision of tools and supports that a VBE participant reasonably determines, within the medical judgment of the applicable practitioner treating the patient, to be preventive care. VBE participants would need to exercise caution in ensuring that tools and supports for which they desire safe harbor protection are reasonably considered preventive care.

We solicit comments on whether the categories of patient engagement tools and supports listed above that would receive protection (*i.e.,* health-related technology, patient health-related monitoring tools and services, or supports and services designed to identify and address a patient's social determinants of health) are sufficiently flexible but also sufficiently targeted to protect against the risks of fraud and abuse associated with providing inappropriate remuneration to patients. For instance, we believe ''health-related technology'' and ''patient health-related monitoring tools and services'' might include wearable monitoring devices, such as a smart watch or tracker designed to collect information and transmit data to a patient's physician for treatment or disease monitoring. We are considering for purposes of the final rule requiring that the VBE participant confirm that the tools and services provided to a patient are not duplicative of, or substantially the same as, tools and services the patient already has. For example, we are considering whether the safe harbor should protect the provision of a new cell phone or wireless service to a patient who needs an application for remote patient monitoring if the patient already has these products and only needs the application.

With respect to the provision of supports and services designed to identify and address social determinants of health, many commenters to the OIG RFI urged us to consider ''social determinants of health,'' also described as ''health-related nonmedical'' items, goods, and services, that address basic needs essential to patients' health, such as food, shelter, safety, clothing, income, and transportation, in designing any proposed safe harbors. There is substantial evidence that unmet social needs related to these determinants of health, such as transportation, nutrition, and safe housing, play a critical role in health outcomes and expenditures.[32] These needs must be considered when thinking about maximizing health outcomes and lowering healthcare costs.

Evidence indicates that efforts that target home and neighborhood-level factors, such as healthcare accessibility for low-income individuals, physical and environmental obstructions to healthy living, and housing and case management, can lead to improved health outcomes for people of all ages.[33] These improved health outcomes include decreased mortality, delay or prevention of preventable and chronic

[30] 42 CFR 425.400(a)(4)(ii). We offer this as an illustrative example. Participants in the Medicare Shared Savings Program and Innovation Center ACO models have existing fraud and abuse law waivers and may not need new safe harbor protection.

[31] We do not intend to incorporate the definition of ''preventive care'' found in the regulations interpreting the beneficiary inducements CMP, 42 CFR 1003.110. Note that the definitions found at 42 CFR 1003.110 apply to part 1003, not part 1001, where the proposed 42 CFR 1001.952(hh) would be located.

[32] *See, e.g.,* Michael Marmot et al., on behalf of the World Health Organization and Commission on Social Determinants of Health, *Closing the gap in a generation: Health equity through action on the social determinants of health,* 372 *Lancet* 9650 (2008), *available at https:/www.thelancet.com/journals/lancet/issue/vol372no9650/PIIS0140-6736(08)X6047-7;* Gayle Shier et al., *Strong Social Support Services, Such As Transportation And Help For Caregivers, Can Lead To Lower Health Care Use And Costs,* 32 Health Affairs 3 (2013), available at *https://www.healthaffairs.org/doi/pdf/10.1377/hlthaff.2012.0170.*

[33] *See, e.g.,* J. Michael McGinnis, Pamela Williams-Russo, and James R. Knickman, *The Case For More Active Policy Attention To Health Promotion,* 21 HEALTH AFFAIRS 2 (Mar. 2002), *available at https://www.healthaffairs.org/doi/10.1377/hlthaff.21.2.78.*

diseases, and lowered healthcare utilization, indicating a higher quality of life.[34]

By addressing health disparities that emerge from the social determinants of health, some research suggests that the United States could save over $230 billion in medical care costs.[35] Moreover, there is research suggesting that policy interventions that focus on the social determinants of health can produce an estimated economic return of $1.02 trillion.[36]

Based on the connection of social determinants to healthcare outcomes and costs, we are considering for purposes of the final rule whether explicitly to include protection for tools and supports that address some social determinants of health that meet all other safe harbor conditions. While all social determinants have the potential to improve health outcomes, some social determinants may be more specifically aligned with preventive care and the coordination and management of care for patients (*e.g.,* transportation to medical appointments, nutrition to address clinical conditions, safe housing for patients discharged to their homes) than others (*e.g.,* a more general need for income through employment). We seek public input on which social determinants are most crucial to improving care coordination and transitioning to value-based care and payment, with respect both to needed arrangements between providers or others in a position to generate Federal health care program referrals between them, and needed arrangements between beneficiaries and providers or others in a position to influence the selection of providers, practitioners, and suppliers.

We are considering, and solicit comments on, how the final safe harbor should make distinctions among the categories of social determinants, such as protecting some types of tools and supports but not others. We are considering for the final rule whether we should specify specific tools and supports that would be permissible, including whether to base such a list on the types of tools and supports described in CMS guidance for the Medicare and Medicaid programs. We are interested in illustrative examples and data supporting commenters' views on this topic, including data supporting (or not supporting) the efficacy from a quality, effectiveness, and cost perspective of particular types of tools and supports related to addressing social determinants of health. Regardless, whether a particular tool or support would, in fact, be protected under the safe harbor when offered by a VBE participant to a patient in a target patient population would depend on the facts and circumstances and whether all safe harbor conditions were satisfied.

We solicit comments on whether, instead of using the proposed categories, the final rule should list specific tools and supports that could be protected under the safe harbor. We are interested in feedback on which tools and supports should be listed and how the rule could account for emerging tools and supports that improve patient engagement, care coordination, and health outcomes.

We do not intend for tools and supports protected by this proposed safe harbor, which includes only in-kind items, goods, and services, to be limited to items or services covered by a Federal health care program (as the term of art, ''items or services,'' when used in the context of the Medicare program, could suggest).[37] In general, the provision of covered items and services to patients does not require safe harbor protection provided that all normal billing rules are followed. That said, the proposed description of a permissible tool or support would include federally reimbursable items and services, and provided that the other requirements of the safe harbor are satisfied, the provision of federally reimbursable items and services could receive safe harbor protection.

We seek comment on potential fraud and abuse risks presented by including items and services that could be reimbursable by a Federal health care program as permitted tools or supports. We are aware of, and deeply concerned about, fraud schemes that involve the provision of items and services, including prescription opioids or other drugs, that are not needed by patients or that are harmful to them. We do not propose to protect such arrangements in this rulemaking, and such arrangements would not be protected in any final rule. Further, as OIG has previously stated, we are concerned that the provision of potentially reimbursable items and services, for free, could result in steering or unfair competition or could create a seeding arrangement, where, for example, a physician could be influenced to prescribe an item or service, which may be free at some point, but would be covered by a third-party payor (including Federal health care programs) in the future.[38] Because of the risks presented by allowing safe harbor protection for the provision of potentially reimbursable items and services, including inappropriate seeding arrangements or the provision of medically unnecessary or harmful items or services, we are considering, and seek comment on, excluding in the final rule federally reimbursable items and services as a protected tool or support. As discussed further below, the proposed patient engagement and support safe harbor would not protect cost-sharing waivers, and thus would not protect billing a Federal program while waiving the beneficiary's share of payment.

The in-kind requirement means that the patient must receive the actual tool or support and not funds to purchase the tool or support. For example, patients may not be given cash reimbursements for items or goods they purchase directly. While cash reimbursements for tools and supports would not satisfy the in-kind requirement, we would consider a voucher for a particular tool or support (*e.g.,* a meal voucher or a voucher for a taxi) to satisfy the in-kind requirement.

a. Cash and Cash Equivalent Incentives

A number of commenters responding to the OIG RFI urged OIG to protect the distribution of cash incentives to patients as a reward for engaging in certain healthcare-related activities. For example, providers responding to the OIG RFI stated that they would like protection to provide cash rewards to patients both for attending appointments (*e.g.,* $10 for patients who attend an initial primary care visit) and for engaging in activities designed to promote the adoption and maintenance of healthy behaviors (*e.g.,* a $25 check offered to patients who complete milestones in a behavioral modification program related to substance use disorders). Commenters cited a number of studies in support of this recommendation.[39]

[34] Marmot, *supra.*

[35] McGinnis, *supra.*

[36] McGinnis, *supra.*

[37] While OIG's regulations found at 42 CFR 1003.110 define ''items and services or items or services,'' we do not cross-reference such definition in this proposed safe harbor, nor do we propose to limit the items, goods, and services potentially protected by this proposed safe harbor to the items and services that would satisfy the definition found at 42 CFR 1003.110. Note also that the definitions found at 42 CFR 1003.110 apply to part 1003, not part 1001, where the proposed 42 CFR 1001.952(hh) would be located.

[38] Adv. Op. No. 18–14, *available at https://oig.hhs.gov/fraud/docs/advisoryopinions/2018/AdvOpn18-14.pdf.*

[39] *See, e.g.,* Cathy J. Bradley & David Neumark, *Small Cash Incentives Can Encourage Primary Care Visits by Low-Income People with New Health Care Coverage,* 36 Health Affairs 8 (2017), *https://www.healthaffairs.org/doi/10.1377/hlthaff.2016.1455;* Scott D. Halpern, MD, Ph.D. et al., *Randomized Trial of Four Financial-Incentive Programs for Smoking Cessation,* 372 New Eng. J.

Commenters to the OIG RFI noted that incentives and supports in the form of cash could help improve patients' adherence to treatment plans, encourage participation in medically necessary care, and motivate patients to lead healthier lifestyles. In addition, commenters to the OIG RFI posited, and some research suggests, that patients prefer cash to in-kind items, goods, or services and that cash may be more effective at maintaining patient engagement and encouraging and reinforcing positive behavioral change. We also have observed congressional interest in allowing providers to offer beneficiaries cash through, by way of example, the recent enactment of the ACO Beneficiary Incentive Program, section 1899(m) of the Act. However, OIG historically has had significant concerns with allowing providers to offer cash or cash equivalents to patients, and our oversight and enforcement experience suggests that cash incentives can: (i) Result in medical identity theft and misuse of patients' Medicare numbers, (ii) lead to inappropriate utilization (in the form of medically unnecessary items and services), and (iii) cause improper steering (including patients selecting a provider because the provider offers the most valuable incentives and not because of the quality of care the provider furnishes).

Notwithstanding, we are considering for the final rule, and seek comment on, whether to protect patient incentives and supports in the form of cash and cash equivalents in certain circumstances.[40] If we do so, we might set a monetary limit on the aggregate amount of remuneration provided annually (such as up to $75 per year, or higher or lower amounts)[41] or include other safeguards to prevent the misuse of cash incentives to steer patients to items or services to influence them to allow others to use their personal information to order unnecessary or inappropriate items and services. Further, we likely would limit the use of cash remuneration to reward patients for attending medically necessary primary care or other clinically prescribed treatment visits, or for successful participation in a clinically appropriate behavioral modification or substance use disorder treatment program. If we were to adopt this approach, we would consider requiring offerors to have an evidence-based reason for using cash to influence patients' adherence to a treatment regimen or clinical program. (This might be the case, depending on the evidence, with respect to a substance use disorder treatment or smoking cessation program.) We solicit comment on potential criteria a party may apply to ensure that the arrangement is evidence-based, such as ensuring the arrangement is supported by the Joint Commission, the Agency for Healthcare Research and Quality, or other independent organization that develops national quality standards or quality measures.

b. Waiver or Reduction of Cost-Sharing Obligations

A number of the comments we received in response to the OIG RFI advocated broad protection from potential anti-kickback statute and beneficiary inducements CMP liability for routinely waived or reduced cost-sharing obligations. As an initial matter, we note that the requirement for cost-sharing in Medicare and Medicaid is a programmatic matter; cost-sharing is required pursuant to statute and regulations set forth by CMS and State Medicaid programs. We do not believe safe harbors to the anti-kickback statute are the right tool to obviate these programmatic requirements. Our concerns regarding routine waivers of cost-sharing amounts are longstanding;[42] such routine waivers may constitute prohibited remuneration to induce referrals. Therefore, as proposed, the patient engagement and support safe harbor would not protect the routine waiver or reduction of cost-sharing obligations (including coupons leading to such waivers or reductions).

We are interested in comments that identify potential benefits of permitting in the final rule the waiver or offset of cost-sharing obligations where the cost-sharing waiver or offset of obligations is part of a value-based arrangement under our value-based framework. In addition, we solicit comments on any safeguards that would mitigate concerns that routine waivers of cost-sharing amounts might undermine prudent consumer incentives of cost-sharing or might allow for abusive ''insurance-only billing'' marketing schemes targeting patients for unnecessary or poor-quality items or services.

Long-standing OIG guidance allows for non-routine, good-faith financial need cost-sharing waivers,[43] and several safe harbors and beneficiary inducements CMP exceptions already offer protection for certain reductions, waivers, and differentials in cost-sharing, such as the exception for the waiver of cost-sharing amounts found at section 1128A(i)(6)(A) of the Act and 42 CFR 1003.110. Those safe harbors and exceptions remain available and unchanged by this proposal. We also are proposing protection for certain cost-sharing waivers or reductions under the CMS-sponsored model patient incentives safe harbor, proposed at 1001.952(ii). As noted above, many VBE participants that would avail themselves of the patient engagement and support safe harbor would not be subject to programmatic requirements, oversight, or monitoring comparable to CMS-sponsored models. Therefore, cost-sharing waivers or reductions offered and provided under the CMS-sponsored models may present fewer risks.

We are aware of concerns expressed by some stakeholders about the collection of small beneficiary cost-sharing amounts associated with certain care coordination services, such as care management and remote monitoring, where the costs of collection exceed the amount to be collected. Stakeholders would like safe harbor protection for waivers of such cost-sharing amounts. We are considering for the final rule whether limited safe harbor protection for such waivers might be appropriate, including whether such safe harbor protection would be consistent with the program rules establishing such beneficiary cost-sharing amounts. We are considering for the final rule, and seek comment regarding, what conditions we should include in any safe harbor for limited cost-sharing waivers that would protect only cost-sharing waivers associated with certain specified services, such as care management and remote monitoring. If we were to finalize such a safe harbor, we likely would include conditions similar to those set forth in proposed 1001.952(hh).

Finally, we are aware of interest among some stakeholders in offering patients a share of savings the patients help generate for a payor. For example, a patient who selects a clinically

Med. 2108 (2015), *https://www.nejm.org/doi/full/10.1056/NEJMoa1414293.*

[40] OIG continues to consider items convertible to cash (such as a check) or that can be used like cash (such as a general purpose debit card) to be cash equivalents.

[41] The $75 amount parallels OIG's 2016 ''Office of Inspector General Policy Statement Regarding Gifts of Nominal Value to Medicare and Medicaid Beneficiaries Policy Statement,'' which currently sets the retail value of permissible ''inexpensive'' or ''nominal value'' gifts at $15 per item and $75 in the aggregate per patient on an annual basis. *See* OIG, Office of Inspector General Policy Statement Regarding Gifts of Nominal Value to Medicare and Medicaid Beneficiaries (Dec. 7, 2016), *available at https://oig.hhs.gov/fraud/docs/alertsandbulletins/OIG-Policy-Statement-Gifts-of-Nominal-Value.pdf.*

[42] *See, e.g.,* Special Fraud Alert: Routine Waiver of Copayments or Deductibles Under Medicare Part B, 59 FR 65372, 65374 (Dec. 19, 1994).

[43] *See, e.g.,* OIG, Special Fraud Alert, 59 FR 65372, 65374 (Dec. 19, 1994).

appropriate but less costly setting to obtain services (*e.g.,* home-based services instead of a treatment in a facility) might share in the savings realized from the lower cost care setting. We believe that in many cases, this type of program would be part of a plan's benefit design. The need for new safe harbor protection for this type of arrangement is unclear, and we solicit comments on this issue.

c. Gift Cards

OIG has never considered gift cards to be in-kind items, goods, or services. The limitation of ''tool or support'' proposed in paragraph 1001.952(hh) would be consistent with OIG's position that gift cards are not in-kind items, goods, and services. OIG recognizes certain risks attendant to providing gift cards as patient engagement tools and supports, some of which may make gift cards indistinguishable from cash (*e.g.,* we recognize that consumers can sell or trade gift cards through gift card redemption sites, which could result in a gift card morphing into cash). Similar to cash and cash equivalents, OIG is concerned that tools and supports in the form of gift cards could induce patients to seek medically unnecessary items and services—leading to inappropriate utilization—and could result in providers improperly steering patients through offering valuable incentives in the form of gift cards.

Nevertheless, because gift cards may be effective at promoting behavioral change, OIG is considering whether to include protection for gift cards in limited circumstances, for example, where they are provided to patients with certain conditions, such as substance use disorders and behavioral health conditions, as part of an evidence-based treatment program, for the purpose of effecting behavioral change. OIG seeks comments on the potential inclusion of gift cards in limited circumstances such as these and requests citations to any recent studies assessing the positive or negative effects of gift card incentives on promoting behavioral change. OIG also solicits comments on whether and how including gift cards as allowable ''tools or supports'' in the circumstances described above would raise the risk of fraud and abuse and specifically whether it would present any anti-competitive effects, particularly for smaller providers and suppliers. OIG also is considering and seeks comment on what additional safeguards, such as limiting protection for gift cards to those that are not pre-paid debit cards,[44] we should include to the extent the safe harbor protects the provision of gift cards.

4. Additional Proposed Conditions

The patient engagement and support safe harbor would impose a number of conditions on the provision of protected patient engagement tools and supports. The intent of these safeguards is to balance the potential benefits of tools and supports with safeguards that minimize the risk of harm to patients, payors, or both.

a. Furnished Directly to the Patient

Under the proposed condition at 1001.952(hh)(1), the tool or support must be furnished directly to the patient by a VBE participant. The reasons for this proposed condition are two-fold. First, the condition would prevent entities that are excluded from participating in a VBE from directly or indirectly furnishing tools and supports to patients. Second, we believe that this condition would help patients understand which entity or individual is furnishing the tool or support, which could aid patients in deciding whether to participate in the program or treatment regimen offered. We are considering for the final rule and seek comment on whether we should include a condition in the final safe harbor that would require the VBE participant to provide any patient receiving a patient engagement tool or support a written notice describing: (i) The VBE participant that is giving the patient the tool or support; (ii) what the remuneration is; and (iii) the purpose of, or reason for, the remuneration. We solicit comments on whether we should expressly permit the VBE participant to furnish the tool or support through someone acting on the VBE participant's behalf and under the VBE participant's direction (*e.g.,* a physician practice that provides the tool or support through an individual member of the practice or nurse employed by the practice). We also seek comments on the applicability of the proposed safe harbor to potential arrangements by which a VBE participant orders or arranges for the delivery of a tool or support from an independent third party.

b. Funding Limitations

Under the proposed condition at 1001.952(hh)(2), we limit who can fund or otherwise contribute to patient engagement tools and supports furnished by a VBE participant. We propose to interpret the requirement at 1001.952(hh)(2) to prohibit the VBE participant from accepting or using funds or free in-kind items or services furnished by any individual or entity outside of the VBE to finance or otherwise facilitate its patient engagement tools, supports, or both, including both the cost of the tool or support and any associated operating costs incurred through the provision of such tool or support (*e.g.,* staff time dedicated to ordering or distributing blood pressure cuffs or technology expenses or help desk services associated with a patient support). We believe this requirement is necessary to reduce the likelihood of undue influence that could result in inappropriate patient steering to specific products, providers, or suppliers.

In addition, this proposed condition would ensure that the entities we propose to exclude as VBE participants would not indirectly furnish patient engagement tools and supports under the safe harbor. For example, a pharmaceutical manufacturer, manufacturer, distributor, or supplier of DMEPOS, or laboratory could not circumvent the proposed exclusion from the definition of ''VBE participant'' by providing funds to a third-party entity and then directing or otherwise controlling any aspect of the third-party entity's provision of patient engagement tools and supports as a VBE participant. Further, this proposed condition would prohibit a non-VBE participant's contribution of in-kind items and services for a VBE participant to provide to patients as tools or supports. By way of example, a pharmaceutical manufacturer's provision of free product to a VBE participant (*e.g.,* a physician) for the VBE participant's distribution to patients as free product samples would not be protected by this proposed safe harbor.[45] We solicit comments on this approach and whether there may be defined, limited circumstances in which non-VBE participants should be able to contribute or otherwise participate in the provision of tools and supports eligible for safe harbor protection.

We note that this proposed safe harbor does not address, or otherwise

[44] OIG recognizes that gift cards can take a number of forms, including tangible gift cards, electronic gift cards, and the replenishment of funds available, through a smartphone application, to purchase items, goods, or services at a particular entity.

[45] For further information regarding the Federal anti-kickback statute and beneficiary inducements CMP implications of free product samples, *see e.g.,* OIG, Compliance Program Guidance for Pharmaceutical Manufacturers, 68 FR 23731, 23739 (May 5, 2003); Adv. Op. No. 08–04, *available at https://oig.hhs.gov/fraud/docs/advisoryopinions/2008/AdvOpn08-04.pdf;* Adv. Op. No. 15–11, *available at https://oig.hhs.gov/fraud/docs/advisoryopinions/2015/AdvOpn15-11.pdf.*

prohibit, arrangements between VBE participants and others (including vendors and manufacturers) for the purchase and sale of tools and supports that the VBE participant would furnish under the safe harbor. Such arrangements must be assessed on a case-by-case basis for compliance with the Federal anti-kickback statute and any other applicable law.

c. Prohibition on Marketing and Patient Recruitment

Under the proposed condition at 1001.952(hh)(3)(iii), the remuneration must not include any in-kind item, good, or service used for patient recruitment or marketing of items or services to patients. We do not intend to protect tools or supports that serve solely as patient recruitment incentives. Similarly, we do not intend to protect tools or supports offered to patients where the party knows or should know that the patient would not use the item as intended under the arrangement and would instead resell the item.

We seek comments on this proposed condition, and in particular, any benefits of permitting in the final rule some targeted marketing or similar outreach to the target patient population for the purposes of engaging them in evidence-based prevention or wellness activities, or in improving population health outcomes, particularly for VBEs or VBE participants at financial risk for the health outcomes of the target patient population. As with our proposal at paragraph 1001.952(ee), we also are interested in comments on how best to preclude marketing of reimbursable items and services and patient recruitment while still permitting beneficial educational efforts and activities that promote patient awareness of care coordination activities and available tools and supports.

d. Direct Connection

Under the proposed condition at 1001.952(hh)(3)(i), the tool or support furnished to the patient must have a ''direct connection'' to the coordination and management of care for the patient. We interpret ''direct connection'' to mean that the VBE has a good faith expectation that the tool or support will further the VBE's coordination and management of care for the patient, as that concept is described in the proposed conditions at 1001.952(ee). Where a direct connection exists, it should not be difficult for the VBE and the VBE participant providing the patient engagement tool or support to clearly articulate the nexus between the tool or support and a care coordination and management purpose of the VBE. We believe that this requirement effectively balances the goals of patient engagement tools and supports, such as patient compliance with a plan of care and adherence to behavior modifications to improve overall health, with the risk that VBE participants could use extravagant tools or supports to steer beneficiaries or incentivize unnecessary or inappropriate care. Consistent with our goals of fostering flexibility, adaptability, and innovation, we are not further describing specific patient engagement tools and supports that would be considered to have a direct connection to the coordination and management of care for the patient. We are considering for the final rule and solicit comments on whether we should require a ''reasonable connection'' rather than a ''direct connection.''

As an alternative or in addition to this approach, we are considering whether, to heighten transparency of patient engagement tools and supports and to ensure that qualifying patient engagement tools and supports are known by and closely related to the VBE itself, we should require the VBE to make a *bona fide* determination that the VBE participant's arrangement to provide tools and supports to patients is directly connected to the coordination and management of care for the patient, as that term is used in the proposed 1001.952(ee). We solicit comments on this approach.

Lastly, we are considering for the final rule, and solicit comment on, whether we should require that patient engagement tools and supports be directly connected to any of the four value-based purposes, as opposed to requiring a direct connection specifically to the coordination and management of the patient's care.

e. Medical Necessity

Under the proposed condition at 1001.052(hh)(3)(iv), the tool or support furnished to the patient must not result in medically unnecessary or inappropriate items or services reimbursed in whole or in party by a Federal health care program. We believe that this is an important protection for patient safety and quality of care.

f. Nature of the Remuneration

Under the proposed conditions at 1001.952(hh)(3)(vi), the tool or support must be recommended by the patient's licensed healthcare provider. This condition seeks not only to ensure that the remuneration is focused specifically on patient care, but also underscore the importance of quality of care, the healthcare provider's medical judgment, and the patient's relationship with his or her chosen healthcare providers in developing plans for treatment and care.

We are considering and solicit comment on, whether we should include as a safeguard a requirement that the patient's licensed healthcare provider certify in writing, under 18 U.S.C. 1001 and 1519, that the particular item or service is recommended solely to treat a documented chronic condition of a patient in a target patient population. We solicit comments on how providers would most efficiently meet such a requirement and whether and how providers should be required to make the certification available.

For all types of remuneration contemplated under this proposed safe harbor, we are considering for the final rule and seek comment on whether we should impose further limitations on the nature of remuneration furnished or other conditions to safeguard against the risks associated with fraud and abuse. For example, we are considering for the final rule and seek comment on some or all of the following additional safeguards:

- A requirement that VBE participants furnishing patient engagement tools and supports demonstrate and document the desired adherence to a treatment regimen, adherence to a drug regimen, adherence to a follow-up care plan, management of a disease or condition, improvement in measurable health outcomes, or patient safety; and
- a monitoring requirement to ensure that the patient engagement tools and supports do not result in diminished quality of care or patient harm.

In addition, we seek specific examples of any other types of remuneration that stakeholders believe should be covered (or should not be covered) by this proposed safe harbor and why, as well as input on whether we can better define categories of remuneration, and any limitations or safeguards necessary to protect against fraud and abuse risks specific to such examples or categories.

g. Advancement of Specified Goals

Under the proposed condition at 1001.952(hh)(3)(vii), the incentives and supports must advance specifically enumerated goals, namely: Adherence to a treatment regimen as determined by the patient's licensed healthcare provider; adherence to a drug regimen as determined by the patient's licensed healthcare provider; adherence to a follow-up care plan established by the patient's licensed healthcare provider; management of a disease or condition as directed by the patient's licensed

healthcare provider; improvement in evidence-based measurable health outcomes for a patient or the target patient population; ensuring patient safety; or some combination of the above.[46] We are not proposing to specify which tools and supports would advance the named goals to provide flexibility for VBE participants and promote innovation. We intend for this proposed condition to protect a range of tools and supports. For example, an item, such as a smart pill bottle, that dispenses medications at preset times for a patient could meet this condition because it is a tool that enables the patient to access the right medication at the appropriate dosage and time. Offering a parking voucher or providing free childcare during medical appointments also could satisfy this condition because these supports would allow a patient to comply with his or her treatment regimen. Conversely, offering a patient movie tickets to reward compliance with a treatment regimen would not satisfy this condition.

While we are concerned about the potential for abuse when patients are offered rewards to induce them to receive items or services, we also are aware that, in some circumstances, patients, or persons at risk of becoming patients with more serious conditions, might be offered tools or supports that result in lower healthcare costs (without compromising quality) or that promote patient wellness and healthcare.

h. No Diversion or Resell

Under the proposed condition at 1001.952(hh)(4), this safe harbor would not protect the provision of a tool or support if the offeror of the remuneration knows or should know that the tool or support is likely to be diverted, sold, or utilized by the patient other than for the express purpose for which the patient engagement tool or support is provided. This proposed condition is designed to prevent VBE participants from providing tools and supports to patients if they likely would divert or sell or otherwise use for purposes other than the coordination and management of care and the goals outlined in (hh)(3)(vi). We seek comments on this approach.

Notwithstanding the foregoing, for the purposes of this safe harbor, we would not consider a tool or support to be diverted if it is furnished to patients indirectly through their caregivers or family members or others acting on patients' behalf if the remuneration otherwise satisfies the conditions of the safe harbor. Specifically, if a patient is unable to care for herself or himself and another person (*e.g.,* a family member or other caregiver) has legal authority or the patient's consent to act on the patient's behalf, then remuneration furnished to that person, on the patient's behalf and for the patient's benefit, would be protected if all conditions of the safe harbor are met. For example, if the patient is a child suffering from asthma, the child's parent or guardian may accept in-kind remuneration, such as a new air purifier for the child's bedroom, on the child's behalf without violating this requirement.

i. Monetary Cap

Under the proposed condition at 1001.952(hh)(5), the aggregate retail value of patient engagement tools and supports furnished by a VBE participant to a patient could not exceed $500 on an annual basis, with certain limited exceptions. With this condition, we have attempted to strike the right balance between flexibility for beneficial patient tools and supports and a bright-line limit on the amount of protected remuneration to protect patients from being improperly influenced by valuable gifts; to protect the Federal health care programs from potential abuse through overutilization and inappropriate utilization due to such gifts; and to allow for innovation and beneficial arrangements that benefit patients and payors. As noted elsewhere in this preamble, our enforcement experience shows that incentives offered to beneficiaries can be used to coerce them into obtaining unnecessary services or harmful care, and this risk may be heightened when the value of remuneration is high or unlimited. However, we are unsure whether a monetary cap would present a barrier to achieving the intended benefits for patients envisioned by this proposed safe harbor. In lieu of a monetary cap, we are considering for the final rule, and seek comments on, whether other combinations of safeguards proposed in this rule would offer meaningful protection against fraud and abuse involving patients and programs, while still achieving the policy goal of promoting value-based care.

We solicit comments on whether this proposed monetary limit of $500 is appropriate, whether $500 per year is too low or too high, and if so, what other figures are more appropriate and the reasons for such other figures (*e.g.,* $100, $200, $1,000, $1,500, or another amount that would be of sufficient magnitude to protect the most beneficial arrangements while also preventing the most abusive ones). For purposes of measuring retail value, we propose that such value be measured at the time the patient engagement tool or support is provided, and we are considering for the final rule whether to interpret ''retail value'' to mean the fair market value to the recipient or commercial value to the recipient. We also solicit comments on the proposed requirement applying the cap to individual VBE participants and whether the requirement should instead apply the annual cap to the VBE as a whole. Under this alternative, we are considering whether only one VBE participant within a VBE could offer remuneration to a patient during the year. If we limited the cap to the VBE instead of a VBE participant, we are interested in comments regarding how this might negatively impact opportunities for patients and providers or create burdensome tracking and recordkeeping obligations for a VBE or VBE participants. We also solicit comments on whether we should apply the annual cap on a value-based arrangement basis; in other words, under each value-based arrangement, a patient could receive aggregate remuneration up to the cap (whether from one or more VBE participants in the arrangement). We are interested in comments about any negative impacts or burdens from this approach.

We propose that the cap could be exceeded for certain patients who lack financial resources. Specifically, the proposed condition at 1001.952(hh)(5) provides that the aggregate retail value of patient engagement tools or supports furnished to a patient by a VBE participant may exceed $500 per year if the patient engagement tools and supports are furnished to a patient based on a good faith, individualized determination of the patient's financial need. OIG has existing guidance related to individualized, good faith determinations of financial need in the context of cost-sharing waivers, and accounting for financial need generally aligns with an existing exception under the CMP. We are not specifying any particular method of determining financial need because we believe what constitutes ''financial need'' varies depending on the circumstances. However, it would be important for VBE participants to make determinations of financial need on a good faith, individualized, case-by-case basis in accordance with a reasonable set of income and resource guidelines

[46] We note here that the word ''drug'' is synonymous with and inclusive of ''medication,'' neither of which terms we are defining for purposes of this proposed safe harbor. Similarly, ''followup care plan'' would include so-called ''discharge plans.''

uniformly applied in all cases. The guidelines would need to be based on objective criteria and appropriate for the applicable locality. A patient's medical costs and liabilities could be taken into account, among other factors, as part of the determination. We seek comments on this approach as applied to the proposed safe harbor as well as whether we should include a cap but not allow for the cap to be exceeded.

We seek comments regarding whether the monetary limit imposed at 1001.952(hh)(5) is necessary and appropriate, or if alternatives that better protect patients and payors exist, such as a limitation on the frequency of such remuneration *(e.g.,* a one-time provision of remuneration, once per year, or once per month), or a per-occurrence limitation, in place of, or in addition to, an aggregate limit. If a per occurrence limitation is desirable, we seek feedback on its amount standing alone and in relation to an aggregate cap (*e.g.,* if the aggregate cap were to be $500 per year, should the per occurrence cap be $100, $200, or some higher or lower figure). We seek comments about, and supporting data for selecting, cap amounts. Finally, we seek comments regarding how we should treat ongoing costs associated with tools and supports (such as batteries, maintenance costs, or upgrades).

j. Materials and Records

Under the proposed condition at 1001.952(hh)(6), the VBE or a VBE participant would be required to make available to the Secretary, upon request, all materials and records sufficient to establish compliance with the conditions of this safe harbor. We are not proposing particular parameters regarding the creation or maintenance of documentation to allow individuals and entities the flexibility to determine what constitutes best documentation practices but welcome comments on whether particular parameters are needed. In particular, we are considering for the final rule and seek comment regarding whether we should include, in the final rule, a requirement that VBE participants retain materials and records sufficient to establish compliance with the conditions of this safe harbor for a set period of time (*e.g.,* at least 6 years or 10 years). Were an entity to be under investigation and assert this safe harbor as a defense, it would need to be able to demonstrate compliance with each condition of the safe harbor.

5. Potential Safeguards

In addition to the proposed conditions set forth above, for the purposes of the proposed patient engagement and support safe harbor, we are considering and seek comment on additional potential safeguards for the final rule. We are considering and seek comment on the possible safeguards outlined below for this proposed safe harbor because many VBE participants that would avail themselves of the proposed patient engagement and support safe harbor would not be subject to governmental programmatic requirements, oversight, or monitoring comparable to CMS-sponsored models (addressed in the proposed safe harbor at 1001.952(ii)).

a. Prohibition on Cost-Shifting

We are considering for the final rule, and seek comment on, a condition prohibiting VBE participants from billing Federal health care programs, other payors, or individuals for the tool or support; claiming the value of the tool or support as a bad debt for payment purposes under a Federal health care program; or otherwise shifting the burden of the value of the tool or support onto a Federal health care program, other payors, or individuals. This requirement, if included in any final rule, would be designed to protect against tools and supports resulting in inappropriately increased costs to Federal health care programs, other payors, and patients. We are considering, and seek comments on, prohibiting both: (1) Directly billing any third party, including patients, for the patient engagement tool or support or any operational costs attendant to the provision of the patient engagement tools and supports; and (2) claiming the cost of the patient engagement tool or support and any operational costs attendant to the provision of patient engagement tools and supports as bad debt for payment purposes under Medicare or a State healthcare program.

b. Consistent Provision of Patient Incentives

We are considering for the final rule, and seek comment on, whether to require VBE participants to provide the same patient engagement tools or supports to an entire target patient population or otherwise consistently offer tools and supports to all patients satisfying specified, uniform criteria. We believe that including such a condition in the safe harbor would protect against a VBE participant targeting certain patients to receive tools and supports based on, for example, the patient's insurance status. We solicit comments on this issue. In particular, we are interested in understanding whether this proposed safeguard would limit certain VBE participants' ability to offer tools and supports due to the potential cost of furnishing the tool or support to an entire target patient population rather than a smaller subset of the target patient population. Similarly, we are interested in comments explaining why offering remuneration to a smaller subset of a target patient population instead of to the entire target population would be appropriate and not increase the risk of fraud and abuse, such as the targeting of particularly lucrative patients to receive tools and supports (cherry picking) or failure to provide tools and supports to high-cost patients (lemon dropping).

c. Monitoring Effectiveness

We are considering adding a condition to the final rule that would require VBE participants to use ''reasonable efforts'' to monitor the effectiveness of the tool or support in achieving the intended coordination and management of care for the patient and would require the VBE or the VBE participant to have policies and procedures in place to address any identified material deficiencies. We believe that including such a condition in the safe harbor would help ensure that the tools and supports VBE participants furnish to patients achieve the stated purpose(s), and in turn, could help prevent VBE participants from offering patients engagement tools and supports that induce them to seek more, potentially unnecessary, care. We solicit comments on whether we should include such a monitoring provision and, if so, any anticipated burdens and ways OIG could minimize any burden. We would apply a facts and circumstances analysis to the ''reasonable efforts'' employed by parties under this condition, using an objective standard of reasonableness. We solicit comments on this approach.

d. Retrieval of Items and Goods

We are considering for the final rule and seek comment on a condition that would require offerors to engage in reasonable efforts to retrieve an item or good furnished as a tool or support in certain circumstances. For example, we are considering requiring that the offeror make reasonable efforts to retrieve the patient engagement tool or support (if it is an item or good) when the patient is no longer in the target patient population, the VBE no longer exists, or the offeror is no longer a VBE participant. This would prevent the safe harbor from being misused to protect inducements to beneficiaries that do not promote value. If we were to include such a requirement, we are considering

setting a minimum value for the item or good above which offerors would be required to make reasonable retrieval efforts (*e.g.,* $100, $200, $500 or a higher or lower amount). We believe such a provision would reduce the burden associated with retrieval efforts. We also are interested in comments regarding whether any retrieval requirement should be limited to tools and supports that are practicable to recover, such as those which are not fixtures or were for short-term use or an otherwise temporary benefit, and where harm to the patient or disproportionate expense to the VBE participant would not result.

e. Advertising

We are considering for the final rule and seek comment on a condition that would require that the VBE participant does not publicly advertise the patient engagement tool or support (to patients or others who are potential referral sources). This would prohibit advertising in the media or posting information for public display or on websites about the availability of free items or services, similar to the local transportation safe harbor, 42 CFR 1001.952(bb). Such prohibition on public advertising would inhibit the use of patient engagement tools and supports as a marketing tool, thus keeping the focus of the safe harbor on improving care coordination and management of patients' care. We solicit comments on this potential safeguard. In particular, we are interested in comments on whether this condition would impose a barrier to the success of care coordination and value-based arrangements by restricting information available to patients about options for receiving better coordinated care.

G. CMS-Sponsored Model Arrangements and CMS-Sponsored Model Patient Incentives (1001.952(ii))

OIG and CMS have jointly issued fraud and abuse waivers of certain provisions of the Federal anti-kickback statute, the physician self-referral law and, for OIG only, certain CMP law authorities for numerous payment models established and tested by CMS under section 1115A(d)(1) of the Act (pertaining to models tested by the Innovation Center)[47] and section 1899 of the Act (pertaining to the Medicare Shared Savings Program).[48] Waivers apply only to: (i) Arrangements described by the models and (ii) model participants and other specified individuals and entities. Further, any protection furnished by the waivers is limited in duration.

Commenters to the OIG RFI generally asked us to simplify and standardize our approach to protecting CMS-sponsored model arrangements under the anti-kickback statute and beneficiary inducements CMP. Waivers issued to date are tailored to the particular CMS model and CMS's design for the model, pursuant to the waiver authorities. Commenters requested that OIG promulgate regulatory protections that would provide uniformity and predictability for parties participating in CMS models.

We propose to create a new anti-kickback statute safe harbor at 42 CFR 1001.952(ii) to: (i) Permit remuneration between and among parties to arrangements (*e.g.,* distribution of capitated payments, shared savings or losses distributions) under a model or other initiative being tested or expanded by the Innovation Center under section 1115A of the Act and the Medicare Shared Savings Program under section 1899 of the Act (collectively, ''CMS-sponsored models'') and (ii) permit remuneration in the form of incentives and supports provided by CMS model participants and their agents under a CMS-sponsored model to patients covered by the CMS-sponsored model. The objective of the proposed safe harbor is to standardize and simplify anti-kickback statute compliance for CMS-sponsored model participants in models for which CMS has determined participants should have the protection that would be afforded by this safe harbor[49] (rather than requiring participants to comply with the law as it would exist without this safe harbor) by applying uniform conditions across all models or initiatives sponsored by CMS.

This proposal focuses on models under sections 1115A and 1899 of the Act; we are considering for the final rule, and solicit comments on, broadening the scope of this safe harbor to protect remuneration between and among parties to arrangements under CMS initiatives that are authorized under other sections of the Act with statutory authority to waive the fraud and abuse laws.

By proposing this safe harbor, we aim to simplify application of the anti-kickback statute and CMP authorities for individuals and entities that participate in CMS-sponsored models in a manner that is consistent with CMS's authorities to operate and test new models and to reduce the need to issue model-by-model waivers of fraud and abuse laws. As with fraud and abuse waivers, our goal is to accommodate CMS's testing and operation of innovative, value-based care delivery and payment models that CMS has determined could improve quality of care, reduce growth in costs, or both, while also including program integrity protections against fraud and abuse. To the extent that an arrangement under a CMS-sponsored model implicates the anti-kickback statute or beneficiary inducements CMP, parties within CMS-sponsored models for which we have issued fraud and abuse waivers may continue to use applicable CMS-sponsored model waivers to protect their arrangements or may choose to structure arrangements to comply with this new safe harbor or any other applicable anti-kickback statute safe harbor or CMP exception.

The degree of flexibility offered by this proposed safe harbor recognizes CMS's ability to oversee and monitor CMS-sponsored models and initiatives and to embed program integrity protections in such models and initiatives in ways that do not necessarily apply to arrangements outside the models. For this reason, this proposal does not extend to commercial and private insurance arrangements that may operate alongside, but outside, a CMS-sponsored model. However, nothing in this proposed safe harbor would prevent commercial and private insurers from implementing arrangements that cover both public and private patients; such arrangements could be structured to satisfy other proposed safe harbor protections that do not distinguish between public and private patient populations.

We are proposing a number of definitions for purposes of this safe harbor. We propose to define a ''CMS-sponsored model party'' as a CMS-sponsored model participant or another individual or entity that the CMS-sponsored model's participation documentation specifies may enter into a CMS-sponsored model arrangement. We propose to define ''participation documentation'' for purposes of this safe harbor as the participation agreement, cooperative agreement, regulations, or model-specific

[47] *See, e.g.,* CMS, Fraud and Abuse Waivers for Select CMS Models and Programs, *available at https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Fraud-and-Abuse-Waivers.html.*

[48] *See, e.g.,* 76 FR 67992 at 67992 (Nov. 2, 2011); 80 FR 66726 at 66726 (Oct. 29, 2015) (Medicare Shared Savings Program is designed to promote the formation of accountable care organizations that are accountable for a Medicare patient population, coordinate items and services under Parts A and B, and encourage investment in infrastructure and redesigned care processes for high-quality and efficient service delivery).

[49] For example, CMS might specify in a participation agreement whether or not this safe harbor would apply to any arrangement under the CMS-sponsored model or to particular types of arrangements under the CMS-sponsored model.

addendum to an existing contract with CMS that: (i) Is currently in effect, and (ii) specifies the terms of a CMS-sponsored model.

We propose to define a ''CMS-sponsored model participant'' as an individual or entity that is subject to, and is operating under, participation documentation with CMS to participate in a CMS-sponsored model. We propose to define a ''CMS-sponsored model arrangement'' as a financial arrangement between or among CMS-sponsored model parties to engage in activities under the CMS-sponsored model and that is consistent with, and is not a type of arrangement prohibited by, the participation documentation. Finally, we propose to define a ''CMS-sponsored model patient incentive'' as remuneration that is not of a type prohibited by the participation documentation and is furnished consistent with the CMS-sponsored model by a CMS-sponsored model participant (or by an agent of the CMS-sponsored model participant under the CMS-sponsored model participant's direction and control) directly to a patient under the CMS-sponsored model.

We would expect CMS to notify CMS-sponsored model participants, through participation documentation, or other public means as determined by CMS, when CMS-sponsored model participants may use this safe harbor under a CMS-sponsored model. For example, CMS may specify the types of CMS-sponsored model patient incentives that a CMS-sponsored model participant may provide under the CMS-sponsored model within a CMS-sponsored model participation agreement. The CMS-sponsored model participant also must satisfy certain programmatic requirements imposed by CMS in connection with the use of this safe harbor. CMS also may require CMS-sponsored model participants to disclose to CMS when they use this safe harbor under a CMS-sponsored model as a condition of participation in the CMS-sponsored model. If this safe harbor is finalized and CMS determines that it be made available for a CMS-sponsored model, the safe harbor would not be available to protect any remuneration that does not satisfy program requirements as may be imposed by CMS on CMS-sponsored model participants.

We solicit comments on these definitions. In particular, we solicit comments regarding the scope of the definition of ''CMS-sponsored model patient incentive,'' recognizing that a CMS-sponsored model participant may not always know whether a particular patient is in a CMS-sponsored model at any given point in time. We are considering for the final rule and solicit comments on extending the definition of ''CMS-sponsored model incentive'' to include patients beyond those under a CMS-sponsored model or, in the alternative, defining ''CMS-sponsored model patient'' such that a CMS-sponsored model participant could provide incentives to any patient (or any beneficiary) that meets the other conditions of the safe harbor.

As proposed, this safe harbor would provide CMS-sponsored model parties an additional pathway to protection from sanctions under the anti-kickback statute and the beneficiary inducements CMP. An arrangement needs to meet the requirements of only one safe harbor to ensure immunity from criminal and civil prosecution under the statute. For example, CMS-sponsored model parties would be able to choose to structure an arrangement to comply with the conditions of this proposed safe harbor, the proposed value-based arrangements safe harbors (paragraphs (ee), (ff), and (gg)), the patient engagement and support safe harbor (paragraph (hh)), any other applicable existing safe harbors or exceptions, or fraud and abuse waivers issued for the CMS-sponsored model. However, to ensure protection, an arrangement must meet all conditions of a particular safe harbor or waiver. We note that depending on the facts and circumstances, an arrangement may comply with fraud and abuse laws absent specific safe harbor or waiver protection.

1. Proposed Conditions for CMS-Sponsored Model Arrangements and CMS-Sponsored Model Patient Incentives

We are proposing below important safeguards to ensure that arrangements protected by this proposed safe harbor operate as intended by the CMS-sponsored models, and the CMS-sponsored models are not undermined by arrangements that might lead to stinting on medically necessary care or induce inappropriate utilization. These safeguards are necessary to ensure that a CMS-sponsored model party's financial arrangements and patient incentives are consistent with the quality, care coordination, and cost-reduction goals of a CMS-sponsored model and can be readily overseen by CMS and OIG.

As a threshold matter, CMS would determine whether the safe harbor protection would be available for arrangements or patient incentives under the particular CMS-sponsored model. CMS may limit participation in a CMS-sponsored model to certain providers or entities (*e.g.,* certain CMS-sponsored models may exclude pharmaceutical manufacturers from participating in a CMS-sponsored model or participating in arrangements under the CMS-sponsored model). CMS has discretion to determine the scope of entities, arrangements, or incentives that may be protected under this safe harbor on a model-by-model basis. Unlike the proposed safe harbors at 42 CFR 1001.952(ee), (ff), (gg) and (hh), which propose to exclude pharmaceutical manufacturers; manufacturers, distributors, and suppliers of DMEPOS; and laboratories from arrangements and tools and supports that would receive protection under the safe harbors, this proposed safe harbor would not exclude any entities from potential protection under the safe harbor. We do not propose any such exclusions to allow: (i) The Innovation Center the discretion to determine the scope of the models it wishes to test and expand and (ii) CMS the discretion to determine how to implement the Medicare Shared Savings Program. In addition, OIG notes that CMS-sponsored models include programmatic rules, monitoring, and oversight not present in value-based arrangements and the provision of patient tools and supports outside of such models, which may mitigate some of the fraud and abuse risks presented by the inclusion of pharmaceutical manufacturers; manufacturers, distributors, and suppliers of DMEPOS; and laboratories in such models.

a. Conditions for CMS-Sponsored Model Arrangements

Proposed paragraph (ii)(1) sets forth the terms for protection of certain remuneration between or among CMS-sponsored model parties under a CMS-sponsored model arrangement in a model for which CMS has determined that the safe harbor is available.

We propose six conditions parties would need to meet to receive safe harbor protection. The first condition would require that CMS-sponsored model participants reasonably determine that the CMS-sponsored model arrangement will advance one or more goals of the CMS-sponsored model. We intend to interpret ''reasonably determine'' to mean that the activities set forth in the written agreement are fairly and verifiably anticipated to achieve at least one or more goals of the CMS-sponsored model. For example, CMS-sponsored model parties may wish to create an implementation protocol explaining the activities and evidence-based processes or guidance relied upon to develop and

implement an arrangement that would advance a goal of a CMS-sponsored model through the CMS-sponsored model arrangement.

The safe harbor would be flexible to permit parties to pursue a wide array of activities under the CMS-sponsored model; however, the arrangement must be consistent with the purposes of the CMS-sponsored model. As stated above, CMS determines the scope of its models and what is being tested. As we propose to reflect in the definition of ''CMS-sponsored model arrangement,'' if an arrangement is a type of arrangement prohibited by the participation documentation, then it does not qualify as a CMS-sponsored model arrangement. If an arrangement does not qualify as a CMS-sponsored model arrangement, then it would not be protected by this safe harbor even if the CMS-sponsored model parties determined that it would advance a purpose of the CMS-sponsored model.

In the second proposed condition, we specify that the exchange of value must not induce CMS-sponsored model parties or other providers or suppliers to furnish medically unnecessary items or reduce or limit medically necessary items or services furnished to CMS-sponsored model patients. We believe that this is an important protection for patient safety and quality of care, and it would be consistent with every CMS-sponsored model.

In the third proposed condition, we are incorporating a key safeguard that we have consistently utilized in our fraud and abuse waivers to prohibit remuneration that is explicitly or implicitly offered, paid, solicited, or received in return for, or to induce or reward, any referrals or other business generated outside of the CMS-sponsored model.

The fourth condition would require CMS-sponsored model parties, in advance of, or contemporaneously with the commencement of, the CMS-sponsored model arrangement, to set forth the terms of the CMS-sponsored model arrangement in a signed writing.

The fifth condition would require parties to the CMS-sponsored model arrangement to make available to the Secretary materials and records sufficient to establish whether the remuneration was exchanged between the parties in a manner that meets the conditions of this safe harbor. We are not proposing particular parameters regarding documentation, but rather specifying only that the writing must describe the activities to be undertaken by the CMS-sponsored model parties and the nature of the remuneration to be exchanged. Therefore, parties under a CMS-sponsored model would have flexibility to determine what type of documentation would best memorialize the arrangement such that they could demonstrate safe harbor compliance to the Secretary or OIG upon request. Nothing in this proposed condition would change or alter any requirements related to documentation (or any other model feature) imposed by CMS as part of its model.

Finally, we propose to include a condition requiring CMS-sponsored model participants to satisfy such other programmatic requirements as may be imposed by CMS in connection with the use of this safe harbor. Because CMS has authority to test and design models, it can also create programmatic requirements integral to testing and monitoring its model design for CMS-sponsored model participants. We are proposing this condition to ensure that parties comply with any additional programmatic requirements as may be imposed by CMS related to the arrangements for which they might seek safe harbor protection. We would expect CMS to set forth these requirements within the CMS-sponsored model's participation documentation or otherwise make such requirements publicly available.

b. Conditions for CMS-Sponsored Model Patient Incentives

With respect to patient incentives, the proposed safe harbor would apply to certain incentives offered by a CMS-sponsored model participant or by an agent of the CMS-sponsored model participant under the CMS-sponsored model participant's direction and control directly to a patient receiving healthcare items and services under the CMS-sponsored model that will advance one or more goals of the CMS-sponsored model.

CMS would determine whether the safe harbor protection would be available for the particular CMS-sponsored model. As stated above, CMS has discretion to determine which entities may avail themselves of this safe harbor or to determine the types of patient incentives CMS-sponsored model parties may provide on a model-by-model basis. We would expect CMS to notify CMS-sponsored model participants of the scope of permissible patient incentives within its participation documentation or to make such determination publicly available.

If CMS determines a type of incentive is prohibited, then it would not qualify as a CMS-sponsored model patient incentive for purposes of this proposed safe harbor.[50] Similarly, some CMS-sponsored models might have their own requirements for giving patient incentives, and this proposed safe harbor would not obviate those programmatic requirements. For example, in making incentive payments to an assigned Medicare beneficiary under the ACO Beneficiary Incentive Program, ACOs are expected to satisfy the programmatic requirements governing such incentive payments at section 1899(m) of the Act and 42 CFR 425.304(c); if this safe harbor is finalized and CMS determines that it be made available for the ACO Beneficiary Incentive Program, the safe harbor would not be available for any incentive payment that does not satisfy such programmatic requirements.

Depending on the goals set forth by CMS for the CMS-sponsored model, we would expect a CMS-sponsored model participant would use this safe harbor to provide its patients with free or below-fair-market-value incentives that advance the goals of the CMS-sponsored model, such as preventive care, adherence to a treatment regimen, or management of a disease or condition. The proposed protection would cover a broad range of incentives, such as, transportation, nutrition support, home monitoring technology, and gift cards, as determined by CMS through the CMS-sponsored model's design. Certain CMS-sponsored models or future models might permit waivers of cost-sharing amounts (for example, copayments and deductibles) or cash incentives to certain patients to promote certain clinical goals of a CMS-sponsored model. All of these patient incentives, when determined by CMS to be appropriate for the CMS-sponsored model design and not prohibited by the participation documentation, could fit within the proposed safe harbor, provided that the arrangement otherwise complies with all safe harbor conditions. We are proposing safeguards specific to the protected patient incentives.

Under the proposed condition at paragraph (ii)(2)(i), the CMS-sponsored model participant must reasonably determine that the patient incentive the CMS-sponsored model participant furnishes to its patients under the CMS-sponsored model will advance one or more goals of the CMS-sponsored model. As stated above, we would expect CMS to notify CMS-sponsored

[50] Unlike the patient engagement and support safe harbor proposed at 1001.952(hh), under the CMS-sponsored model patient incentives safe harbor, CMS would determine the types of patient incentives CMS-sponsored model parties may provide on a model-by-model basis.

model participants, through participation documentation, or other means as determined by CMS, when CMS-sponsored model participants may use this safe harbor under a CMS-sponsored model and the types of patient incentives they may offer. CMS-sponsored model participants may look to their participation documentation for potential descriptions or guidance on patient incentives that would be consistent with the goals of the CMS-sponsored model. For example, the participation documentation might specify that any incentives furnished must be preventive care items or services or must advance one or more clinical goals for patients under the CMS-sponsored model by engaging him or her in better managing his or her own health.

Under the second proposed condition, we propose to require that the patient incentive have a direct connection to the patient's healthcare. We believe this condition to be consistent with the design of all CMS models and initiatives contemplated as part of this safe harbor. This condition is consistent with requirements we have imposed previously within our fraud and abuse waivers for a number of CMS-sponsored models. For the same reasons described further in our discussion of the proposed patient engagement and support safe harbor at proposed paragraph 1001.952(hh), we propose that this requirement would warrant a dual consideration: Whether a direct connection exists from a healthcare perspective and whether a direct connection exists from a financial perspective.

We are not proposing specific documentation under the third condition for patient incentives offered by CMS-sponsored model participants; however, CMS-sponsored model participants must maintain documentation sufficient to establish whether the patient incentive was distributed in a manner that meets the conditions of the safe harbor. Under this proposed condition, CMS-sponsored model participants would have flexibility to determine what type of documentation would best establish whether the CMS-sponsored model patient incentive was distributed appropriately.

Finally, as described above, if this safe harbor is finalized and CMS determines that it would be available for a particular CMS-sponsored model, the safe harbor would not protect remuneration that does not satisfy such programmatic requirements as may be imposed by CMS under the CMS-sponsored model in connection with the use of this safe harbor.

c. Duration of Protection

Under our proposal, as reflected in the defined terms, the duration of safe harbor protection aligns with the duration of the participation documentation under a CMS-sponsored model. For example, the proposed definition of ''CMS-sponsored model arrangement'' specifies that the protected arrangement is to ''engage in activities under the CMS-sponsored model.'' Similarly, the proposed definition of ''participation documentation'' specifies that it is ''currently in effect.'' The CMS-sponsored models, and arrangements between parties operating under CMS-sponsored models, have various terms, some of which are described in a CMS-sponsored model's participation documentation. In order to meet the conditions set forth in the proposed safe harbor, the CMS-sponsored model arrangement or a CMS-sponsored model patient incentive must begin and end while the parties are operating under an existing CMS-sponsored model.

The safe harbor would protect arrangements during the period under which a CMS-sponsored model participant participates in the CMS-sponsored model but would not extend to protect remuneration exchanged after participation in the CMS-sponsored model ends. In some cases, certain activities associated with a CMS-sponsored model may extend beyond the last performance period during which a CMS-sponsored model participant provides services under the CMS-sponsored model. For example, the participation documentation might provide for a certain period of time after a termination date or after the end of the performance period to conduct reconciliation or make final payment to providers (*e.g.,* a shared savings distribution). This safe harbor would protect the last payment or exchange of value made by or received by a CMS-sponsored model party following the final performance period that the CMS-sponsored model participant that is a party to the arrangement participates in the CMS-sponsored model. We are considering each of the following options for 1001.952(ii) and may finalize one or a combination of these options: (i) Terminating protection after the end of the performance period or within a certain time period after the end of a performance period; (ii) terminating protection upon termination of the CMS-sponsored model participation documentation or within a certain period of time after that; and (iii) until the last payment or exchange of anything of value made by a CMS-sponsored model party under a CMS-sponsored model occurs, even if the model has otherwise terminated. We solicit comments on whether the final rule should allow safe harbor protection for one or a combination of the above options.

Similarly, we solicit comments on whether under the final rule a CMS-sponsored model participant should be able to continue to provide the outstanding portion of any service to a patient if the service was initiated before its participation documentation terminated or expired. If we provide additional time under the final rule, we are interested in including conditions to prevent gaming of the length of time remuneration is provided after a CMS-sponsored model participant has been terminated from a model (or the model has terminated) to protect beneficiaries from improper inducements unrelated to a CMS-sponsored model. We note that, under our proposal, patients would be able to retain any incentives received prior to the termination or expiration of the participation documentation.

H. Cybersecurity Technology and Related Services (1001.952(jj))

We propose a safe harbor to protect donations of certain cybersecurity technology and related services with appropriate safeguards. We believe this proposed safe harbor could help improve the cybersecurity posture of the healthcare industry by removing a real or perceived barrier that would allow parties to address the growing threat of cyberattacks that infiltrate data systems and corrupt or prevent access to health records and other information essential to the delivery of healthcare.

In recent years we have received numerous comments and suggestions urging the creation of a safe harbor to protect donations of cybersecurity technology and services.[51] The digitization of the healthcare delivery system and related rules designed to increase interoperability and data sharing in the delivery of healthcare create numerous targets for cyberattacks. The healthcare industry and the technology used to deliver healthcare have been described as an interconnected ''ecosystem'' where the ''weakest link'' in the system can compromise the entire system.[52] Given

[51] *See, e.g.,* OIG, *Semiannual Report to Congress,* Apr. 1, 2018–Sept. 30, 2018, at 84.

[52] *See, e.g.,* Health Care Industry Cybersecurity Task Force, *Report on Improving Cybersecurity in the Health Care Industry,* June 2017 (HCIC Task Force Report), *available at https://www.phe.gov/*

Continued

the prevalence of protected electronic health information and other personally identifiable information stored within these systems, as well as the processing and transmission of this information and other critical information within a given provider's systems as well as across the healthcare industry, the risks associated with cyberattacks may be most immediate for the ''weak links'' but have implications for the entire healthcare system.

In response to the OIG RFI, we received overwhelming support for a cybersecurity technology donation safe harbor. Many commenters highlighted the increasing prevalence of cyberattacks and other threats. Commenters noted that cyberattacks pose a fundamental risk to the healthcare ecosystem and that data breaches can result in patient harm as well as high costs to the healthcare industry. Moreover, disclosures of PHI through a data breach can result in identity fraud.

Relatedly, protecting Department data, systems, and beneficiaries from cybersecurity threats, and otherwise securing the exchange and use of health information technology and data, are challenges that OIG has identified in the Department's annual Top Management and Performance Challenges for the last decade.[53]

The Health Care Industry Cybersecurity (HCIC) Task Force, created by the Cybersecurity Information Sharing Act of 2015 (CISA),[54] was established in March 2016 and is comprised of government and private sector experts. The HCIC Task Force produced its HCIC Task Force Report in June 2017.[55] The HCIC Task Force recommended, among other things, that Congress ''evaluate an amendment to [the physician self-referral law and the anti-kickback statute] specifically for cybersecurity software that would allow healthcare organizations the ability to assist physicians in the acquisition of this technology, through either donation or subsidy'' and noted that the regulatory exception to the physician self-referral law and the safe harbor for electronic health records technology could serve as a template for a new statutory exception.[56]

However, in general, any donation of valuable technology or services to physicians or other sources of Federal health care program referrals can pose risks of fraud or abuse that may increase as the value of the donated technology or services increases. In some respects, the fraud and abuse risks posed by the donation of cybersecurity technology or services to physicians or other healthcare providers or suppliers are similar to the risks associated with the provision of electronic health records technology because, like electronic health records technology, cybersecurity technology is inherently valuable to recipients in terms of actual cost, avoided overhead, and administrative expenses. Additionally, the types of cybersecurity technology and services are highly variable; their costs and value also vary greatly. For example, cybersecurity technology or services may consist only of anti-virus software for a single workstation in a physician's office or it may include incident response services for several primary and specialty group practices. Further, adding robust cybersecurity technology and services may provide recipients a valuable shield from liability for fines, ransom, and litigation risk given the prevalence of cybersecurity threats to healthcare providers and breaches involving protected health information and electronic health records. Finally, responses to the OIG RFI indicate that the cost, or value, of cybersecurity technology and services has increased dramatically, to the point where some providers and suppliers are unable to adequately invest in cybersecurity measures.

We believe that this proposed safe harbor would (i) minimize the risks inherent in any type of valuable remuneration between referral sources and (ii) remove an actual or perceived barrier that will allow the healthcare industry to take additional action to mitigate the risks posed by cybersecurity threats. Specifically, we believe this proposed safe harbor would promote increased security for interconnected and interoperable healthcare information technology systems without protecting arrangements that either serve as marketing platforms or inappropriately influence clinical decision-making.

This proposed safe harbor would protect certain cybersecurity donations. CMS is proposing a similar exception to the physician self-referral law. We coordinated closely with CMS to ensure as much consistency as possible between our proposed safe harbor and CMS's proposed exception, despite the differences in the respective underlying statutes. Because of the close nexus between this proposed rule and CMS's proposed rule, we may consider and take additional actions based on comments submitted in response to CMS's proposed rule in addition to those submitted in response to this rulemaking, if warranted.

We propose to protect nonmonetary remuneration in the form of certain types of cybersecurity technology and services. Specifically, as explained below, we propose to define ''cybersecurity'' to mean ''the process of protecting information by preventing, detecting, and responding to cyberattacks.'' We propose to include within the scope of covered technology, ''any software or other types of information technology, other than hardware.'' In an effort to foster beneficial cybersecurity donation arrangements without permitting arrangements that negatively impact beneficiaries of Federal health care programs, this safe harbor would impose a number of conditions on cybersecurity donations, as set forth below. Most notably, the first proposed condition of the safe harbor requires the donation to be necessary and used predominantly to implement and maintain effective cybersecurity.

We also have included an alternative proposal for an additional, optional condition to this proposed safe harbor. The optional condition imposes an additional safeguard that parties can satisfy in exchange for protecting certain cybersecurity hardware.

1. Definitions

We propose two definitions at 1001.952(jj)(6): ''cybersecurity'' and ''technology.'' These definitions are integral to understanding the conditions of the safe harbor, so we first elaborate on the definitions. For purposes of this safe harbor, we propose to define the terms ''cybersecurity'' and ''technology'' as follows:

- ''Cybersecurity'' means the process of protecting information by preventing, detecting, and responding to cyberattacks.
- ''Technology'' means any software or other types of information technology, other than hardware.

This proposed definition of ''cybersecurity'' is derived from the National Institute for Standards and Technology (NIST) ''Framework for

preparedness/planning/cybertf/documents/report2017.pdf.

[53] *See, e.g.,* OIG, 2018 Top Management & Performance Challenges Facing HHS, *available at https://oig.hhs.gov/reports-and-publications/top-challenges/2018/.*

[54] Public Law 114–113, 129 Stat. 2242.

[55] HCIC Task Force Report, *available at https://www.phe.gov/preparedness/planning/cybertf/documents/report2017.pdf.*

[56] *Id.* at 27.

Improving Critical Infrastructure.'' [57] We intend for the definition to be broad and propose to rely on a definition in a NIST framework that does not apply directly to the healthcare industry but applies generally to any United States critical infrastructure. Our goal is to broadly define cybersecurity and avoid unintentionally limiting donations by relying on a narrow definition or a definition that might become obsolete over time. We solicit comment on this approach and whether a definition tailored to the healthcare industry would be more appropriate.

Similarly, the proposed definition of ''technology'' is broad, but for the exclusion of hardware. The intent of the safe harbor is to be agnostic to specific types of non-hardware cybersecurity technology. We intend for this safe harbor to be broad enough to include cybersecurity software and other information technology (*e.g.,* an Application Programming Interface (API), which is neither software nor a service as those terms are generally used) that is available now and technology that may become available as the industry continues to develop.

The proposed definition of ''technology'' excludes hardware under this new safe harbor. While we recognize that effective cybersecurity may require hardware that meets certain standards (*e.g.,* encrypted endpoints, updated servers), we remain concerned that donations of valuable, multifunctional hardware pose a higher risk of constituting a disguised payment for referrals. Consistent with the proposed condition at 1001.952(jj)(1), we believe that donations with multiple uses outside of cybersecurity present a greater risk that the donation is being made to influence referrals. Hardware is most likely to be multifunctional and, as a result, would not be necessary and used predominantly to implement and maintain effective cybersecurity. For example, the safe harbor would not protect a laptop computer or tablet used in the general course by a physician to enter patient visit information into an electronic health record and respond to emails. However, it would protect encryption software for a laptop. This also is consistent with a similar exclusion of hardware in the electronic health record donation safe harbor at 1001.952(y), which identifies a similar rationale for excluding hardware from protection.[58] We solicit comments on this approach.

As we describe below, however, we are not proposing a requirement for recipients to contribute a portion of the donor's costs. Consistent with the HCIC Task Force Report, we recognize that many providers do not have adequate resources to significantly invest in the cybersecurity items and services protected by this proposed safe harbor. Consequently, we believe that omitting a contribution requirement may allow providers with limited resources to receive protected cybersecurity donations while also using their own resources to invest in other technology not protected by the safe harbor, such as updating legacy hardware that may pose a cybersecurity risk, or simply investing in their own computers, phones, and other hardware that are core to their businesses, notwithstanding their relationship with a donor who contributes cybersecurity technology. We solicit comments on excluding donations of hardware from this safe harbor and the omission of a contribution requirement, and in particular, any specific cybersecurity risks or limitations that would result from such exclusion and omission.

We are considering for the final rule adding limited protection for specific hardware that is necessary for cybersecurity, is stand-alone (*i.e.,* is not integrated within multifunctional equipment), and serves only cybersecurity purposes (*e.g.,* a two-factor authentication dongle), and solicit comments on what types of hardware might qualify and whether we should protect them under this safe harbor.

Finally, we note that this proposed safe harbor only protects cybersecurity technology and services as defined. It does not extend to other types of cybersecurity measures outside of technology or services. For example, this safe harbor would not protect donations of installation, improvement, or repair of infrastructure related to physical safeguards, even if they could improve cybersecurity (*e.g.,* upgraded wiring or installing high security doors). Donations of infrastructure upgrades are extremely valuable and have multiple benefits in addition to cybersecurity, together which pose an increased risk that one purpose of the donation is to pay for or influence referrals.

2. Conditions on Donation and Protected Donors

To be protected non-monetary remuneration, donations of cybersecurity technology and services must meet five conditions in 1001.952(jj)(1)–(5). The first two conditions relate to the purpose of the donation and prohibit donors taking into account the volume or value of referrals or other business generated.

First, at 1001.952(jj)(1), we propose to limit safe harbor protection to donated technology and services that are necessary and used predominantly to implement and maintain effective cybersecurity. The goal of this condition is to ensure that donations are being made for the purposes of addressing legitimate cybersecurity needs of donors and recipients. Explained differently, the core function of the donated technology or service must be to protect information by preventing, detecting, and responding to cyberattacks. Our intent is to protect a wide range of technology and services that are specifically donated for the purpose of, and are necessary for, ensuring that donors and recipients have effective cybersecurity.

As stated previously, our intent is to be technology agnostic, including as to the types and versions of software that can receive protection. By way of example, the types of technology protected by this safe harbor may include, but are not limited to, software that provides malware prevention, software security measures to protect endpoints that allow for network access control, business continuity software that mitigates the effect of cyberattacks, data protection and encryption, and email traffic filtering. We believe these examples are indicative of the types of technology that are necessary and used predominantly for effective cybersecurity. We also do not distinguish between cloud-based software or software that must be installed locally. We solicit comments on the proposed breadth of protected technology as well as whether we should expressly include other technology or categories of technology in this safe harbor.

Similarly, we propose to protect a broad range of services. Such services could include, for example:

- Any services associated with developing, installing, and updating cybersecurity software;
- any kind of cybersecurity training services, such as training recipients on how to use the cybersecurity technology, how to prevent, detect, and respond to cyber threats, and how to troubleshoot problems with the cybersecurity technology (*e.g.,* ''help desk'' services specific to cybersecurity);
- any kind of cybersecurity services for business continuity and data recovery services to ensure the recipient's operations can continue during and after a cyberattack;
- any kind of ''cybersecurity as a service'' model that relies on a third-

[57] Appendix B, Version 1.1 (Apr. 16, 2018) *available at https://nvlpubs.nist.gov/nistpubs/CSWP/NIST.CSWP.04162018.pdf.*

[58] 71 FR 45110, 45120 (Aug. 8, 2006).

party service provider to manage, monitor, or operate cybersecurity of a recipient;

- any services associated with performing a cybersecurity risk assessment or analysis, vulnerability analysis, or penetration test; or
- any services associated with sharing information about known cyber threats, and assisting recipients responding to threats or attacks on their systems.

We believe these types of services are indicative of the types of services that are necessary and used predominantly for effective cybersecurity. We solicit comments on the proposed breadth of protected services as well as whether we should expressly include other services or categories of services in this safe harbor. We note, in addition, that the donation of services must be non-monetary. For example, donating the time of a consultant to implement a cybersecurity program could be protected, but if an entity were to experience a cyberattack that involved ransomware, payment of the ransom amount on behalf of a recipient or paying the recipient the ransom amount would not be protected.

We do not intend to protect donations of technology or services that have multiple, general uses outside of cybersecurity. As explained in our discussion of the definition of ''hardware'' above, we remain concerned that donations of valuable multi-use technology or services pose a higher risk of constituting a disguised payment for, or otherwise influencing, referrals. Similarly, we do not intend to protect donations of technology or services that are otherwise used in the normal course of the recipient's business (*e.g.,* general help desk services related to use of a practice's information technology). We solicit comment on this approach and whether this proposed condition unintentionally limits the donation of cybersecurity technology and services that are vital to improving the cybersecurity posture of the healthcare industry.

For the purposes of meeting the proposed condition at 1001.952(jj)(1), we are considering for the final rule, and seek comment on, whether to add a deeming provision that would allow donors or recipients to demonstrate that donations are necessary and predominantly used to implement and maintain effective cybersecurity. This deeming provision would allow donors and recipients to demonstrate that the donation furthers a recipient's ability to comply with a written cybersecurity program that reasonably conforms to a widely recognized cybersecurity framework or set of standards, such as one developed or endorsed by NIST, another American National Standards Institute-accredited standards body, or an international voluntary standards body such as the International Organization for Standardization. Any such provision would not require compliance with a particular framework or set of standards, but rather would provide an option for donors to demonstrate that the donation is necessary and predominantly used to implement and maintain effective cybersecurity. We believe such a provision may provide some assurance to donors and recipients about how to demonstrate that donations are necessary and predominantly used to implement and maintain effective cybersecurity. If we were to finalize this deeming provision, we would add a sentence to 1001.952(jj)(1) that would deem a donation to meet this condition if the parties demonstrate that the donation furthers a recipient's ability to comply with a written cybersecurity program that reasonably conforms to a widely recognized cybersecurity framework or set of standards. We solicit comments on incorporating this proposed deeming provision in 1001.952(jj)(1).

Regarding this proposed deeming provision, we also solicit comments on how donors and recipients could practically demonstrate that a donation furthers a recipient's ability to comply with a written cybersecurity program that reasonably conforms to a widely recognized cybersecurity framework or set of standards. We are not proposing to condition protection on demonstrating compliance with a specific framework or set of standards, but we seek to provide a practical method that allows parties to demonstrate that a donation meets the potential deeming provision we are considering for 1001.952(jj)(1).

Understanding that our intent is not to incorporate a specific framework or set of standards, we seek comments on whether there are other ways that parties could reliably demonstrate that a donation meets the potential cybersecurity deeming provision in 1001.952(jj)(1). For instance, we are interested in comments regarding whether parties could demonstrate that a donation meets the cybersecurity deeming provision through documentation, certifications, or other methods not prescribed by regulation.

Second, at 1001.952(jj)(2), we propose to require that donors do not directly take into account the volume or value of referrals or other business between the parties when determining the eligibility of a potential recipient for the technology or services, or the amount or nature of the technology or services to be donated. In addition, we propose that donors do not condition the donation of technology or services, or the amount or nature of the technology or services to be donated, on future referrals. In other words, we propose that a donor cannot require, explicitly or implicitly, that a recipient either refer to the donor or recommend the donor's business as a condition of receiving a cybersecurity donation. We understand that the purpose of donating cybersecurity technology and services is to guard against threats that come from interconnected systems, and we understand and expect that a donor would provide the cybersecurity technology and services only to individuals and entities that connect to its systems, which includes those that refer to it (or that receive referrals from it). However, this condition would restrict a donor from conditioning the donation on referrals or other business generated.[59]

This proposed condition would not require a donor to donate cybersecurity technology and services to every individual or entity that connects to its system. Donors would be able to use selective criteria for choosing recipients, provided that neither a recipient's eligibility, nor the amount or nature of the cybersecurity technology or services donated, is determined in a manner that directly takes into account the volume or value of referrals or other business generated between the parties. For example, a donor could perform a risk assessment of a potential recipient (or require a potential recipient to provide the donor with a risk assessment) before determining whether to make a donation, or the scope of a donation. Similarly, for example, if a donor is a hospital, the hospital might choose to limit donations to physicians who are on the hospital's medical staff. Additionally, selective criteria might be based on the type of connection between a donor and recipient, such as a simple read-only connection to a properly implemented, standards-based API that enables only the secure transmission of a copy of the patient's record at the patient's request to the recipient. That type of connection poses less risk to a donor's systems than a connection that allows for information to be written directly into the donor's systems. Thus, a donor contemplating allowing a higher-risk connection (such as a bi-directional read-write

[59] We note that, if a system is only as strong as its weakest link, then even a very low-referring entity poses a cybersecurity risk.

connection) to a potential recipient's systems could develop selective criteria based on that difference in risk of the connection. We solicit comments on this condition.

We have declined to propose a list of selection criteria which, if met, would be deemed not to directly take into account the volume or value of referrals or other business generated between the parties, as we did in the electronic health records safe harbor at 1001.952(y)(5). We do not believe donations of cybersecurity technology and services present the same types of risks as donations of electronic health records software and information technology. Primarily, cybersecurity donations are further removed from the volume and value of referrals than electronic health record donations. Cybersecurity donations, if legitimate, are more likely to be based on considerations such as security risks and are less likely to be based on considerations that are closely related to the volume and value of referrals or other business generated (*e.g.,* the total number of prescriptions written by the recipient). Therefore, we do not believe that cybersecurity donations need a similar list of selection criteria to ensure that parties can meet the volume or value condition at 1001.952(jj)(2).

Nonetheless, we are considering whether to add such a list in the final rule and whether the list should be based on the permitted conduct at 1001.952(y)(5)(i)–(vii). We solicit comments on this approach and any other conditions or permitted conduct we should enumerate in this safe harbor, with respect to determinations related to cybersecurity donations.

Related to these two conditions, we do not propose to restrict the types of individuals and entities that may donate cybersecurity donations under this safe harbor. Although donating cybersecurity technology and services would relieve a recipient of a cost that it otherwise would incur, the fraud and abuse risks associated with cybersecurity are different than donations of other valuable technology, such as electronic health records items and services. We generally view donating cybersecurity technology and services to be a self-protective measure because a cybersecurity breach in the donor's system can have a devastating impact on the donor and anyone who maintains a connection to the donor's systems. Meanwhile, electronic health record donations facilitate the exchange of clinical information between the recipient referral source and the donor and, thus, present a greater risk that one purpose of the donation is for the donor to secure additional referrals from the recipient or otherwise influence referrals or other business generated.

We are concerned that technology donations risk referral sources becoming beholden to the donors, and therefore we are considering narrowing the scope of protected donors as we have done in other safe harbors. We solicit comments on whether particular types of individuals and entities should be excluded from donating cybersecurity technology and services, and if so, why. Specifically, in past rulemakings we have distinguished between individuals and entities with direct and primary patient care relationships that have a central role in the healthcare delivery infrastructure such as hospitals and physician practices, and providers and suppliers of ancillary services such as pharmaceutical, device, and DMEPOS manufacturers, and other manufacturers or vendors that indirectly furnish items and services used in the care of patients.[60] We seek comments as to whether our historical enforcement concerns and other considerations regarding direct and indirect patient care are present for purposes of cybersecurity donations.

3. Conditions for Recipients

In proposed 1001.952(jj)(3), similar to the condition at (jj)(2) on donors discussed previously, this proposed condition would require that neither a potential recipient, nor a potential recipient's practice (or any affiliated individual or entity), can demand, explicitly or implicitly, a donation of cybersecurity technology and services as a condition of doing business or continuing to do business with the donor.

We do not propose a recipient contribution requirement as part of this safe harbor. As we explain above, with this proposed safe harbor we seek to remove a barrier to donations that improve cybersecurity throughout the healthcare industry in response to the critical cybersecurity issues identified in the HCIC Task Force Report and elsewhere. We propose to include only those conditions for safe harbor protection that we believe are critical to guarding against fraud and abuse. In the case of cybersecurity, we do not believe a specified recipient contribution to the cost is necessary or practical. We recognize that the level of services for each recipient might vary, and might be higher or lower each year, each month, or even each week. Similarly, donors may aggregate the cost of certain services across all recipients, such as cybersecurity patches and updates, on a regular basis, which may result in a contribution requirement becoming a barrier to widespread, low-cost improvements in cybersecurity because of the practical challenges in collecting a contribution from recipients. For instance, attempting to quantify the value of a frequent cybersecurity scans included in a vendor's suite of services as part of a cybersecurity donation, across dozens of recipient practices, and determining the pro rata share each practice must contribute based on the size of the practice as well as the relative size of the donation made to each practice, might become unworkable for many donors.

Importantly, we note that our proposal to omit a contribution requirement as a condition of the safe harbor does not prohibit donors from requiring a contribution. Donors are free to require recipients to contribute to the cost, so long as the determination of a contribution requirement does not take into account the volume or value of referrals between the parties. For example, if a donor gave a full suite of cybersecurity technology and services for free to a high-referring practice but required a low-referring practice to contribute 20 percent of the cost, then the donor could violate the conditions at proposed paragraphs (jj)(2)(i) and (ii). In addition, we do not intend for this safe harbor to require that donations be solely between two parties. For example, two hospitals and a large multi-specialty physician practice might agree to jointly subsidize cybersecurity technology and services for smaller physician practices in their area.

We do not propose to impose restrictions on the type of individual or entity that can receive donations of cybersecurity technology or related services. We note that, because we do not propose to restrict the scope of protected recipients under this safe harbor, we believe patients would be included as protected recipients. Donations to patients, just like other recipients, would only be protected if they precisely met all conditions of the safe harbor. As discussed previously, donations of multifunctional technology or services would not be protected

[60] *See* OIG, Final Rule: Safe Harbors for Certain Electronic Prescribing and Electronic Health Records Arrangements Under the Anti-Kickback Statute, 71 FR 45110, 45128 (Aug. 8, 2006) (excluding pharmaceutical, device, DMEPOS manufacturers, or other entities that indirectly furnish items and services used in the care of patients both because ''[our] enforcement experience demonstrates that unscrupulous manufacturers have offered remuneration in the form of free goods and services to induce referrals of their products'' and because they lack ''a direct and central patient care role that justifies safe harbor protection for the provision of electronic health records technology'').

because all cybersecurity donations must be necessary and used predominately to implement and maintain effective cybersecurity.

We anticipate that donations to patients would be more limited than donations to healthcare providers and suppliers (*e.g.,* anti-malware tools). However, we solicit comments on what types of cybersecurity technology or services a donor might anticipate giving to a patient, whether we would need additional or different safeguards when a patient is the recipient, and whether patients should be protected recipients at all under the safe harbor. More specifically, we solicit comments on whether we should include additional conditions for donations of cybersecurity technology services to patient recipients that are similar to the beneficiary inducements CMP's exceptions under 42 CFR 1003.110. For example, we are considering whether cybersecurity technology or service donations to patients should not be offered as part of any advertisement or solicitation or not be tied to the provision of other items or services reimbursed in whole or in part by the Medicare program under Title VIII or a State health care program (as defined in section 1128(h) of the Act).

4. Written Agreement

At 1001.952(jj)(4), we propose to require that the donor and recipient enter into a signed, written agreement. While we do not interpret this condition to require every item of cybersecurity technology and every potential service to be specified in the agreement, we propose that the written agreement must include a general description of the cybersecurity technology and services to be provided over the term of the agreement and a reasonable estimate of the value of the donation. In addition, to the extent the parties share any financial responsibility for the cost of the cybersecurity technology and services, those financial terms, including the amount of the contribution, must be memorialized in the written agreement. We solicit comments on the conditions proposed here, as well as whether additional or different terms should be required in a written agreement.

5. Prohibition on Cost Shifting

At 1001.952(jj)(5), we propose to prohibit donors from shifting the costs of any cybersecurity donations to Federal health care programs. For example, under this proposed condition, while a hospital's own cybersecurity costs could be an administrative expense on its cost report, donations of cybersecurity technology or services to other individuals or entities could not be included as an administrative expense on the hospital's cost report.

6. Alternative Proposed Condition for Protection of Cybersecurity Hardware

We also propose and solicit comments on an alternative approach that would add an additional, optional safeguard to the proposed cybersecurity safe harbor. This alternative approach would protect cybersecurity hardware donations if the parties choose to meet an additional condition, along with the other five conditions proposed at 1001.952(jj)(1)–(5). Under this alternative proposal, a protected donation could also include cybersecurity hardware that a donor has determined is reasonably necessary based on a risk assessment of its own organization and that of the potential recipient.

The goal of this alternate proposal is to provide donors and recipients more flexibility regarding the types of cybersecurity donations that are protected, while also adding an additional safeguard to further ensure that the donation is necessary and used predominantly to implement and maintain effective cybersecurity.

We believe this alternative proposal builds on existing legal requirements and best practices related to information security generally and the healthcare industry more specifically. For example, the HHS Office for Civil Rights explained that conducting a risk analysis is the first step in identifying and implementing safeguards that comply with and carry out the standards and implementation specifications in the HIPAA Security Rule.[61] More generally, NIST Special Publication 800–30, which does not directly apply to the healthcare industry, but represents industry standards for information security practices, explains that the purpose of a risk assessment is to inform decision makers and support risk responses by identifying: (i) Relevant threats to organizations or threats directed through organizations against other organizations; (ii) vulnerabilities both internal and external to organizations; (iii) impact (*i.e.,* harm) to organizations that may occur given the potential for threats exploiting vulnerabilities; and (iv) likelihood that harm will occur. The end result is a determination of risk, which is typically a function of the degree of harm and likelihood of harm occurring.[62]

Risk assessments are a key component to developing effective organization-wide risk management for information security. We believe that risk assessments conducted consistent with industry standards would provide a reasonable basis for donors to identify risks and threats to their organizational information security that need to be mitigated by donating cybersecurity hardware to other entities. Additionally, donations that are made in response to risk assessments are likely to meet the purpose of this safe harbor that donations are necessary and used predominantly to implement and maintain effective cybersecurity. Under this proposal, a donor would perform or have an existing risk assessment for its own organization, and would require a potential recipient to have, perform, or obtain a risk assessment, that would provide a reasonable basis to determine that the donated cybersecurity hardware is needed to address a risk or threat identified by a risk assessment.

Consistent with the HCIC Task Force Report and comments we received in response to the OIG RFI, we recognize that ''[m]any organizations cannot afford to retain in-house information security personnel, or designate an information technology (IT) staff member with cybersecurity as a collateral duty.'' Understanding that resource constraint, one goal of this safe harbor is to increase the avenues available for all healthcare organizations to improve their cybersecurity practices. We believe protecting a cybersecurity hardware donation based on the risk assessment of a recipient would further the goal of increasing the avenues available to improve cybersecurity for all healthcare entities, regardless of their available resources.

We recognize that a potential recipient with limited resources and cybersecurity experience may not be able to conduct or pay for its own risk assessment. As noted above, one cybersecurity service that would be a protected donation under the proposed safe harbor is a risk assessment. Under the alternative proposal, donors could then make additional cybersecurity hardware donations that are reasonably based on the risk assessments of the donor and recipients.

We recognize that risk assessment practices vary across the healthcare industry and may be depend on the size

[61] HIPAA for Professionals, *Guidance on Risk Analysis* (Mar. 2017), *available at https://www.hhs.gov/hipaa/for-professionals/security/guidance/guidance-risk-analysis/index.html.*

[62] NIST Special Publication 800–30 Revision 1, *Guide for Conducting Risk Assessments* (Sept. 2012), *available at https://nvlpubs.nist.gov/nistpubs/legacy/sp/nistspecialpublication800-30r1.pdf.*

and sophistication of any provider or entity. We solicit comments on this alternative proposal to understand whether entities that are potential donors or recipients already conduct risk assessments that would provide a reasonable basis to determine that a cybersecurity hardware donation is reasonable and necessary. We would propose to define ''risk assessment'' based on NIST Special Publication 800–30 and solicit comment on whether that definition is sufficient for this cybersecurity donation safe harbor. Additionally, we solicit comments on whether this proposal should incorporate specific standards or requirements, such as NIST Special Publication 800–30.

We are considering for the final rule, and seek comment on, adding safeguards to this alternate proposal. For instance, we are considering limiting the additional cybersecurity hardware permitted under the alternative proposal to certain kinds of hardware. We are interested in comments, particularly from providers, that explain what types of hardware would be necessary for effective cybersecurity under this alternate proposal. We note that because this alternate proposal builds upon the proposed conditions at proposed 1001.952(jj)(1)–(5), multifunctional hardware still would be prohibited because it would not be necessary and predominantly used to implement and maintain effective cybersecurity, as required under proposed 1001.952(jj)(1). If the donation includes hardware, we are also considering requiring a contribution from the recipient, similar to the electronic health records safe harbor at 1001.952(y)(11), and we are considering requiring the contribution amount to be 15 percent. We are interested in comments on this approach, and whether we should consider other contribution amounts instead, such as 5 percent, or 20 or 30 percent.

If we add this contribution requirement, we are considering excepting small and rural practices, and we are interested in comments on this approach. Relatedly, we solicit comments on how ''small or rural practices'' should be defined. For example, we solicit comments on whether ''rural practices'' should be defined as those located in rural areas, as defined in the safe harbor for local transportation at 42 CFR 1001.952(bb). We also solicit comments on whether ''small practices'' should be defined as those in medically underserved areas, as designated by the Secretary under section 330(b)(3) of the Public Health Service Act, or defined similarly to a ''small provider of services or small supplier'' as set forth in the requirements related to the electronic submission of Medicare claims at 42 CFR 424.32. We also are considering for the final rule and solicit comments on whether other subsets of potential recipients, for example critical access hospitals, should be exempted from the 15-percent contribution requirement because it would impose a significant financial burden on the recipient. Additionally, if a contribution requirement is included in the final rule, we are considering exempting contributions for the upgrades, updates, or patches of remuneration that was previously donated. Based on our experience with the electronic health records arrangements safe harbor, we recognize the practical challenges in collecting contributions from recipients for minor upgrades, updates, and patches that are necessary to keep the donated technology compliant with new security policies.

If we were to finalize this alternate proposal, we would modify the proposed safe harbor by adding new conditions and a definition in the safe harbor. Primarily, we would add a new condition that would require a donor to perform or have an existing risk assessment for its own organization, and require a potential recipient to have, perform, or obtain a risk assessment, that provides a reasonable basis to determine that the donated cybersecurity hardware is needed to address a risk or threat identified by the donor's and recipient's risk assessments. We also would add definitions of hardware and risk assessment in proposed 1001.952(jj)(6).

7. Solicitation of Comments

The goal of the proposed safe harbor is to help improve the cybersecurity posture of the healthcare industry by removing a real or perceived barrier. To achieve this goal, we must appropriately balance the risk of cybersecurity threats against risks associated with permitting parties to donate valuable technology and services. In doing so, we recognize that cyberattacks are ubiquitous, dynamic, potentially funded by nation-states or well-funded criminal enterprises, and can have consequences to beneficiary health, safety, and privacy that are difficult to mitigate. To help improve the cybersecurity hygiene of the healthcare industry without comprising program integrity, it is important that we strike the right balance.

We drafted the proposed safe harbor with this aim in mind, but we recognize that appropriately balancing these risks is a difficult task. We solicit comment on whether the proposed safe harbor establishes the right balance and if not, request comments that recommend specific changes to do so. Commenters should consider the safe harbor in its entirety, including the proposed conditions, optional deeming provision, alternate condition, and definitions when commenting on this issue. We are especially interested in comments from healthcare providers because they both bear the cybersecurity risks and likely have relevant compliance experience with other safe harbors.

To facilitate specific comments on this issue, we ask the following questions: Does the proposed condition at 1001.952(jj)(1) permit the donation of the right types of cybersecurity technology and services that could meaningfully improve the cybersecurity posture of the healthcare industry while also ensuring that the donated technology and services do not pose undue risk of improperly influencing referrals? If not, what other standard or limitation would be appropriate to strike the right balance between cybersecurity risks and program integrity risks? Does excluding hardware from the definition of ''technology'' further our aim of balancing cybersecurity risks with the program integrity risks? If not, what other conditions should we impose to limit the value of remuneration protected by the proposed safe harbor, so it does not improperly influence referrals? For example, should the safe harbor impose a monetary value limit on the total amount of donations that a donor can make to a recipient or should the safe harbor require the recipient to contribute to the costs of a donation once the value has exceeded certain monetary thresholds?

I. Electronic Health Records (1001.952(y))

On August 8, 2006, we published a final rule (the 2006 Final EHR Safe Harbor Rule) that, among other things, finalized a safe harbor (the EHR safe harbor) at 42 CFR 1001.952(y) protecting certain arrangements involving the donation of interoperable electronic health records software or information technology and training services. The EHR safe harbor was initially scheduled to sunset on December 31, 2013.

On December 27, 2013, we published a final rule (the 2013 Final EHR Safe Harbor Rule) modifying the EHR safe harbor by, among other things, extending the expiration date of the safe harbor to December 31, 2021; excluding laboratory companies from the types of entities that may donate electronic

health records items and services under the safe harbor; and updating the provision under which electronic health records software is deemed interoperable.

The present proposed rule sets forth certain proposed changes to the EHR safe harbor. CMS is proposing almost identical changes to the physician self-referral law electronic health records exception elsewhere in this issue of the **Federal Register**. We attempted to ensure as much consistency as possible between our proposed safe harbor changes and CMS's proposed exception changes, despite the differences in the respective underlying statutes. Because of the close nexus between this proposed rule and CMS's proposed rule, we may consider comments submitted in response to CMS's proposed rule and take additional actions when crafting our final rule.

1. Interoperability

The conditions at 1001.952(y)(2) and (y)(3) require donated items and services to be interoperable and prohibit the donor (or someone acting on the donor's behalf) from taking action to limit the interoperability of the donated item or service. We are proposing changes that impact 42 CFR 1001.952(y)(2) and (3) based on the 21st Century Cures Act (Cures Act) and the Office of the National Coordinator for Health Information Technology (ONC), HHS Notice of Proposed Rulemaking ''21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program'' (ONC NPRM) that proposes to implement key provisions in Title IV of the Cures Act.[63] Among other things, the ONC NPRM proposes conditions and maintenance of certification requirements for health information technology (health IT) developers under the ONC Health IT Certification Program (certification program) and reasonable and necessary activities that do not constitute information blocking for purposes of section 3022(a)(1) of the Public Health Service Act (PHSA). These proposed changes, if finalized, affect the EHR safe harbor conditions at 1001.952(y)(2), which is known as the ''deeming provision,'' and 1001.952(y)(3) related to interoperability and ''data lock-in.''

2. Deeming

The deeming provision provides certainty to parties seeking protection of the EHR safe harbor by providing an optional method of ensuring that donated items or services meet the interoperable condition in 1001.952(y)(2) by deeming software to be interoperable if it is certified under the certification program. In the 2013 Final EHR Safe Harbor Rule we modified the deeming provision to reflect developments in the certification program and track ONC's anticipated regulatory cycle. By relying on the certification program and related updates of criteria and standards, we stated that the deeming provision would meet ''our objective of ensuring that software is certified to the current required standard of interoperability when it is donated.''[64] We propose to retain this general construct for the updated safe harbor. However, we propose two textual clarifications to this provision. Current language specifies that the software is ''deemed to be interoperable if, on the date it is provided to the recipient, it has been certified by a certifying body . . . .'' We propose to modify this language to clarify that, on the date the software is provided, it ''is'' certified. In other words, the certification must be current as of the date of the donation, as opposed to the software having been certified at some point in the past but no longer maintaining certification on the date of the donation. We also propose to remove reference to ''editions'' of certification criteria to align with proposed changes to the certification program. We solicit comments on these clarifications.

As we describe in more detail below, however, we are updating the definition of ''interoperable.'' Although this revised definition would not require a textual change to this paragraph (y)(2), the revision would impact the deeming provision, and we solicit comments regarding this update.

3. Information Blocking

The current condition at 1001.952(y)(3) prohibits the donor (or any person on the donor's behalf) from taking any action to limit or restrict the use, compatibility, or interoperability of the items or services with other electronic prescribing or electronic health records systems (including, but not limited to, health information technology applications, products, or services). As explained in the 2006 Final EHR Safe Harbor Rule and reaffirmed in the 2013 Final EHR Safe Harbor Rule, 1001.952(y)(3) has been designed to: (i) Prevent the misuse of the safe harbor that results in data and referral lock-in and (ii) encourage the free exchange of data (in accordance with protections for privacy).[65] Since that time, significant legislative, regulatory, policy, and other Federal Government action defined this problem further (now commonly referred to as ''information blocking'') and established penalties for certain types of individuals and entities that engage in information blocking. Most notably, the 21st Century Cures Act added section 3022 of the PHSA, known as ''the information blocking provision,'' which defines conduct by healthcare providers, health IT developers of certified health IT, exchanges, and networks that constitutes information blocking. Section 3022(a)(1) of the PHSA defines ''information blocking'' in broad terms, while section 3022(a)(3) authorizes and charges the Secretary to identify reasonable and necessary activities that do not constitute information blocking. The ONC NPRM would implement the statutory definition of ''information blocking,'' define certain terms related to the statutory definition of ''information blocking,'' and proposes seven exceptions to the information blocking definition.[66]

We propose modifications to 1001.952(y)(3) to recognize these significant updates since the 2013 Final EHR Safe Harbor Rule. Specifically, we propose aligning the condition at 1001.952(y)(3) with the proposed information blocking definition and related exceptions in 45 CFR part 171. We note that the EHR safe harbor conditions, while not using the term ''information blocking,'' already include concepts similar to those found in the 21st Century Cures Act's prohibition on information blocking. For example, we were concerned about donors (or those on the donor's behalf) taking steps to limit the interoperability of donated software to lock in or steer referrals, which is prohibited by the anti-kickback statute.[67] These proposed modifications are not intended to change the purpose of this condition, but instead further our longstanding goal of preventing abusive arrangements that lead to information blocking and referral lock-in through updated understandings of those concepts established in the 21st Century Cures Act.[68]

[63] 84 FR 7424 (Mar. 4, 2019).

[64] 78 FR 79201, 79204 (Dec. 27, 2013).

[65] 78 FR 79213 (Dec. 27, 2013).

[66] 84 FR at 7602–05.

[67] *See Implementation of the 21st Century Cures Act: Achieving the Promise of Health Information Technology Before the S. Comm. On Health, Education, Labor, & Pensions,* 115th Cong. 1 (2017) (statement of James Cannatti, Senior Counselor for Health Information Technology HHS OIG).

[68] We recognize that the ONC NPRM is not a final rule and is subject to change. However, we base our proposal on both the statutory language and the language in ONC's proposed rule for purposes of soliciting public input on our proposals.

We note that health plans, which are protected donors under the EHR safe harbor, may not be subject to the information blocking provisions of the 21st Century Cures Act or the ONC NPRM. Nevertheless, health plans that seek the protection of this safe harbor do so voluntarily. We note that the definition of ''information blocking'' at PHSA section 3022(a)(1) applies a different knowledge standard to health IT developers of certified health IT, health information networks, and health information exchanges than it does to healthcare providers. A healthcare provider engages in a practice of information blocking if such a provider ''knows that such practice is unreasonable and is likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information.'' [69] The EHR safe harbor primarily applies to healthcare providers due to the limitations on the types of donors permitted under 1001.952(y)(1). Therefore, most donors under the EHR safe harbor would be subject to the information blocking knowledge standard at section 3022(a)(1)(B)(ii) of the PHSA. Rather than have different conditions for healthcare providers and health plans, we believe it is reasonable to have one condition that applies the same information blocking knowledge standard to all parties who voluntarily use the safe harbor to protect donations of EHR items and services. For purposes of donations under this safe harbor, we propose to apply the knowledge standard articulated in the PHSA at section 3022(a)(1)(B)(ii) as applicable to both providers and health plans, and we seek comments on this approach.

Additionally, the current condition at 1001.952(y)(3), as adopted in the 2006 Final EHR Safe Harbor Rule [70] was intended to prevent donors, including health plans, from donating EHR software and then engaging in practices of information blocking that would limit the interoperability of the donated items, notwithstanding that we did not use that exact terminology. As a result, we do not believe this proposed modification places any additional burden on health plans that voluntarily seek to protect donations. We solicit comments on aligning the condition at 1001.952(y)(3) with the proposed information blocking definition in 45 CFR part 171.

4. Cybersecurity

We propose to amend the safe harbor to clarify that certain cybersecurity software and services have always been protected under this safe harbor,[71] and to more broadly protect the donation of software and services related to cybersecurity. Currently, the safe harbor protects electronic health records software or information technology and training services necessary and used predominantly to create, maintain, transmit, or receive electronic health records. We propose to modify this language to include certain cybersecurity software and services that ''protect'' electronic health records.

In the 2006 Final EHR Safe Harbor Rule, we emphasized the requirement that software, information technology, and training services donated must be ''closely related to electronic health records'' and that the ''electronic health records functions must be predominant.'' We stated that ''[t]he core functionality of the technology must be the creation, maintenance, transmission, or receipt of individual patients' electronic health records,'' but, recognizing that the electronic health records software is commonly integrated with other features, we also stated that arrangements in which the software package included other functionality related to the care and treatment of individual patients would be protected. Under our proposal, the same criteria would apply to cybersecurity software and services: The predominant purpose of the software or service must be cybersecurity associated with the electronic health records.

We note that we also are proposing a new safe harbor specifically to protect donations of cybersecurity technology and related services. As proposed, the cybersecurity safe harbor is broader and includes fewer conditions than the EHR safe harbor. However, we are proposing to expand the EHR safe harbor to expressly include cybersecurity software and services so that it is clear that an entity donating electronic health records software and providing training and other related services may also donate related cybersecurity software and services to protect the electronic health records. For clarity, we also propose to incorporate a definition of ''cybersecurity'' in this safe harbor that mirrors the definition we propose in the stand-alone cybersecurity safe harbor. A party seeking safe harbor protection needs to comply with the requirements of only one safe harbor. We solicit comments on this approach. In particular, with the addition of a stand-alone cybersecurity safe harbor, we solicit comments on whether it necessary to modify the EHR safe harbor to expressly include cybersecurity.

5. The Sunset Provision

The EHR safe harbor originally was scheduled to sunset on December 31, 2013. In adopting this condition of the EHR safe harbor, we acknowledged in the 2006 Final EHR Safe Harbor Rule ''that the need for a safe harbor for donations of electronic health records technology should diminish substantially over time as the use of such technology becomes a standard and expected part of medical practice.''

In the 2013 notice of proposed rulemaking for an amendment to the EHR safe harbor (2013 Proposed Rule), we acknowledged that while electronic health record technology adoption had risen dramatically, use of such technology had not yet been universally adopted nation-wide. Because continued electronic health record technology adoption remained an important Departmental goal, we solicited comments regarding an extension of the safe harbor. In response to those comments, in the 2013 Final EHR Safe Harbor Rule we extended the sunset date of the safe harbor to December 31, 2021, a date that corresponds to the end of the electronic health record Medicaid incentives. We stated our continued belief that as progress on this goal is achieved, the need for a safe harbor for donations should continue to diminish over time. Since publication of the 2013 Final EHR Safe Harbor Rule, however, numerous commenters have urged us to extend or make permanent the safe harbor at 42 CFR 1001.952(y). Specifically, commenters have suggested this modification in response to OIG's annual Solicitation of New Safe Harbors and Special Fraud Alerts, and also in response to the OIG RFI and the CMS RFI.

While we acknowledge that widespread adoption of electronic health record technology, though not universal, largely has been achieved, we no longer believe that once this goal is achieved the need for a safe harbor for donations of such technology will diminish over time or completely disappear. New entrants into medical practice, coupled with aging EHR technology at existing practices and the emergence of new and better technology, necessitate the availability of this safe harbor to achieve the Department's policy objectives. Our experience indicates that the continued availability of the safe harbor plays a part in achieving the Department's goal

[69] PHSA § 3022(a)(1)(B)(ii).

[70] 71 FR 45136.

[71] For instance, a secure log-in or encrypted access mechanism included with an EHR system or EHR software suite would be cybersecurity features of the EHR that are protected under the existing EHR safe harbor.

of promoting electronic health records technology adoption by providing certainty with respect to the cost of electronic health records items and services for recipients, and by encouraging adoption by physicians who are new entrants into medical practice or have postponed adoption based on financial concerns regarding the ongoing costs of maintaining and supporting an electronic health records system. Ongoing protection of electronic health record items and services donations would further new Department priorities and policies by allowing donors and recipients to ensure new technology is adopted that, for example, may improve the interoperability of electronic health information.

We are proposing to eliminate the sunset provision at 42 CFR 1001.952(y)(13). As an alternative to this proposed elimination of the sunset provision, we are considering an extension of the sunset date for the final rule. We seek comment on whether we should select a later sunset date instead of making the safe harbor permanent, and if so, what that date should be.

6. Definitions

We are proposing to modify the definitions of ''interoperable'' and ''electronic health record.'' In the 2006 Final EHR Safe Harbor Rule, we finalized these definitions based on then-current terminology, the emerging standards for electronic health records, and other resources cited by commenters. The following proposed modifications to these definitions are largely based on terms and provisions in the Cures Act that update or supersede terminology we used in the 2006 Final EHR Safe Harbor Rule.

In the current note to paragraph (y) under 1001.952, ''electronic health record'' is defined as ''a repository of consumer health status information in computer processable form used for clinical diagnosis and treatment for a broad array of clinical conditions.'' We propose to modify the definition of ''electronic health record'' to mean: ''a repository of electronic health information that: (A) is transmitted by or maintained in electronic media; and (B) relates to the past, present, or future health or condition of an individual or the provision of healthcare to an individual.''

The proposed revision to the definition of ''electronic health record'' is not intended to substantively change the scope of protection. We are proposing these modifications to this definition to reflect the term ''electronic health information'' that is used throughout the Cures Act and that is central to the definition of ''interoperability'' at PHSA § 3000(9) and the information blocking provision at PHSA § 3022. Additionally, the ONC NPRM proposes a definition of ''electronic health information.'' [72] We have based the proposed modifications, in part, on ONC's proposed definition of ''electronic health information'' to reflect more modern terminology used to describe the type of information that is part of an electronic health record. We solicit comments on this updated definition.

In the note to paragraph (y) under 1001.952, the existing definition of ''interoperable'' means ''able to communicate and exchange data accurately, effectively, securely, and consistently with different information technology systems, software applications, and networks, in various settings, and exchange data such that the clinical or operational purpose and meaning of the data are preserved and unaltered.'' As explained in the 2006 Final EHR Safe Harbor Rule, this definition was based on 44 U.S.C. 3601(6) (pertaining to the management and promotion of electronic Government services) and several comments we received in response to the proposed rule that referenced emerging industry definitions and standards related to interoperability.[73]

We propose to update the definition of the term ''interoperable'' to align with the statutory definition of ''interoperability'' added by the Cures Act to Section 3000(9) of the PHSA and as proposed in the ONC NPRM. We propose modifications to match the statutory definition and the ONC NPRM definition of ''interoperability.'' Consistent with PHSA § 3000(9), we propose to define ''interoperable'' to mean able to: ''(i) securely exchange data with, and use data from other health information technology without special effort on the part of the user; (ii) allow for complete access, exchange, and use of all electronically accessible health information for authorized use under applicable State or Federal law; and (iii) does not constitute information blocking as defined in 45 CFR part 171.'' The only difference between the statutory definition of ''interoperability'' and the definition in the ONC NPRM is the reference to the regulatory definition of ''information blocking'' in 45 CFR part 171, which we propose to adopt. We will work closely with ONC as they finalize the information blocking rule to ensure definitions align across the EHR safe harbor and the final information blocking regulations.

We believe the statutory definition of ''interoperability'' includes similar concepts to the existing definition of ''interoperable'' in the note to paragraph (y) (*e.g.,* the ability to securely exchange data across different systems or technology). Two new concepts in the statutory definition are included in the proposed modification: (i) Interoperable means the ability to exchange electronic health information ''without special effort on the part of the user'' and (ii) interoperable expressly does not mean information blocking.[74] As a practical matter, we believe these two concepts are not substantively different from the existing definition and only reflect an updated understanding of interoperability and related terminology. We solicit comments on the proposed definition that would align the definition of ''interoperable'' with the statutory definition of ''interoperability.''

We also are considering linking the definition of ''interoperable'' with the proposed definition of ''interoperability'' at 45 CFR 170.102 in the ONC NPRM [75] if that proposed definition is finalized. We note that ONC's proposed regulatory definition of ''interoperability'' matches the statutory definition. However, linking the ONC regulatory definition of ''interoperability'' may allow for additional, future updates to be adopted by reference in the EHR safe harbor. We solicit comments on this proposal.

In the alternative, we are considering revising our regulations to eliminate the term ''interoperable'' and instead incorporate the term ''interoperability'' and define this term by reference to section 3000(9) of the PHSA and proposed in 45 CFR part 170. Under this alternative proposal, we would revise § 1001.952(y)(2) to require donations of software to meet interoperability standards established under Title XXX of the PHSA and its implementing regulations. Software would be deemed to meet interoperability standards if, on the date it is provided to the recipient, it is certified by a certifying body authorized by ONC to health information technology certification criteria identified in 45 CFR part 170. We seek comment regarding whether using terminology identical to the PHSA and proposed ONC regulations would facilitate compliance with the requirements of the EHR safe harbor and reduce any regulatory burden resulting from the differences in the agencies'

[72] 84 FR 7424, 7513 (Mar. 4, 2019).

[73] 71 FR 45110, 45126 (August 8, 2006).

[74] PHSA § 3000(9); 42 U.S.C. 300jj(9).

[75] 84 FR 7424, 7589 (Mar. 4, 2019).

different terminology related to the singular concept of interoperability.

Finally, for ease of reference, we propose to amend the safe harbor by moving the undesignated definitions set forth in the note to paragraph (y) to a new paragraph (y)(14).

7. Additional Proposals and Considerations

a. 15-Percent Recipient Contribution

In the 2006 Final EHR Safe Harbor Rule, we agreed with a number of commenters who suggested that cost sharing is an appropriate method to address some of the fraud and abuse risks inherent in unlimited donations of technology. Accordingly, we incorporated a requirement into 42 CFR 1001.952(y) that the recipient pays 15 percent of the donor's cost of the technology. We noted in the 2006 Final EHR Safe Harbor Rule that ''the 15 percent cost sharing requirement is high enough to encourage prudent and robust electronic health records arrangements, without imposing a prohibitive financial burden on recipients.'' Moreover, we stated, ''this approach requires recipients to contribute toward the benefits they may experience from the adoption of interoperable electronic health records (for example, a decrease in practice expenses or access to incentive payments related to the adoption of health information technology).''

We are aware that the 15-percent contribution requirement has proven burdensome to some recipients and may act as a barrier to adoption of electronic health records technology. We understand that this burden may be particularly acute for small and rural practices that cannot afford the contribution. We also recognize that applying the 15-percent contribution requirement to upgrades and updates to electronic health record technology is restrictive and cumbersome and similarly may act as a barrier.

We are not proposing specific amendments to the 15-percent contribution requirement at this time, and we are considering retaining this requirement without change in the final rule. However, we also are considering and solicit comments on the three alternatives to the existing requirement as outlined below. We solicit comment on each of the alternatives as separate proposed modifications to the contribution requirement.

First, for purposes of the final rule, we are considering eliminating or reducing the percentage contribution required for small or rural practices. We specifically seek comment on whether and how we should eliminate or reduce the 15-percent contribution requirement as applied to a specific subset of recipients such as small or rural practices. In particular, we solicit comments on how ''small or rural practices'' should be defined. For example, we solicit comments on whether ''rural practices'' should be defined as those located in rural areas, as defined in the safe harbor for local transportation at 42 CFR 1001.952(bb). We also solicit comments on whether ''small practices'' should be defined as those in medically underserved areas, as designated by the Secretary under section 330(b)(3) of the Public Health Service Act, or defined similarly to a ''small provider of services or small supplier'' as set forth in the requirements related to the electronic submission of Medicare claims at 42 CFR 424.32. We also are considering for the final rule and solicit comments on whether other subsets of potential recipients, for example critical access hospitals, should be exempted from the 15-percent contribution because it would impose a significant financial burden on the recipient.

Second, and in the alternative, we are considering reducing or eliminating the 15-percent contribution requirement in this safe harbor for all recipients. We solicit comments regarding the impact this might have on the use and adoption of electronic health records technology, and any attendant risks of fraud and abuse. We are interested in specific examples of the prohibitive costs associated with the 15-percent contribution requirement, both for the initial donation of electronic health records technology, and subsequent upgrades and updates to the technology.

Finally, if we retain a 15-percent contribution requirement or reduce that contribution requirement for some or all recipients, we are considering modifying or eliminating the contribution requirement for updates to previously donated EHR software or technology. We solicit comments on this approach as well as what such a modification should entail. For example, we are considering requiring a contribution for the initial investment only, as well as any ''new'' modules, but not requiring a contribution for any update of the software already purchased. We solicit comments on these alternatives, or another similar alternative that would still involve some contribution but could reduce the uncertainty and administrative burden associated with assessing a contribution for each update.

b. Replacement Technology

In the 2013 Final EHR Safe Harbor Rule, we highlighted one commenter's assertion that ''the prohibition on donating equivalent technology currently included in the safe harbor locks physician practices into a vendor, even if they are dissatisfied with the technology, because the recipient must choose between paying the full amount for a new system and continuing to pay 15 percent of the cost of the substandard system.'' The same commenter asserted that ''the cost difference between these two options is too high and effectively locks physician practices into electronic health record technology vendors.'' In the 2013 Final EHR Safe Harbor Rule, we responded that ''we continue to believe that items and services are not ''necessary'' if the recipient already possesses the equivalent items or services. We noted that providing equivalent items and services confers independent value on the recipient and noted our expectation that ''physicians would not select or continue to use a substandard system if it posed a threat to patient safety.''

We appreciate that advancements in electronic health records technology are continuous, rapid, and sometimes prohibitively expensive for the purchaser of such technology, and that in some situations, replacement technology is appropriate. We are proposing to delete the condition that prohibits the donation of equivalent items or services at current 1001.952(y)(7) to allow donations of replacement electronic health records technology. We specifically seek comment as to whether deleting this condition is necessary, and in what situations replacement technology would be appropriate. We further solicit comment as to how we might safeguard against situations where donors inappropriately offer, or recipients inappropriately solicit, unnecessary technology instead of upgrading their existing technology for appropriate reasons.

c. Protected Donors

We are considering expanding the group of entities that may be protected donors under the EHR safe harbor, for purposes of the final rule. As background, in the preamble to the 2006 Final EHR Safe Harbor Rule for the EHR safe harbor, we were mindful that broad safe harbor protection would significantly further the important public policy goal of promoting electronic health records, and thus concluded that the safe harbor should protect any donor that is an individual

or entity that provides patients with healthcare items or services covered by a Federal health care program and submits claims or requests for payment for those items or services (directly or pursuant to reassignment) to Medicare, Medicaid, or other Federal health care programs (and otherwise meets the safe harbor conditions).[76] Notwithstanding this conclusion, we indicated that ''[w]e remain concerned about the potential for abuse by laboratories, durable medical equipment suppliers, and others'' and noted that ''[w]e intend to monitor the situation. If abuses occur, we may revisit our determination.'' [77]

In the 2013 Final EHR Safe Harbor Rule, we finalized a proposal to remove laboratory companies from the scope of protected donors under the safe harbor to address, among other things, potential abuse identified by some of the commenters involving potential recipients conditioning referrals for laboratory services on the receipt of, or redirecting referrals for laboratory services following, donations from laboratory companies, and general misuse of donations by donors to secure referrals.

We remain concerned about the potential for fraud and abuse by certain donors that we articulated in the 2006 Final EHR Safe Harbor Rule and the 2013 Final EHR Safe Harbor Rule. However, in light of the Department's continued objective to advance the adoption of electronic health records technology, particularly as related to the Regulatory Sprint, and in response to certain comments received to the OIG RFI, we are considering expanding the scope of protected donors by eliminating or revising the requirement in 42 CFR 1001.952(y)(1)(i) that protected donors be limited to those who ''submit[ ] claims or requests for payment, either directly or through reassignment, to the Federal health care program.'' If we were to revise rather than eliminate the restriction, we are considering broadening it in the final rule to entities with indirect responsibility for patient care. This expansion would protect as donors, for example, entities like health systems or accountable care organizations that neither are health plans nor submit claims for payment. Certain commenters to the OIG RFI also recommended permitting any risk-bearing entity that participates in an Advanced APM entity under the Medicare Quality Payment Program (QPP) to be a donor. We are interested in understanding other types of entities and potential donors who would avail themselves of a broadening of the protected donors. In addition, we specifically solicit comments regarding the removal of this restriction and whether and how removal would impact the widespread adoption of electronic health records technology as well as comments regarding any attendant risks of fraud and abuse.

J. Personal Services and Management Contracts and Outcomes-Based Payment Arrangements (1001.952(d))

We propose to modify the existing safe harbor for personal services and management contracts at 42 CFR 1001.952(d) to: (i) Substitute, for the requirement that aggregate compensation under these agreements be set in advance, a requirement that the methodology for determining compensation be set in advance; (ii) eliminate the requirement that, if an agreement provides for the services of an agent on a periodic, sporadic or part-time basis, the contract must specify the schedule, length, and the exact charge for such intervals; (iii) create a new paragraph (d)(2) to protect certain outcomes-based payments, as defined below; and (iv) to make certain technical changes. These proposals seek to modernize the safe harbor and respond to comments in response to the RFI that existing safe harbor requirements present barriers to certain care coordination and value-based arrangements.

1. Elimination of Requirement To Set Aggregate Compensation in Advance

The existing safe harbor for personal services and management contracts requires that such agreements be for a term of at least 1 year, and that the aggregate compensation be set in advance. In addition, the compensation must be consistent with fair market value in arm's-length transactions. Consistent with our existing safe harbor, compensation under personal services and management contracts may not be determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made in whole or in part under Medicare, Medicaid or other Federal health care programs. Also, the aggregate services performed under the agreement must not exceed those which are reasonably necessary to accomplish the commercially reasonable business purpose of the services.[78] The purpose of these requirements is to limit the opportunity to provide financial incentives in exchange for referrals.

To provide the healthcare industry enhanced flexibility to undertake innovative arrangements, we are proposing to revise the safe harbor to remove the requirement at 42 CFR 1001.952(d)(5) that the ''aggregate'' amount of compensation paid over the term of the agreement must be set forth in advance. To mitigate the risk of parties to the agreement periodically adjusting the compensation to reward referrals or unnecessary utilization, the proposed modification to the safe harbor would require the parties to an arrangement to determine the arrangement's compensation *methodology* in advance of the initial payment under the arrangement. In addition, under (d)(1) of our proposal, the safe harbor would continue to require that the compensation reflect fair market value, be commercially reasonable, and not take into account the volume or value of referrals or business otherwise generated between the parties.

We anticipate this proposal would more closely align this safe harbor with the personal service arrangements exception to the physician self-referral law, 42 CFR 411.357(d).

2. Elimination of Requirement To Specify Schedule of Part-Time Arrangements

We propose to eliminate the requirements set forth at 42 CFR 1001.952(d)(3) relating to agreements for services provided on a periodic, sporadic, or part-time basis. This paragraph of the safe harbor requires contracts that provide for services on such a basis to specify ''exactly the schedule of such intervals, their precise length, and the exact charge for such intervals.'' Removing this requirement would afford parties additional flexibility in designing *bona fide* business arrangements, including care coordination and quality-based arrangements, where parties provide legitimate services as needed.

The existing safe harbor requires part-time contractual arrangements between healthcare providers to specify their timing or duration because of our concern that such arrangements are especially vulnerable to abuse. Specifically, part-time arrangements could be readily modified based on changing referral patterns between the parties. However, we believe that existing safeguards under (d)(1) of our proposal would provide sufficient safeguards against the manipulation of these arrangements to reward referrals, namely: The term of the arrangement

[76] 71 FR 45127.

[77] *Id.* at 45128.

[78] 42 CFR 1001.952(d)(4), (5) and (7).

must be not less than 1 year; the compensation terms must reflect fair market value, be commercially reasonable, and not take into account the volume or value of any referrals or business otherwise generated between the parties; and the methodology for determining compensation must be set in advance.

As with our first proposal, we anticipate this proposal would more closely align this safe harbor with the personal service arrangements exception to the physician self-referral law, 42 CFR 411.357(d).

3. Proposal To Protect Outcomes-Based Payments

We propose to protect outcomes-based payment arrangements in certain circumstances under proposed new paragraph (d)(2) and (d)(3). Our proposal is in response to the evolution of new payment models, such as shared savings, shared losses, episodic payments, gainsharing, and pay-for-performance, and recognizes that such arrangements may facilitate care coordination, encourage provider engagement across care settings, and promote the shift to value.

a. Outcomes-Based Payments

We propose to define ''outcomes-based payment'' as payments from a principal to an agent that: (i) Reward the agent for improving (or maintaining improvement in) patient or population health by achieving one or more outcome measures that effectively and efficiently coordinate care across care settings; or (ii) achieve one or more outcome measures that appropriately reduce payor costs while improving, or maintaining the improved, quality of care for patients.

We further propose that such payments would exclude any payments made, directly or indirectly, by a pharmaceutical manufacturer; a manufacturer, distributor, or supplier of DMEPOS; or a laboratory. Such payments would also exclude any payment that relates solely to the achievement of internal cost savings for the principal. We solicit comments on potential alternative definitions of the term ''outcomes-based payment'' that would be consistent with the goals described in the preceding paragraphs of this preamble section. For example, we are considering for the final rule defining the term by reference to specific types of payments, such as those described as examples of outcomes-based payments below.

Examples of outcomes-based payment arrangements could include shared savings payments, shared losses payments, gainsharing payments, pay-for-performance payments, or episodic or bundled payments. We are considering and solicit comments on whether, if we take this approach, we should further define specific types of payment arrangements that would qualify for this safe harbor in the final rule. To the extent we further define such arrangements, we are considering basing potential definitions on arrangements defined in various Innovation Center models and the Medicare Shared Savings Program. Such terms might include:

- ''Shared savings payment'' could be defined to mean a payment from a payor to a principal or the downstream payment by the principal to the agent of a share of payor savings realized from the agent's activities for a specified patient population. Shared savings payments encourage the use of the lowest cost service for the patient population to achieve certain desired health outcomes.
- ''Shared losses payment'' could be defined to mean a payment from a principal to a payor or from a downstream agent to a principal to repay the payor for a portion of the payor's losses incurred with respect to a specific patient population under a shared savings arrangement when a principal's expenditures for the patient population for the applicable performance period exceed specific performance benchmarks.
- ''Gainsharing payment'' could be defined to mean a payment from a principal to an agent to incentivize the agent to appropriately reduce healthcare costs (other than solely the principal's internal costs) for a specified patient population while achieving certain outcome measures in accordance with a principal's arrangement with a payor.
- ''Episodic or bundled payment'' could be defined to mean a payment from a payor to a principal or from a principal to a downstream agent for an episode of care across care settings for a specified patient population. This could include a retrospective bundled payment arrangement where actual healthcare expenditures of the payor and principal for the patient population are reconciled against a target price for an episode of care and a portion of such payment to the principal may be made to the agent or a prospectively determined bundled payment from the payor to the principal or a portion of such payment to the principal made to the agent that encompasses all healthcare services furnished by the principal and agent for the patient population during the episode of care.
- ''Pay-for-performance arrangement'' could be defined to mean a payment from a principal to an agent (or a payor to a principal) for the achievement of a legitimate cost, quality, or operational performance metric (*e.g.,* bonus payment) on behalf of the principal for a specified patient population.

We anticipate such outcomes-based payment arrangements would largely mirror, in concept, similar arrangements used in various Innovation Center models and the Medicare Shared Savings Program and would, more specifically, encompass examples like the following: (i) An ACO makes a ''shared savings'' payment to its member physicians, with such payments representing a percentage of payor savings generated by the ACO as a result of its members' efforts to reduce total patient care costs and improve quality; (ii) where an ACO incurs financial loss and is obligated to pay money to its payor, a hospital makes ''shared losses'' payments to the ACO, representing an agreed upon percentage of the ACO's loss; and (iii) a hospital and group of physicians and post-acute care providers agree collectively to be paid by a payor for an episode of care (*e.g.,* inpatient stay and 90 days post-discharge) and share among themselves the savings or losses generated against a benchmark. In some cases involving reconciliation, the hospital might be responsible for sharing any savings among its partners; in others, the hospital might be responsible for paying its partners for the services they furnish the patients under the episode.

As noted previously, our proposed definition of ''outcomes-based payment'' excludes arrangements that relate solely to achievement of internal cost savings for the principal. For example, outcomes-based payment arrangements would not include arrangements that involve sharing in financial risk or gain only as it relates to the prospective payment systems for acute inpatient hospitals, home health agencies, hospice, outpatient hospitals, inpatient psychiatric facilities, inpatient rehabilitation facilities, long-term care hospitals, or SNFs. Although arrangements reimbursed by Federal health care programs under the prospective payment systems may create internal cost savings for a provider, the savings under the arrangement would not accrue to the payor.

Thus, and for example, this safe harbor would not protect an outcomes-based payment arrangement between a hospital and physician group, where the parties share financial risk or gain only with respect to items or services

reimbursed to the hospital under the Medicare prospective payment system for acute inpatient hospitals. However, an outcomes-based payment arrangement that involves a hospital and physician group sharing financial risk or gain realized *across* care settings would be protected (*e.g.,* for a patient's inpatient stay and the 60-day post-discharge period), provided all safe harbor requirements were met.

b. Entities Not Included

Based on our enforcement and oversight experience and as explained with respect to a similar exclusion in the definition of VBE participant in this proposed rule, we are proposing to exclude pharmaceutical manufacturers; manufacturers, distributors, and suppliers of DMEPOS; and laboratories from the proposed safe harbor for outcomes-based payments. As stated previously, we are concerned that these types of entities, which are heavily dependent upon practitioner prescriptions and referrals, might use outcomes-based payments primarily to market their products to providers and patients.

As with the proposed definition of a VBE participant, we are also considering for the final safe harbor at 1001.952(d)(2) excluding pharmacies (including compounding pharmacies), PBMs, wholesalers, and distributors. We solicit comments about these proposed exclusions, as well as illustrative examples of beneficial or problematic outcomes-based payment arrangements that might be excluded or included if we finalize some or all of these exclusions.

We also are considering whether to more specifically target the final safe harbor on outcomes-based payment arrangements that further value-based care or care coordination by limiting protection for outcomes-based payment arrangements to VBE participants, as that term is defined in (ee)(12)(vi) of this proposed rule.

c. Collaboration and Outcomes-Based Payments

As proposed, under the safe harbor conditions, all outcomes-based payments must be made between or among parties that are collaborating to measurably improve quality of patient care appropriately and materially reduce costs while maintaining quality, or both. Moreover, if specific services are to be performed, the agreement must specify all of the services the parties perform (or refrain from performing) to qualify for the outcomes-based payments. We are mindful that with some value-based payment arrangements, there may not be a direct correlation between the level or value of services provided by a particular recipient of payments and that party's share of savings or outcomes-based payments (*e.g.,* shared savings payments may be distributed on a basis unrelated to actual services provided). While the two requirements described do not expressly require that the outcomes-based payment arrangement include the provision of services (merely that the parties collaborate, and to the extent the parties' arrangement includes services, that they be documented), we anticipate that many arrangements would include a service component.

d. Safe Harbor Conditions

Our proposal for outcomes-based payment arrangements includes safe harbor conditions, some of which mirror program integrity safeguards set forth in the existing personal services and management contracts safe harbor and some of which are new safeguards specific to outcomes-based payment arrangements. As detailed below, our proposed safe harbor conditions are based on our experience with these types of arrangements through the advisory opinion process and the development of waivers for CMS models.

e. Goal of the Outcomes-Based Payment Arrangement

As stated above, all outcomes-based payments must be made between or among parties that are collaborating to measurably improve quality of patient care (or maintain improvement); appropriately and materially reduce costs to, or growth in expenditures of, payors while improving or maintaining the improved quality of care; or both. We propose to limit safe harbor protection to outcomes-based payment arrangements that foster these two goals because we believe that such arrangements may best facilitate care coordination, encourage provider engagement across care settings, and promote the shift to value.

f. Outcome Measures

We propose to require the parties to an arrangement to establish one or more specific evidence-based, valid outcome measures that the agent must satisfy to receive the outcomes-based monetary remuneration. This requirement largely mirrors the outcome-measure requirement in the proposed care coordination arrangements safe harbor at paragraph (ee), and we refer readers to the discussion of this requirement in the preamble above. That being said, we note certain key differences, such as: This proposed safe harbor requires satisfaction of an outcome measure to receive an outcomes-based payment, whereas the care coordination arrangements safe harbor requires monitoring and assessment related to such outcome measures; and the achievement of outcomes measures is not a prerequisite to the provision or use of in-kind remuneration under the proposed safe harbor at paragraph (ee). Such differences are deliberate and due to the variations in type and scope of potential remuneration that could be exchanged under the respective safe harbors.

For the proposed outcomes-based payment arrangements amendments to the safe harbor, outcome measures must relate to improving quality of patient care; appropriately and materially reducing costs to, or growth in expenditures of, payors while improving, or maintaining the improved quality of care for patients; or both. As an additional safeguard, parties must select outcome measures based upon clinical evidence or credible medical support.

Any outcome measures established pursuant to the parties' arrangement must be measurable and valid, and such measures must promote improved quality or efficiencies in the delivery of care, or appropriate cost reduction. Measures that simply seek to reward the status quo would not meet this requirement. In some circumstances, we acknowledge that payment for the maintenance of high quality may be low risk (*e.g.,* where an established ACO that has made demonstrable quality improvements over the course of several years seeks to reward its members to maintain such improvements). We solicit comments on whether, and if so how, we should protect such arrangements in the final rule without protecting arrangements that may be disguised payments for referrals. We are concerned that arrangements that reward the status quo are more likely to be mere payments for referrals.

Because we believe the provision of monetary remuneration presents a higher risk of fraud and abuse than the provision of in-kind remuneration, we are considering for the final rule, and solicit comments on, whether to impose a different, potentially stricter standard for outcome measures in this proposed safe harbor than in the proposed care coordination arrangements safe harbor at paragraph (ee). To mitigate this risk, we propose to require the parties to regularly monitor and assess the agent's performance on each outcome measure under the agreement. This condition is similar to the assessment and

monitoring requirements in the care coordination arrangements safe harbor at paragraph (ee). For example, regularly monitoring and assessing the agent's performance could include: (i) Determining whether the arrangement has measurably improved quality of patient care, (ii) evaluating any deficiencies in the delivery of quality care, and (iii) measuring the agent's satisfaction of the specific, evidence-based, valid outcome measure(s) in the outcomes-based arrangement.

We recognize that outcomes-based payment arrangements may vary in structure and strive to provide flexibility for parties to design arrangements to achieve appropriate quality of patient care as well as appropriate efficiency and cost savings goals. However, we are proposing to include an express requirement that parties rebase the benchmark or outcome measure for outcomes-based payments periodically in outcomes-based payment arrangements where rebasing is feasible under paragraph (d)(2)(vii)(B). By ''rebasing'' we mean resetting the benchmark used to determine whether payments will be made to take into account improvements already achieved. We anticipate periodic ''rebasing'' will prevent parties from inappropriately carrying over savings from previous performance periods or from receiving payments that do not reflect legitimate achievement of outcomes.

This proposed requirement is intended to address a concern that ''evergreen'' outcomes-based payment arrangements, in which outcome measures are not properly monitored or assessed, could be used as a vehicle to reward referrals well after the desired provider behavior change or savings benchmark has been met. Such perpetual arrangements might also fail to meet the proposed requirement that the measures be evidence-based. We are considering for the final rule, and solicit comments on, whether a specific timeframe within a specified performance period under the arrangement (*e.g.,* 3 years) or a shorter (*e.g.,* 1-year) or longer (*e.g.,* 5-year) timeframe is appropriate and realistic for requiring parties to rebase the benchmarks for outcomes-based payments. We solicit comments on the definition of ''rebase'' and when and how frequently rebasing would be necessary and appropriate to ensure that outcomes-based payments are based on valid, measurable outcomes, reducing the risk that the payments would be mere payments for referrals.

g. Methodology

To increase transparency of outcomes-based payment arrangements, we propose that the methodology for determining the aggregate compensation (including any outcomes-based payments) paid between or among the parties over the term of the agreement is: Set in advance; commercially reasonable; consistent with fair market value; and not determined in a manner that directly takes into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made in whole or in part by a Federal health care program. We view these conditions as essential safeguards to ensuring any outcomes-based payment arrangement is not a vehicle to reward referrals and generate revenue but rather reflects a deliberate, collaborative effort by the parties to the arrangement to realize improved outcomes, cost savings to payors, or both.

Because our proposed set-in-advance and commercially reasonable requirements are consistent with our existing personal services arrangement and management contracts safe harbor (as proposed to be amended with respect to the set-in-advance requirement), we do not address these requirements here in further detail. We discuss our proposed fair market value and volume or value conditions below.

i. Fair Market Value

We propose that the methodology for determining the aggregate compensation (including any outcomes-based payments) paid between or among the parties over the term of the agreement be consistent with fair market value. We acknowledge our proposed aggregate fair market value requirement may pose challenges to the extent there are not industry standards yet developed to determine fair market value for some outcomes-based payment arrangements in the value-based care arena and because we understand that some of the outcomes-based payment arrangements we propose to protect do not necessarily correlate payments with actual services performed (and in some cases, reward not performing services).

Nonetheless, we anticipate the industry will evolve and adapt to assess fair market value for value-driven outcomes-based payment arrangements, even where the provision of traditional services may be a less prominent component. We solicit comments on this approach. We are considering for the final rule whether we should take a different approach (including whether to value outcomes-based payments separately from other compensation or whether to substitute the fair market value requirement with a different safeguard that would help ensure that payments are for legitimate participation in arrangements that drive value-based care and are not merely disguised payments for referrals).

ii. Volume or Value of Referrals

We propose to require that the compensation methodology for determining the outcomes-based payment not be determined in a manner that directly takes into account the volume or value of referrals or other business generated between the parties. We recognize that to incentivize care coordination and appropriate behavioral changes through outcomes-based payments, parties may need to establish payment methodologies that at least indirectly take into account the volume or value of referrals or other business generated between the parties. We believe it should be possible to structure payments so that they do not directly take into account the volume or value of referrals of other business.

h. Writing and Monitoring

We propose that the outcomes-based payment be made between or among parties that are collaborating, pursuant to a written agreement signed by the parties in advance of, or contemporaneous with, the commencement of the terms of the outcomes-based payment arrangement. We further propose that the written agreement specify all of the services the parties would perform for the term of the agreement. As detailed in the above section, while this does not mandate that parties to an outcomes-based payment arrangement include services, if services are furnished pursuant to the parties' arrangement, such services must be documented in writing.

We further propose to require that the written agreement include the outcome measure(s), the evidence-based data or information upon which the parties relied to select the outcome measure(s), and the schedule for the parties to regularly monitor and assess the outcome measure(s). In addition to the writing requirements set forth in (d)(2)(viii), parties may consider documenting and retaining such documentation necessary to demonstrate compliance with each prong of this safe harbor. For example, the parties may document payments made pursuant to the outcomes-based payment arrangement and data showing the agent's achievement of the outcome measure(s).

i. Impact on Patient Quality of Care

Properly structured and operated, outcomes-based payments hold the potential to improve the delivery of care; however, when improperly structured and operated, they hold the potential to incentivize behavior harmful to patients, such as stinting on care (underutilization), cherry picking lucrative or adherent patients, or lemon dropping costly or noncompliant patients.[79] Accordingly, we are proposing to require that the agreement neither limits any party's ability to make medically appropriate decisions for patients, nor induces the reduction of medically necessary services.

j. Additional Safeguards

We propose that the term of the agreement is not less than 1 year and that the services performed under the agreement do not involve the counseling or promotion of a business arrangement or other activity that violates any State or Federal law. These conditions are identical to those included in the personal services and management contracts safe harbor.

k. Technical Modifications

Due to the proposed additions of paragraphs (d)(2) and (d)(3), setting forth provisions on outcomes-based payments and definitions, we propose to move the existing personal services and management contracts provisions, as proposed to be amended in this rulemaking, to a new paragraph (d)(1).

K. Warranties (1001.952(g))

In an effort to update the existing safe harbor for warranties at 42 CFR 1001.952(g) and to promote higher value items covered by warranties, we propose to modify the safe harbor to: (i) Protect warranties for one or more items and related services upon certain conditions; (ii) exclude beneficiaries from the reporting requirements applicable to buyers; and (iii) define ''warranty'' directly and not by reference to 15 U.S.C. 2301(6). We also propose to make a technical correction to paragraph (3)(i) to change the text from ''paragraphs (a)(1) and (a)(2) of this section'' to ''paragraphs (g)(1) and (g)(2) of this section.'' For ease of reference, we propose to amend the safe harbor by moving the undesignated definition at the end of the safe harbor to a new paragraph (g)(7).

1. Bundled Warranties

The warranties safe harbor protects remuneration consisting of ''any payment or exchange of anything of value under a warranty provided by a manufacturer or supplier of an item to the buyer (such as a health care provider or beneficiary) of the item,'' as long as the buyer and seller comply with the safe harbor's requirements.[80] We confirmed in Advisory Opinion No. 18–10 that this safe harbor applies only to warranties for a single item and not to bundled items.[81] We received comments in response to the OIG RFI requesting revisions to the warranties safe harbor to protect warranty arrangements that pertain to bundled items and services. Commenters suggested that such revisions would promote beneficial and innovative arrangements. Based on these comments, other input OIG has received, and our own consideration of the potential benefits of expanding the warranties safe harbor to foster value, we propose to revise the safe harbor to protect bundled warranties for one or more items and related services, when certain conditions are met. This modification would allow manufacturers and suppliers to warrant that a bundle of items or one or more items in combination with related services, such as product support services, will meet a specified level of performance under a warranty agreement.

We believe this proposed modification could promote beneficial arrangements between sellers and buyers by allowing them to enter into warranty arrangements conditioned on the collective value of the warranted items and related services. We also believe this proposed modification could enhance the use and utility of warranted items by protecting warranties that encompass services, such as support and educational services. For example, this proposed modification would protect arrangements such as the one at issue in Advisory Opinion No. 01–08, where the requestor operated a warranty program covering wound care products and certain related support services, such as access to a wound specialist and an online wound documentation system, that the requestor made available to buyers of its products.[82]

a. Inclusion of Services in Bundled Warranties

We are proposing to protect warranty arrangements that apply to one or more items and services (provided the warranty covers at least one item). This modification would allow manufacturers and suppliers to warrant that certain services, in combination with one or more items, will result in a specified level of performance.[83] We are mindful that the provision of certain warranted services, such as medication adherence services by manufacturers and suppliers, could increase the risk of patient harm and inappropriate utilization because manufacturers and many suppliers do not necessarily have direct patient care responsibilities and thus may not have the same patient safety considerations that physicians and providers with direct patient care responsibilities have. Using medication adherence services offered by drug manufacturers as an example, we are concerned that manufacturers may promote patients' adherence to

[79] We note that section 1128A(b)(1) of the Act (the ''Gainsharing CMP'') prohibits a hospital from knowingly making payments, directly or indirectly, to a physician to induce the physician to reduce or limit medically necessary services to Medicare or Medicaid beneficiaries who are under the physician's direct care. Hospitals that make (and physicians who receive) payments prohibited by this provision are liable for civil money penalties for each patient for which the prohibited payment was made. However, our proposed condition is in recognition that other parties, besides hospitals and physicians, may seek protection under this safe harbor.

[80] 42 CFR 1001.952(g).

[81] Adv. Op. No. 18–10, *available at https://www.oig.hhs.gov/fraud/docs/advisoryopinions/2018/AdvOpn18-10.pdf.*

[82] Adv. Op. No. 01–08, *available at https://www.oig.hhs.gov/fraud/docs/advisoryopinions/2001/ao01-08.pdf.* OIG acknowledged that the arrangement at issue in advisory opinion number 01–08 implicated the anti-kickback statute and did not fit in the warranties safe harbor but approved the arrangement on the basis that it presented a sufficiently low risk of fraud and abuse under the anti-kickback statute.

[83] We clarify that our proposed changes would not protect free or reduced-price items or services that sellers provide either as part of a bundled warranty agreement or ancillary to a warranty agreement. Whether a seller's provision of free or reduced-price items or services in connection with a warranty arrangement would implicate and potentially violate the anti-kickback statute would depend on whether other safe harbor protection exists for the arrangement, and if not, whether those items or services have independent value to a buyer other than for purposes of determining whether the terms of a warranty have been met. For example, laboratory testing required for patient care may be necessary to determine if a warranted outcome was achieved, but the laboratory test would have independent value to the buyer. A seller's provision of laboratory testing for free or at a reduced charge as part of a warranty agreement would implicate the anti-kickback statute. Additionally, the provision of medication adherence services for free or below fair market value would implicate the anti-kickback statute. In contrast, if sellers provide items and services with no independent value to a buyer, other than to determine whether the conditions of a warranty have been satisfied, the items and services may not constitute remuneration under the anti-kickback statute, and thus, may not implicate the statute. *See* OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 FR 23731, 23735 (May 5, 2003), for a discussion of pharmaceutical manufacturers' provision of limited support services tailored to the manufacturers' products that may not implicate the anti-kickback statute.

prescribed medications, even when a patient is experiencing harmful side effects, or the medication is not achieving the purpose for which it was prescribed. Because manufacturers have financial incentives for patients to use and reorder their medications but do not have the medical expertise the prescribing physicians have to determine whether continued use of medications is clinically appropriate for a specific patient, medication adherence services offered by manufacturers, such as phone or message communications directing patients to take their medications, could result in patient harm or inappropriate utilization of drugs.

We are considering safeguards we could include in the final rule to protect against these risks, such as a safeguard that would prohibit direct patient outreach by a seller offering a warranty but that would allow the seller to pay an independent intermediary to perform services that require direct patient outreach, as long as compensation for the patient outreach services is not tied to the volume or value of any warranted item used by the patient.

Our proposed expansion of this safe harbor does not protect warranties covering only services. We believe warranties for services that are not tied to one or more related items could present heightened fraud and abuse risks. Manufacturers and suppliers could warrant that services will achieve certain clinical goals and offer remuneration to induce referrals from referral sources under the guise of warranty remedies. The services manufacturers and suppliers may offer could take many different forms, and it may be difficult to verify whether services, which can more subjective in nature than items, failed to achieve the clinical goals established by a warranty arrangement. Additionally, because the services subject to a warranty may not be federally reimbursable, it may be difficult to determine whether the services being warranted are *bona fide* services or sham services offered as part of a warranty agreement and designed to transfer remuneration to referral sources upon the failure of such services to achieve the warranted result. If physicians, for example, could warrant that their services will achieve certain clinical results, the potential to receive money as a warranty remedy may induce patients to select physicians offering warranties over other physicians, particularly where the clinical results being warranted are not easily achievable, regardless of which physician a patient selects. We are considering for the final rule extending safe harbor protection for warranties applying only to services if sufficient safeguards exist to mitigate these risks, and we are soliciting comments on the potential fraud and abuse risks that may arise if we expand the safe harbor to include services-only warranties and potential safeguards to mitigate these risks.

b. Conditions on Bundled Warranties

We propose to impose the following conditions on bundled warranty arrangements: (i) All federally reimbursable items and services subject to bundled warranty arrangements must be reimbursed by the same Federal health care program and in the same payment; (ii) a manufacturer or supplier must not pay any individual (other than a beneficiary) or entity for any medical, surgical, or hospital expense incurred by a beneficiary other than for the cost of the items and services subject to the warranty; and (iii) manufacturers and suppliers cannot condition bundled warranties on the exclusive use of one or more items or services or impose minimum-purchase requirements of any items or services. We believe these requirements would promote beneficial arrangements while protecting beneficiaries and the Federal health care programs from harmful practices, such as inappropriate utilization and product steering, as explained below.

c. Requirement for Federally Reimbursable Items and Services Subject to Bundled Warranty Arrangements To Be Reimbursed by the Same Federal Health Care Program and in the Same Payment

Under a new paragraph (5), we propose to require that all federally reimbursable items and services subject to the bundled warranty be reimbursed by the same Federal health care program and in the same payment. This requirement would be satisfied when federally reimbursable items and services subject to a bundled warranty are reimbursed by, for example, the same Part A Medicare Severity-Diagnosis Related Group (MS–DRG) payment, the same Medicare Part B ambulatory payment classification payment, or the same Medicaid managed care payment. Allowing sellers to bundle items and services reimbursed by different Federal health care program payments could create incentives for overutilization or inappropriate utilization of items and services included in the bundle. Unlike bundled payments, such as MS–DRG payments, payments that reimburse providers separately for each item and service they order do not incentivize providers to contain their costs because the providers would receive reimbursement for each discrete item and service they order, regardless of whether those items and services present the best value. Without cost-containment incentives, providers may order devices or drugs subject to a bundled warranty, regardless of whether lower-cost, equally effective devices or drugs are available, because providers would be reimbursed separately for each item and reimbursable service and could be eligible to receive the full cost of the separately billed items and reimbursable services in the bundle if even one item or reimbursable service fails to perform as expected.

We believe these risks are mitigated when bundled warranties apply only to federally reimbursable items and services that are reimbursed by the same Federal health care program payment, such as under an MS–DRG payment. However, we are aware that bundled warranties could result in barriers to entry for certain manufacturers and suppliers that cannot offer bundled warranties, and we are considering for the final rule, and solicit comments on, additional safeguards we should include to limit the potential anti-competitive effects that bundled warranties may have in the drug and device markets. Additionally, we solicit specific examples where the protections we propose would not be sufficient to protect against anti-competitive conduct.

We recognize that the proposed requirement above might inhibit warranties conditioned on the collective performance of warranted items across a patient population (population-based warranties) because these items would not be reimbursed in the same payment. We are considering whether, and if so, how, we might craft the safe harbor to allow for population-based warranties without creating risks of increased costs to the Federal health care programs, as described above. For example, we are considering for the final rule whether we could require that all items and services be reimbursed according to the same payment methodology, but not necessarily the same payment, to allow for population-based warranties. We solicit comments on this approach and the potential benefits and fraud and abuse risks it may present. We note that retrospective reconciliation payments, such as those often used under the Innovation Center payment models, would not constitute one payment, as required under our proposal, when the reconciliation payments are paid to one entity but are not direct payment for

items and services provided only by that entity.

In addition, we are considering for the final rule, and seek comments on, whether we should include any exceptions to the requirement that all federally reimbursable items and services subject to a bundled warranty be paid by the same payment, such as when bundled items are reimbursed according to the same payment under the Medicare program but are reimbursed separately under Medicaid. For example, in Advisory Opinion No. 18–10, we noted that the items subject to the requestor's warranty program were reimbursable under the same MS–DRG payment but potentially were separately reimbursable under certain states' Medicaid programs. We encourage commenters to provide specific examples where an exception may be needed.

2. Capped Amount of Warranty Remedies; Prohibition on Exclusivity and Minimum-Purchase Requirements

We propose to modify paragraph (4) of the safe harbor by limiting the remuneration a manufacturer or supplier may pay to any individual (other than a beneficiary) or entity for any medical, surgical, or hospital expense incurred by a beneficiary to the cost of the items and services subject to the warranty. We view this limitation as an important protection against manufacturers and suppliers providing excessive remuneration to induce further business. In a new paragraph (6), we also propose to prohibit manufacturers and suppliers from conditioning warranties on the exclusive use of one or more items or services and from imposing minimum-purchase requirements of any items or services. We view such steering practices as highly problematic and solicit comments on the prevalence of these practices in warranty arrangements. We also solicit comments on the effectiveness of the proposed safeguards in preventing or mitigating fraud and abuse risks, as well as additional safeguards we could impose.

3. Reporting Requirements

Stakeholders have expressed concern that the reporting requirements under the safe harbor may not allow for outcomes-based warranty arrangements in which buyers could receive return payments from manufacturers over several years if a therapy does not meet clinical outcomes at designated points in time. We solicit comments on any burden the current reporting requirements impose and the need for more flexible reporting requirements under the safe harbor to better facilitate warranties tied to clinical outcomes. We understand that delayed reporting may be necessary when, for example, the efficacy of a drug therapy may not be known for several years after the initial purchase. We are considering ways in which we could modify the reporting requirements under the safe harbor to accommodate outcomes-based warranty arrangements while protecting the Government's interest in having an accurate and timely report of any price reductions a seller offers a buyer under a warranty arrangement protected by the safe harbor. We also propose to expressly exclude beneficiaries from the reporting requirement applicable to other buyers since beneficiaries do not report costs to the Government.

4. Definition of ''Warranty''

We propose to define ''warranty'' directly and not by reference to 15 U.S.C. 2301(6). The Magnuson-Moss Act enacted 15 U.S.C. 2301, which in paragraph (6) defines ''written warranty'' in connection with the sale of a ''consumer product.'' However, courts have held that an item regulated under the Federal Food, Drug, and Cosmetic Act is not a ''consumer product'' for purposes of the Magnuson-Moss Act.[84] The reference to 15 U.S.C. 2301(6) in the definition of ''warranty'' therefore creates unintentional ambiguity as to whether the safe harbor covers warranties for drugs and devices regulated under the Federal Food, Drug, and Cosmetic Act. We propose revisions to the definition of ''warranty'' to clarify that the warranties safe harbor applies to FDA-regulated drugs and devices.

We propose a definition for ''warranty'' that largely models the definition in 15 U.S.C. 2301(6) but replaces references to a ''product,'' where applicable, with ''item or bundle of items, or services in combination with one or more related items,'' to allow for single-item and bundled warranties. Additionally, the proposed definition substitutes references to the ''material'' of a product with ''quality'' to reflect the inclusion of warranted services in addition to items. The proposed definition of ''warranty'' continues to include a ''written affirmation of fact or written promise [that] affirms or promises that [items and services] . . . will meet a specified level of performance over a specified period of time.'' We interpret this provision to provide protection for warranty arrangements conditioned on clinical outcome guarantees, provided the warranty arrangements meet all the safe harbor's requirements.

L. Local Transportation (1001.952(bb))

Increasingly, experts are recognizing the important role transportation plays in patient access to care, quality of care, healthcare outcomes, and effective coordination of care for patients, particularly for patients who lack their own transportation or who live in ''transportation deserts.'' As part of this rulemaking, we are revisiting certain provisions of the existing safe harbor for local transportation at 42 CFR 1001.952(bb) and, as described above, proposing new safe harbor protection for certain patient engagement tools and supports. The proposed patient engagement and support safe harbor would include transportation services for patients that meet the proposed safe harbor requirements.

We propose to modify the existing safe harbor for local transportation at 42 CFR 1001.952(bb) to: (i) Expand the distance which residents of rural areas may be transported; and (ii) remove any mileage limit on transportation of a patient from a healthcare facility from which the patient has been discharged to the patient's residence.

For purposes of clarification, we also provide guidance on the application of the safe harbor to transportation through ride-sharing services. We are not proposing to amend the safe harbor to explicitly include such services, because we believe that nothing in the existing language excludes them from protection.

Finally, for ease of reference, we propose to amend the safe harbor by moving the undesignated definitions set forth in the note to paragraph (bb) to a new paragraph (bb)(3).

1. Expansion of Mileage Limit for Patients Residing in Rural Areas

The safe harbor provides that transportation is protected if provided ''[w]ithin 25 miles of the health care provider or supplier to or from which the patient would be transported, or within 50 miles if the patient resides in a rural area, as defined in this paragraph (bb).'' [85] In response to the OIG RFI, some commenters stated that the 50-mile limit for residents of rural areas is insufficient, as many rural residents need to travel more than 50 miles to obtain medically necessary services. Accordingly, we are proposing to increase the limit on transportation of residents of rural communities to 75

[84] *See, e.g., Kanter* v. *Warner-Lambert Co.,* 99 Cal. App. 4th 780, 798 (2002); *Goldsmith* v. *Mentor Corp.,* 913 F. Supp. 56, 63 (D.N.H. 1995); *Kemp* v. *Pfizer, Inc.,* 835 F. Supp. 1015, 1024–25 (E.D. Mich. 1993).

[85] 42 CFR 1001.952(bb)(1)(iv)(B).

miles, but we solicit comments on whether an increase to 75 miles is sufficient. We urge commenters to provide data or other evidence to support the most appropriate distance for the purposes of this rulemaking. We request that commenters provide specific information, if available, about the patients within the commenters' communities or service areas who cannot obtain care within the existing distance limits. We also seek comments on how an entity would provide transportation over distances in excess of 50 miles (*e.g.,* by shuttle, as defined in the existing safe harbor), ride-sharing programs, reimbursement of mileage, reimbursement of bus or taxi fare, or other means. Such information will assist us in determining whether an increased distance limit is necessary and practical and whether it is likely to be subject to abuse. While the current safe harbor does not require any showing of need on the part of patients, we solicit comments on whether the final rule should protect transportation in excess of the current limits only where there is a demonstration of financial, medical, or transportation need. We also solicit comments on what safeguards would be necessary to prevent abuse of an expansion of these limits for rural or other patients.

2. Elimination of Distance Limit on Transportation of Discharged Patients

Comments on the OIG RFI and other information raise concerns about patients discharged from healthcare facilities who do not have a ride home. In some cases, these patients have been brought to the facility from a great distance. Some patients in behavioral health facilities are brought to the facility over long distances by law enforcement personnel. Commenters urged that the local transportation safe harbor be expanded to protect facilities that want to provide safe transportation home.

We agree that transportation home after discharge from an inpatient facility does not pose the same level of risk of inducing patient referrals as transportation to the facility. Accordingly, we are proposing to eliminate any distance limit on transportation of a patient who has been discharged from a facility after admission as an inpatient, regardless of whether the patient resides in an urban or rural area, if the transportation is to the patient's residence, another residence of the patient's choice (such as the residence of a friend or relative who is caring for the patient post-discharge). We are also considering protecting transportation to any location of the patient's choice, including to another healthcare facility. We are soliciting comment on the fraud and abuse risks that may arise from permitting transportation to another healthcare facility. In addition, we are considering for the final rule whether, and under what circumstances, transportation home or to another facility should be protected when a patient has not been admitted to an inpatient facility. For example, we are soliciting comments on whether transportation should be protected after a patient has been seen in the emergency room, under observation status at a hospital for an extended period, but not admitted, or after a procedure at an ambulatory surgery center (ASC). If transportation is protected under these circumstances, we welcome comments on what limitations should be imposed (*e.g.,* observation status at a hospital for at least 24 hours, or a procedure at an ASC or medical condition evaluated or treated at an emergency department that results in a patient being unable to travel home safely unaccompanied).

The safe harbor does not require an entity to offer transportation to patients, and an entity may impose its own mileage limits on any transportation offer, as long as it imposes such limits consistently and makes the transportation available without regard to the volume or value of Federal health care program business. For example, the entity sponsoring the transportation cannot offer the transportation only to facilities affiliated with it.

As with our proposal to increase the mileage limit for transportation of rural patients, we solicit comments on whether transportation of discharged patients, if in excess of otherwise applicable safe harbor mileage limits, should be limited to patients with demonstrated need (either financial need or transportation need), and if so, what standards should apply to such demonstration of need. Finally, we solicit comments on whether, if this proposal to eliminate any mileage limit for discharged patients is adopted, there remains a need to increase the distance limit for transportation of patients who reside in rural areas.

3. Local Transportation for Health-Related, Non-Medical Purposes

In the preamble to the final rule establishing the local transportation safe harbor, we declined to extend safe harbor protection to transportation for purposes other than to obtain medically necessary items or services, although we noted that a shuttle service protected by the safe harbor could make stops at locations that do not relate to a particular patient's medical care. We also stated that we would consider in a future rulemaking whether permitting transportation to non-medical services that are part of care coordination arrangements or are related to improving healthcare would be appropriate.[86]

In response to the OIG RFI, we received comments suggesting that the local transportation safe harbor should protect transportation for non-medical purposes that may nevertheless improve or maintain health. Such transportation might be to food stores or food banks, social services facilities (such as to apply for food stamps or housing assistance), exercise facilities, or chronic disease support groups, for example. In many cases, such transportation might help address both patients' health outcomes as well as social determinants of health, such as transportation, nutrition, and housing. We are considering including non-medical purposes in the final safe harbor, and we seek comments on whether and how the safe harbor could be expanded in this manner to foster innovative arrangements that are likely to improve health outcomes and address non-medical needs that significantly influence those outcomes, without creating an unacceptable risk of fraud and abuse, such as inducing beneficiaries to receive unnecessary healthcare items and services. We are considering whether such expansion of the safe harbor should be limited to certain beneficiary populations, such as chronically ill patients, or to patients who are being discharged from a hospital or other facility. Responses to this solicitation of comments will inform our consideration of potentially extending this safe harbor in the final rule to include these arrangements or potentially protecting arrangements in the patient engagement and support safe harbor, if finalized.

Elsewhere in this rulemaking, we are proposing a new safe harbor for patient engagement tools and supports provided by VBE participants, which could include transportation for health-related, non-medical purposes. The protection of this safe harbor would not be available outside the context of a VBE, however, since the proposed safe harbor limits protection to patient engagement tools and supports furnished by VBE participants. We refer commenters to the standards and safeguards proposed for the separate safe harbor for patient engagement tools and supports (proposed at

[86] *See* 81 FR 88368, 88384 (Dec. 7, 2016).

1001.952(hh)), and we solicit comments on whether these standards and safeguards are also appropriate for the local transportation safe harbor, to the extent that were to apply to transportation for non-medical purposes. In addition, we seek comments on whether an extension of the local transportation safe harbor in this manner is needed or appropriate, if the proposed separate safe harbor for patient engagement and support offered by VBE participants is adopted (proposed 1001.952(hh)).

4. Use of Ride-Sharing Services

We are aware that some entities are providing transportation for medical items and services through the use of ride-sharing services. As we understand the use of these services, a hospital, for example, could arrange with a ride-sharing service to provide rides for its patients, for which the hospital would be billed. We are aware that some members of the public may be uncertain about the application of the safe harbor in these circumstances.

In the preamble to the final rule establishing the local transportation safe harbor, we noted the possibility that patient transportation would be provided via taxi.[87] Although we did not explicitly refer to ride-sharing services, we see no difference between these services and taxis, for purposes of the safe harbor. We believe that nothing in the language of the safe harbor precludes their use. (By the same logic, the safe harbor does not preclude transportation via self-driving cars or other similar technology that serve as a taxi service, should they become available.) We invite any commenters who disagree to provide comments explaining the possible basis for the exclusion of ride-sharing programs from protection from the existing safe harbor. If we find such comments persuasive, we will consider an amendment to the safe harbor to explicitly protect transportation through ride-sharing programs.

We note, however, that the same safe harbor requirements that apply to other forms of transportation also apply to transportation provided by ride-sharing services. These include the requirement that the availability of free or discounted transportation not be advertised. A taxi company, ride-sharing service, or other provider of transportation could advertise that it provides transportation to medical appointments and suggest contacting medical providers to determine if free or discounted transportation is available to their facilities. It cannot, however, advertise that it provides free or discounted transportation to a particular healthcare provider or group of providers. Such customer-specific advertising is within the control of the customer to prohibit, and therefore would be imputed to the customer (*i.e.,* the entity paying for the transportation, regardless of whether that entity pays for the advertising), thus disqualifying the arrangement from safe harbor protection.

To the extent that the ride-sharing service provides services other than transportation for the purpose of obtaining medical care, such services would not be protected by the safe harbor. Like a taxi driver, a ride-share driver could assist a patient in getting from a residence into a vehicle and from a vehicle into a medical provider's facility, and this could include assisting the patient with a wheelchair, oxygen equipment, or the like. This would be considered part of the transportation service. In addition, a ride-sharing driver, taxi driver, or shuttle could, for example, provide the patient with transportation from a physician's office or hospital to a pharmacy, for the purpose of obtaining a prescription (a medically necessary item) before taking the patient home. As noted in the preamble to the 2016 final rule establishing this safe harbor, a shuttle could also include a food store among its stops.[88] However, transportation to a food store or any other location not for the purpose of obtaining medically necessary items or services, when provided on a patient-specific basis (*i.e.,* not by a shuttle), is not protected by this safe harbor. Such transportation may be protected by the proposed safe harbor for value-based arrangements, as discussed elsewhere in this proposed rule.

Finally, we note that, as with all safe harbors, the local transportation safe harbor applies only to the Federal anti-kickback statute (and the beneficiary inducements CMP). Providers of transportation remain subject to all other federal, state and local laws and regulations that may be applicable to their activities and arrangements.

M. ACO Beneficiary Incentive Program

1. Overview of Medicare Shared Savings Program and Provisions of the Budget Act of 2018 for ACO Beneficiary Incentive Programs

Section 1899 of the Act established the Medicare Shared Savings Program, which promotes accountability for a patient population, fosters coordination of items and services under Medicare Parts A and B, encourages investment in infrastructure and redesigned care processes for high-quality and efficient healthcare service delivery, and promotes higher value care. The Medicare Shared Savings Program is a voluntary program that encourages groups of doctors, hospitals, and other healthcare providers to come together as an ACO to lower growth in expenditures and improve quality. An ACO agrees to be held accountable for the quality, cost, and experience of care of an assigned Medicare FFS beneficiary population. ACOs that successfully meet quality and savings requirements share a percentage of the achieved savings with Medicare.

Section 1899(m)(1)(A) of the Act, as added by section 50341 of the Budget Act of 2018,[89] permits ACOs under certain two-sided models to operate CMS-approved beneficiary incentive programs to provide incentive payments to assigned beneficiaries who receive qualifying primary care services. According to CMS, and as intended by section 1899(m)(1)(A) of the Act, the beneficiary incentive programs will encourage beneficiaries assigned to certain ACOs to obtain medically necessary primary care services while requiring such ACOs to comply with program integrity and other requirements.[90] CMS, in a final rule establishing regulations governing ACO Beneficiary Incentive Programs states that the agency ''believe[s] that such amendments will empower individuals and caregivers in care delivery.'' [91]

Specifically, the Budget Act of 2018 added section 1899(m)(1)(A) of the Act, which allows ACOs to apply to operate an ACO Beneficiary Incentive Program. The Budget Act of 2018 also added a new subsection (m)(2) to section 1899 of the Act, which provides clarification regarding the general features, implementation, duration, and scope of approved ACO Beneficiary Incentive Programs. In addition, the Budget Act of 2018 added section 1899(b)(2)(I) of the Act, which requires ACOs that seek to operate a beneficiary incentive program to apply to operate the program at such time, in such manner, and with such information as the Secretary may require.[92]

[87] 81 FR at 88387.

[88] 81 FR 88384.

[89] Public Law 115–123, 132 Stat. 64.

[90] Medicare Program; Medicare Shared Savings Program; Accountable Care Organizations—Pathways to Success and Extreme and Uncontrollable Circumstances Policies for Performance Year 2017, 83 FR 67816, 67823 (Dec. 31, 2018).

[91] *Id.* at 67980.

[92] For additional background information on section 1899(m) and 1899(b)(2)(I), *see* Medicare

In order to implement the changes set forth in section 1899(b)(2) and (m) of the Act, CMS added regulation text at 42 CFR 425.304(c) that allows ACOs participating under certain two-sided models to establish CMS-approved beneficiary incentive programs to provide incentive payments to assigned beneficiaries who receive qualifying services.

2. ACO Beneficiary Incentives Program Statutory Exception and Proposed Safe Harbor (1001.952(kk))

Section 50341(b) of the Budget Act of 2018, which added section 1128B(b)(3)(K) of the Act, states that ''illegal remuneration'' under the anti-kickback statute does not include ''. . . an incentive payment made to a Medicare fee-for-service beneficiary by an ACO under an ACO Beneficiary Incentive Program established under subsection (m) of section 1899, if the payment is made in accordance with the requirements of such subsection and meets such other conditions as the Secretary may establish.''

We propose to codify the statutory exception to the definition of ''remuneration'' at section 1128B(b)(3)(K) of the Act in our regulations at proposed paragraph 1001.952(kk). We propose to adopt regulatory language nearly identical to the statutory language, with two exceptions. First, the text of the proposed safe harbor would make it clear that an ACO may furnish incentive payments only to assigned beneficiaries. Second, the safe harbor would modify the statutory language stating, ''if the payment is made in accordance with the requirements of such subsection,'' to ''if the incentive payment is made in accordance with the requirements found in such subsection.'' Note that we do not propose the establishment of any additional safe harbor conditions that incentive payments made by an ACO to an assigned beneficiary under an ACO Beneficiary Incentive Program established under section 1899(m) of the Act must satisfy.

The ACO Beneficiary Incentive Program statutory exception, found at section 1128B(b)(3)(K) of the Act, requires that ''the payment is made in accordance with the requirements of [section 1899(m)].'' We read this provision to broadly incorporate all of the requirements found in section 1899(m) as requirements of the ACO Beneficiary Incentive Program statutory exception to the definition of ''remuneration'' under the Federal anti-kickback statute. In other words, we believe that for an incentive payment to satisfy the ACO Beneficiary Incentive Program statutory exception, and the corresponding safe harbor proposed at paragraph 1001.952(kk), all of the requirements enumerated at section 1899(m)—related both to ACO Beneficiary Incentive Programs and incentive payments made pursuant to such programs—must, and would be required to, be satisfied.

While section 1899(m) of the Act also includes a provision that states, ''[t]he Secretary shall permit such an ACO to establish such a program at the Secretary's discretion and subject to such requirements, including program integrity requirements, as the Secretary determines necessary,'' [93] we do not interpret the statutory exception found at section 1128B(b)(3)(K) of the Act to require satisfaction of any requirements found outside of section 1899(m) (*e.g.,* the regulatory requirements established by CMS implementing the ACO Beneficiary Incentive Program, found at 42 CFR 425.304(c)).[94] In other words, OIG interprets the statutory exception found at section 1128B(b)(3)(K) of the Act and would interpret the corresponding safe harbor proposed at paragraph 1001.952(kk), to require that the incentive payment is made in accordance with the requirements found in section 1899(m) of the Act.

Given the requirements imposed on ACO Beneficiary Incentive Programs and incentive payments made pursuant to an ACO Beneficiary Incentive Program, found in section 1899(m), at this time, we do not believe it is necessary to create additional conditions under the proposed ACO Beneficiary Incentives Program safe harbor, paragraph 1001.952(kk). However, we are considering and seek comment on whether OIG should include additional conditions in this safe harbor.

IV. Provisions of the Proposed Rule: Beneficiary Inducements CMP Exception

This proposed rule would amend 42 CFR 1003.110 by codifying amendments that were enacted in the Budget Act of 2018. This proposed rule would add an exception for the provision of certain telehealth technologies related to in-home dialysis services to the definition of ''remuneration'' applicable to the beneficiary inducements CMP, which prohibits offering inducements to Medicare or Medicaid beneficiaries that the offeror knows or should know are likely to influence the selection of particular providers, practitioners or suppliers.

A. Statutory Exception for Telehealth Technologies for In-Home Dialysis

As part of the Creating High-Quality Results and Outcomes Necessary to Improve Chronic Care Act of 2018, section 50302 of the Budget Act of 2018 amends section 1881(b)(3) of the Act to permit an individual with ESRD receiving home dialysis to elect to receive their monthly ESRD-related clinical assessments via telehealth, if certain other conditions are met.[95] Section 50302(c) of the Budget Act of 2018 creates a new exception to the definition of ''remuneration'' in the beneficiary inducements CMP. Specifically, section 50302(c) of the Budget Act of 2018 adds the following exception as new section 1128A(i)(6)(J) of the Act:

The provision of telehealth technologies (as defined by the Secretary) on or after January 1, 2019, by a provider of services or a renal dialysis facility (as such terms are defined for purposes of title XVIII) to an individual with end stage renal disease who is receiving home dialysis for which payment is being made under part B of such title, if:

Program; Medicare Shared Savings Program; Accountable Care Organizations—Pathways to Success and Extreme and Uncontrollable Circumstances Policies for Performance Year 2017, 83 FR 67816 (Dec. 31, 2018).

[93] Section 1899(m)(1)(A) of the Act.

[94] CMS, in the final rule establishing the ACO Beneficiary Incentive Program, determined that the ACO Beneficiary Incentive Program required additional program integrity safeguards. CMS included several requirements at 42 CFR 425.304(c) to help mitigate the program integrity risks associated with ACO Beneficiary Incentive Programs. Under 42 CFR 425.304(c)(4)(iv), for example, ACOs are prohibited from offering an incentive payment as part of an advertisement or solicitation to beneficiaries.

[95] Section 50302(b) of the Budget Act of 2018 made additional changes related to the provision of telehealth services to ESRD patients, such as the inclusion of a renal dialysis facility and the home of an individual as telehealth originating sites but only for the purposes of the monthly ESRD-related clinical assessments furnished through telehealth provided under section 1881(b)(3)(B) of the Act. For additional information, *see* Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2019; Medicare Shared Savings Program Requirements; Quality Payment Program; Medicaid Promoting Interoperability Program; Quality Payment Program-Extreme and Uncontrollable Circumstance Policy for the 2019 MIPS Payment Year; Provisions From the Medicare Shared Savings Program-Accountable Care Organizations-Pathways to Success; and Expanding the Use of Telehealth Services for the Treatment of Opioid Use Disorder Under the Substance Use-Disorder Prevention That Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act 83 FR 59452, 59495 (Nov. 23, 2018), *available at https://www.govinfo.gov/content/pkg/FR-2018-11-23/pdf/2018-24170.pdf. See also* 42 CFR 410.78, 414.65.

(i) The telehealth technologies are not offered as part of any advertisement or solicitation;

(ii) the telehealth technologies are provided for the purpose of furnishing telehealth services related to the individual's end stage renal disease; and

(iii) the provision of the telehealth technologies meets any other requirements set forth in regulations promulgated by the Secretary.

This exception would be available only for telehealth technologies, as defined below, furnished by a provider of services or a renal dialysis facility to patients with ESRD who receive in-home dialysis that is payable by Medicare Part B. We propose to interpret this exception, in our proposed condition (i), to require that the telehealth technologies be furnished to the individual by the provider of services or the renal dialysis facility (as those terms are defined in title XVIII of the Act) that is currently providing the in-home dialysis, telehealth visits, or other ESRD care to the patient. The underlying intent of this proposed condition (i) is to prevent arrangements where providers and suppliers offer telehealth technologies to patients with whom they do not have a prior clinical relationship in an attempt to steer patients to a particular provider or supplier. We seek comment on this proposed condition (i), and in particular, any challenges this condition would create. In addition, while we are aware of the increasing proliferation of telehealth services, and the likely desire of other healthcare industry stakeholders to furnish telehealth technologies to patients receiving telehealth services, the statutory exception, and therefore, this proposal, is limited to a subset of patients receiving in-home dialysis and certain, enumerated providers in the statutory exception. We further note that the provision of telehealth technologies might qualify for protection under other existing or proposed exceptions or safe harbors, including the proposed safe harbor for patient engagement and support, paragraph 1001.952(hh). That being said, we seek comment on whether we should, for purposes of the final rule, interpret the statutory exception to apply not only to the ''provider of services or the renal dialysis facility (as those terms are defined in tile XVIII of the Act),'' but also suppliers, as defined in title XVIII of the Act. We solicit comments on this issue, in recognition of the underlying congressional intent and policy goals set forth in Section 50302(b) of the Budget Act of 2018: Expanding patient access to in-home dialysis care, furnished by their physician.

The first criterion included in the statutory exception provides that protected items or services may not be offered as part of any advertisement or solicitation. We are including this requirement in our proposed regulation at proposed condition (ii). As we have said in other rulemakings, we propose that stakeholders interpret the terms ''advertisement'' and ''solicitation'' consistent with their common usage in the healthcare industry.[96]

The second criterion included in the statutory exception requires the telehealth technologies to be provided for the purpose of furnishing telehealth services related to the individual's ESRD. At proposed condition (iii), we propose to interpret ''for the purpose of furnishing telehealth services related to the individual's end stage renal disease'' to mean that the technology contributes substantially to the provision of telehealth services related to the individual's ESRD, is not of excessive value, and is not duplicative of technology that the beneficiary already owns if that technology is adequate for the telehealth purposes. We would consider technology to be of excessive value if the retail value of the technology is substantially more than is required for the telehealth purpose. For example, if a readily available $300 smartphone would adequately run the telehealth technology, the safe harbor would not protect a donation of a $600 smartphone. To ensure that this proposed safe harbor protects the provision of telehealth technologies ''for the purpose of furnishing telehealth services related to the individual's end stage renal disease'' and not to induce referrals, we are also considering for the final rule, and seek comment on, a condition that would require the provider or facility to retain ownership of any hardware and make reasonable efforts to retrieve the hardware once the beneficiary no longer needs it for the permitted telehealth purposes (such that the hardware is loaned to the beneficiary).

We remain concerned that the provision of telehealth technology with substantial independent value to the beneficiary might serve to induce the beneficiary to choose a particular provider or facility. We are considering, and solicit comments about, whether the final rule should interpret ''for the purpose of furnishing telehealth services related to the individual's end stage renal disease'' in a more restrictive manner. For example, we are considering for the final rule and seek comments on whether the exception should protect telehealth technologies that provide the beneficiary with no more than a *de minimis* benefit for any purpose other than furnishing telehealth services related to the individual's ESRD. We also are considering for the final rule and seek comments on another standard that would protect telehealth technologies only when furnished predominantly for the purpose of furnishing telehealth services related to the individual's ESRD.

We propose to interpret ''telehealth services related to the individual's end stage renal disease'' to mean only those telehealth services paid for by Medicare Part B. CMS maintains a list of services payable under the Medicare Physician Fee Schedule when furnished via telehealth. We solicit comments on this interpretation.

The statutory exception's third criterion allows the Secretary to develop additional requirements not specified in the statutory exception and requires the Secretary to define ''telehealth technologies.'' Below we propose a definition of ''telehealth technologies'' and further enumerate requirements under the new exception to the definition of ''remuneration'' for the beneficiary inducements CMP.

B. Additional Proposed Conditions for the Telehealth Technologies Exception

Under proposed condition (iv), a person must not bill Federal health care programs, other payors, or individuals for the telehealth technologies, claim the value of the item or service as a bad debt for payment purposes under a Federal health care program, or otherwise shift the burden of the value of the telehealth technologies onto a Federal health care program, other payors, or individuals. This proposed requirement is designed to protect against the telehealth technologies resulting in inappropriately increased costs to Federal health care programs, other payors, and patients. In this requirement, we propose to prohibit claiming the cost of the telehealth technologies and any operational costs attendant to providing telehealth technologies as bad debt for payment purposes under Medicare or a State healthcare program or otherwise shifting the burden of the cost of the telehealth technologies and any operational costs attendant to the provision of patient incentives to Medicare, a State healthcare program, other payors, or individuals. We seek comments on this proposed condition.

[96] *See, e.g.,* 81 FR 88368, 88373 (Dec. 7, 2016).

C. Defining Telehealth Technologies

We propose to define ''telehealth technologies'' for the purposes of the definition of the term ''remuneration'' as set forth in 42 CFR 1003.110 and the telehealth technologies exception to section 50302(c) of the Budget Act of 2018. In proposing such definition, we consulted with CMS and solicited comments in the OIG RFI regarding how OIG should define ''telehealth technologies'' and if the definition should include ''services.'' Based on the collective input we received, we propose to adopt, as part of our definition of ''telehealth technologies,'' the definition of ''interactive telecommunications system'' found at 42 CFR 410.78. Under 42 CFR 410.78, Medicare Part B pays for covered telehealth services included on the telehealth list when furnished using an ''interactive telecommunications system'' if certain conditions are met. 42 CFR 410.78(a)(3) defines an ''interactive telecommunications system'' to mean ''multimedia communications equipment that includes, at a minimum, audio and video equipment permitting two-way, real-time interactive communication between the patient and distant site physician or practitioner. Telephones, facsimile machines, and electronic mail systems do not meet the definition of an interactive telecommunications system.''

For the purposes of this exception, we propose to define ''telehealth technologies'' as the following: ''multimedia communications equipment that includes, at a minimum, audio and video equipment permitting two-way, real-time interactive communication between the patient and distant site physician or practitioner used in the diagnosis, intervention or ongoing care management—paid for by Medicare Part B—between a patient and the remote healthcare provider. Telephones, facsimile machines, and electronic mail systems do not meet the definition of 'telehealth technologies.' '' For the purposes of our definition of ''telehealth technologies,'' smart phones that allow for two-way, real-time interactive communication through secure, video conferencing applications would not be considered ''telephones.'' We solicit comments this definition, and are interested in comments that explain whether, and why, this definition would be too narrow, or too broad, and elaborate upon any attendant risks of fraud and abuse associated with the adoption of this definition. We also solicit comments on whether ''[t]elephones, facsimile machines, and electronic mail systems,'' as used in in 42 CFR 410.78(a)(3), should be excluded from our definition of ''telehealth technologies.'' We are also considering for the final rule, and seek comment on, whether to define ''telehealth technologies'' to include technologies such as software, a webcam, data plan, or broadband internet access that facilitates the telehealth encounter. This might include, for example, software that allows a patient to use his or her existing smartphone, tablet, or computer to receive telehealth consultations. We are interested in comments on whether and how broadening the exception to include these kinds of technologies might impact access to medically necessary care for beneficiaries. We are further interested in comments on whether such broadening would create an undue risk of remuneration that would inappropriately steer beneficiaries to particular providers or suppliers to obtain federally reimbursable items and services, and whether there would be limitations or conditions on the provision of telehealth technologies that we could include in an exception to curb potential abuses, such as a limitation on the value of the remuneration (*e.g.,* a cap on the retail value of the telehealth technologies furnished, such as $100, $200, $500, or another amount that would be of sufficient magnitude to protect the most beneficial arrangements while also preventing the most abusive ones).

D. Other Potential Safeguards

1. Consistent Provision of Telehealth Technologies

In addition to the proposed conditions set forth above, we are considering for the final rule and seek comment on whether, as a condition of safe harbor protection, parties should be prohibited from discriminating in the offering of telehealth technologies. Such a safe harbor condition would require providers and renal dialysis facilities to provide the same telehealth technologies to any Medicare Part B eligible patient receiving in-home dialysis, or to otherwise consistently offer telehealth technologies to all patients satisfying specified, uniform criteria. This potential condition could reduce the likelihood that telehealth technologies would be offered selectively based on whether the patient generates other billable business for the provider or facility. We solicit comments on this issue. In particular, we are interested in understanding whether this proposed safeguard would limit providers of services' or renal dialysis facilities' ability to offer incentives due to the potential cost of furnishing the incentive to all qualifying patients rather than a smaller subset. Similarly, we are interested in why offering remuneration to a smaller subset of qualifying patients might be appropriate and not increase the risk of fraud and abuse.

2. Necessary Technology

For purposes of the final rule, we are considering allowing a person to furnish telehealth technologies under the safe harbor only after making a good faith determination that the individual to whom the technology is furnished does not already have the necessary telehealth technology, and that such technology is necessary for the telehealth services provided. For instance, if an application on a patient's existing phone would be sufficient, but the patient is furnished a new tablet, this would be considered duplicative or unnecessary. Should the recipient already possess technology that allows the telehealth visit to occur, we are concerned that a person may furnish additional valuable or duplicative technology for inappropriate purposes (*e.g.,* to induce a patient to select a particular provider for in-home dialysis, or to seek other items and services from that provider). We seek comment on this potential safeguard. We also are considering, and seek comment regarding, a condition in the final rule that would require the person who furnishes the telehealth technologies to take reasonable steps to limit the use of the telehealth technologies by the individual to the telehealth services described on the Medicare telehealth list.

3. Notice to Patients

One commenter to the OIG RFI noted that patients may be confused by the technology, or the reason they are receiving a piece of technology, and unaware of costs associated with telehealth visits. We are considering adding in the final rule a condition that requires providers or facilities to provide a written explanation of the reason for the technology and any potential ''hidden'' costs associated with the telehealth services to any patient who elects to receive telehealth technology. We solicit comments on these perceived risks to patients, and whether to include a written notice requirement in the final rule, and if so, what that notice should state.

4. Patient Freedom of Choice

We also are considering finalizing a condition that is designed to preserve patient freedom of choice among

healthcare providers and the manner in which he or she receives dialysis services under arrangements that would use the proposed exception. In particular, we are considering a condition in the exception that would require offerors of telehealth technologies to advise patients when they receive such technology that they retain the freedom to choose any provider or supplier of dialysis services and to receive dialysis in any appropriate setting. We are also concerned that some patients may be persuaded to opt for telehealth visits due to the generous telehealth technologies and services being offered, rather than clinical appropriateness. We solicit comments on including this potential safeguard, and whether adding freedom of choice language to a patient notification would reduce this concern.

5. Materials and Records Requirement

The proposed exception would not include a materials and records or other documentation requirement given the somewhat narrow scope of the remuneration that would be excepted from the definition of ''remuneration'' and consistent with other exceptions to the definition of ''remuneration'' set forth in 42 CFR 1003.110. We solicit comments on this approach and any fraud and abuse risks presented by not including a condition related to materials and records.

V. Regulatory Impact Statement

As set forth below, we have examined the impact of this proposed rule as required by Executive Order 12866, the Regulatory Flexibility Act (RFA) of 1980, the Unfunded Mandates Reform Act of 1995, Executive Order 13132, and Executive Order 13771. We provide additional supporting analyses in sections F, G, and H.

A. Executive Order 12866

Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and if regulations are necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects; distributive impacts; and equity). A regulatory impact analysis must be prepared for major rules with economically significant effects (*i.e.,* $100 million or more in any given year). This proposed rule would codify a new CMP exception and implement new or revised anti-kickback statute safe harbors. The vast majority of providers and Federal health care programs would be minimally impacted from an economic perspective, if at all, by these proposed revisions. The changes to the safe harbors and CMP exceptions would allow providers to enter into certain beneficial arrangements. In doing so, this regulation would impose no requirements on any party. Providers would be allowed to voluntarily seek to comply with these provisions so that they would have assurance that participating in certain arrangements would not subject them to liability under the anti-kickback statute and the beneficiary inducements CMP. These safe harbors and exceptions facilitate providers' ability to provide important healthcare and related services to communities in need. We believe that the aggregate economic impact of the changes to these regulations would be minimal and would have no effect on the economy or on Federal or State expenditures. Accordingly, we believe that the likely aggregate economic effect of these regulations would be significantly less than $100 million. However, this rule is considered significant under Executive Order 12866. Notwithstanding our determination that the aggregate economic impact of the changes to these regulations would be minimal and would have no effect on the economy or on Federal or State expenditures, we solicit comments on whether stakeholders believe there would be increases or decreases in utilization or costs savings or expenses to the Government as a result of this proposed rule. We are interested in potential behavioral changes as well.

B. Regulatory Flexibility Act

The RFA and the Small Business Regulatory Enforcement and Fairness Act of 1996, which amended the RFA, require agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and Government agencies. Most providers are considered small entities by having revenues of $7 million to $35.5 million or less in any one year. For purposes of the RFA, most physicians and suppliers are considered small entities. We estimate the changes to the CMP exceptions and the anti-kickback statute safe harbors would not significantly affect small providers, as these changes would not impose any requirement on any party. As a result, we have concluded that this proposed rule likely will not have a significant impact on a substantial number of small providers and that a regulatory flexibility analysis is not required for this rulemaking. In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule under Titles XVIII or XIX or section B of Title XI of the Act may have a significant impact on the operations of a substantial number of small rural hospitals. For the reasons stated above, we do not believe that any provisions or changes finalized here would have a significant impact on the operations of rural hospitals. Thus, an analysis under section 1102(b) of the Act is not required for this rulemaking.

C. Unfunded Mandates Reform Act

Section 202 of the Unfunded Mandates Reform Act of 1995, Public Law 104–4, also requires that agencies assess anticipated costs and benefits before issuing any rule that may result in expenditures in any one year by State, local, or Tribal Governments, in the aggregate, or by the private sector, of $100 million, adjusted for inflation. We believe that no significant costs would be associated with these proposed revisions that would impose any mandates on State, local, or Tribal Governments or the private sector that would result in an expenditure of $154 million (after adjustment for inflation) in any given year.

D. Executive Order 13132

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a rule that imposes substantial direct requirements or costs on State and local Governments, preempts State law, or otherwise has Federalism implications. In reviewing this rule under the threshold criteria of Executive Order 13132, we have determined that this proposed rule would not significantly affect the rights, roles, and responsibilities of State or local Governments.

E. Executive Order 13771

Executive Order 13771 (January 30, 2017) requires that the costs associated with significant new regulations ''to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations.'' This proposed rule has been designated a significant regulatory action as defined by Executive Order 12866 but imposes no more than *de minimis* costs. The designation of this rule, if finalized, will be informed by public comments received; however, this proposed rule, if finalized as proposed, would be neither a regulatory nor a deregulatory action under Executive Order 13771.

F. Statement of Need

The Department has identified the broad reach of the Federal anti-kickback

statute and beneficiary inducements CMP as potentially inhibiting beneficial arrangements that would advance the ability of providers, suppliers, and others to transition more effectively and efficiently to value-based care and to better coordinate care among providers, suppliers, and others in both the Federal health care programs and commercial sectors. Industry stakeholders have informed us that, because the consequences of potential noncompliance with the Federal anti-kickback statute and beneficiary inducements CMP could be significant, providers, suppliers, and others may be discouraged from entering into innovative arrangements that could improve quality outcomes, produce health system efficiencies, and lower healthcare costs (or slow their rate of growth). To the extent providers are discouraged from entering into these innovative arrangements, patient care may not be provided as efficiently as possible. In addition, the potential consequences of noncompliance with these statutes may impede the ability of providers, suppliers, and others, including small providers and suppliers or those serving rural or medically underserved populations, to raise capital to invest in the transition to value-based care or to obtain infrastructure necessary to coordinate patient care, including technology. This unnecessarily slows the transition toward more efficient patient care. This proposed rule attempts to address these concerns by removing unnecessary impediments to the transformation of the healthcare system into one that better pays for and delivers value.

To remove regulatory barriers to care coordination and support value-based arrangements, we faced the challenge of designing safe harbor protections for emerging healthcare arrangements, the optimal form, design, and efficacy of which remain unknown or unproven. These arrangements will be driven by the determinations and experiences of a wide range of providers, suppliers, and others as they innovate in delivering value-based care. This challenge is further complicated by the substantial variation in care coordination and value-based arrangements contemplated by the healthcare industry and others (meaning that one-size-fits-all safe harbor designs may not be optimal), variation among patient populations and provider characteristics, emerging health technologies and data capabilities, the still-developing science of quality and performance measurement, and our desire not to chill beneficial innovations.

It is difficult to gauge the effects of this regulatory action in a rapidly evolving and diverse healthcare ecosystem of substantial innovation, experimentation, and deployment of technology and digital data. For example, it is difficult to gauge reductions in wasteful healthcare spending and improved health outcomes as a result of new arrangements made possible by this proposed rule. It is also difficult to quantify savings or losses that could occur as a result of new fraudulent or abusive conduct that could increase costs or lead to poor outcomes as a result of new arrangements. In some cases, innovations and the availability of more actionable, transparent data may enhance program integrity and protect against fraud and abuse, reducing costs and increasing benefits. There is a compelling concern that uncertainty and regulatory barriers under current regulations could prevent the best and most efficacious innovations from emerging and being tested in the marketplace. Our goal is to finalize safe harbors that protect arrangements that foster beneficial arrangements and promote value, while also protecting programs and beneficiaries against harms cause by fraud and abuse.

G. Anticipated Effects

This proposed rule would add a new CMP exception and anti-kickback statute safe harbors and modify existing anti-kickback statute safe harbors. Specifically, we propose to add several new safe harbor protections for certain value-based arrangements, including care coordination arrangements, arrangements with varying levels of downside financial risk, as well as outcomes-based payment arrangements, and protection for certain remuneration provided to Federal health care program beneficiaries in the form of incentives and supports.

We anticipate that the proposed rule would have potential relevance to the majority of the types of providers and suppliers participating in Federal health care programs and others in commercial sectors, as well as the Federal health care programs and Federal health care program beneficiaries. We note that certain categories of providers, suppliers, and others are not eligible to use the proposed rule: Pharmaceutical manufacturers; manufacturers, distributors, and suppliers of DMEPOS; and laboratories. To estimate the number of providers and suppliers affected by this rule, we use US Census data. According to the US Census, there were 7,370 medical, dental, and hospital equipment and supplies merchant wholesaler firms; 482,522 ambulatory healthcare service firms; 3,293 hospital firms; and 9,153 nursing care facility firms operating in the US in 2015.[97] We request public comment on the entities affected by the rule.

We anticipate that a growing proportion of such providers and suppliers would be interested in reviewing and using these voluntary rules over time. Because compliance with safe harbors and CMP exceptions is voluntary and an arrangement need not fit in a safe harbor or exception to be legal, we anticipate that not all providers and suppliers would review the new regulations and use them. We estimate that 5 percent of affected entities that would be eligible to use the proposed rules may be interested in exploring value-based arrangements made possible by the rule in each of the first 10 years following publication of the final rule, leading those entities to review the rule. We estimate that reviewing the final rule will require an average of one hour of time each from a compliance officer and a lawyer. To estimate the costs associated with this review, we use a 2018 wage rate of $34.86 for compliance officers and $69.34 for lawyers from the Bureau of Labor Statistics,[98] and we double those wages to account for overhead and benefits. As a result, we estimate total regulatory review costs of $5.2 million in each of the first 10 years following finalization of the rule. We note that these costs are divided among approximately 25,000 entities each year, and therefore should be considered *de minimis* from the perspective of affected entities. We seek public comment on these assumptions.

The Department does not collect data regarding the number of providers, suppliers, and other individuals and entities that have entered into an arrangement that meets an existing safe harbor. Compliance with safe harbors is voluntary, and generally the question whether an arrangement complies with a safe harbor arises in the context of a defense raised by a defendant in an enforcement matter. Therefore, we cannot quantify with certainty the number of arrangements or number of healthcare providers, suppliers, and others who may avail themselves of these protections. For this reason, it is

[97] U.S. Census Bureau, 2015 SUSB Annual Data Tables by Establishment Industry, *https://www.census.gov/data/tables/2015/econ/susb/2015-susb-annual.html.*

[98] U.S. Department of Labor, Bureau of Labor Statistics, May 2018 National Occupational Employment and Wage Estimates United States, *https://www.bls.gov/oes/2018/may/oes_nat.htm.*

difficult, if not impossible, to assess the costs and benefits of these proposals, and to estimate changes in the number of arrangements that meet new or existing safe harbors. We seek public comment on the effect of this rule on changes in the number of agreements or arrangements that meet new or existing safe harbors.

Many affected providers and suppliers currently incur costs related to structuring arrangements to comply with existing fraud and abuse laws. While these proposals may not result in a reduction in compliance-related costs, we do not expect this rulemaking to increase total incremental costs. Rather, we expect that providers and suppliers interested in taking advantage of these new arrangements in order to more efficiently deliver care will shift resources currently devoted to complying with existing requirements to create and analyze new arrangements under these proposals. By way of example only, should a hospital expend resources to review—from a Federal anti-kickback statute perspective—a financial arrangement with a skilled nursing facility, any newly promulgated or revised safe harbors would be unlikely to change the amount of resources necessary to conduct such a review. As another example, should a hospital already document—by a written agreement—any financial arrangement with a skilled nursing facility, any newly promulgated or revised safe harbors would be unlikely to change the amount of resources necessary to enter into that written agreement. We seek public comment on these assumptions.

We also propose to add or revise safe harbor protections under the Federal anti-kickback statute for donations of cybersecurity technology, EHR arrangements, warranties, and local transportation. The new proposed safe harbor for cybersecurity technology and related services would be available to any provider, supplier, or other individual or entity. We expect broad use of this proposed safe harbor, with reduced costs for smaller and less well-equipped providers and overall savings for the national health system in reduced costs from cyberattacks, ransomware, and similar threats. Proposed modifications to the EHR safe harbor are modest and would clarify that protection for certain cybersecurity technology is included as part of an electronic health records arrangement, update provisions regarding interoperability to align with newer CMS and ONC standards in a manner that is not expected to increase costs as a result of this rulemaking and remove the sunset date. The EHR safe harbor would continue to be available to health plans and any individuals or entities, other than laboratories, that provide services covered by, and submit claims or requests for payment to, a Federal health care program. We would expect the same entities that are currently using the EHR safe harbor to continue to use the safe harbor with minimal, if any, additional regulatory review or compliance costs above current levels. We seek public comment on these assumptions.

We propose to modify the existing local transportation safe harbor slightly to expand mileage limits for rural areas and for transportation for discharged patients. This would primarily expand protection under the AKS for hospitals and physician practices in rural areas voluntarily to transport patients to necessary medical appointments or to their homes following a hospital stay. We anticipate no incremental regulatory costs to hospitals or others from the proposed rule, which changes only the distance traveled and no other regulatory requirements. This safe harbor would continue to be available only to established patients and eligible entities, which do not include individuals or entities (or family members or others acting on their behalf) that primarily supply healthcare items.

Further, the proposed rule would add a new safe harbor to protect certain arrangements and patient incentives provided by and among parties participating in CMS-sponsored models. CMS and OIG collectively, and OIG individually, have issued fraud and abuse waivers for 14 of these models. This proposed safe harbor would reduce the need for issuance of waivers, saving OIG 1,040 employee hours per year.

We expect that CMS, including the Innovation Center, will continue to test these models and others in the future. The purpose of this safe harbor is to streamline participation in existing and future CMS-sponsored models to reduce complexity and the administrative burden on participants that seek protection under the fraud and abuse laws while participating in a CMS-sponsored model. Although we cannot calculate the number of arrangements that CMS-sponsored model participants and CMS-sponsored model parties would undertake in the future, we expect this proposal would reduce the burden of documentation and the time, effort, and financial resources necessary to implement CMS-sponsored model arrangements and to provide CMS-sponsored model patient incentives. The proposal also would result in uniform requirements under the anti-kickback statute and beneficiary inducements CMP for those models that qualify, further reducing burden on entities, such as hospitals and physician practices, that participate in multiple models that currently have different conditions for each waiver. We seek public comment on the extent to which these provisions will affect these models.

Finally, the proposed rule would add a new safe harbor related to beneficiary incentives under the Medicare Shared Savings Program and a new CMP exception for certain telehealth technologies offered to patients receiving in-home dialysis, pursuant to the Budget Act of 2018. Although we cannot calculate the number of ACOs and their participants who would enter into arrangements that may qualify for protection under this safe harbor, we believe that this regulatory action would not create incremental costs for ACOs because it would reduce the amount of compliance resources ACOs currently use to provide beneficiary incentives. For example, we believe this action would reduce time, effort, and financial resources ACOs typically would incur to provide these beneficiary incentives under the applicable fraud and abuse waivers. We believe that the proposed telehealth technologies exception would reduce barriers to the use of in-home dialysis and could encourage increased use of home dialysis for beneficiaries. This could result in increased use of in-home dialysis for patients who would benefit relative to other treatment options. Ultimately, this could result in improved quality of care for beneficiaries with end-stage renal disease and overall cost savings to Federal health care programs because dialysis providers will have certainty that their arrangements will not result in CMP liability. This will also reduce burden by eliminating unnecessary travel costs for patients where in-home dialysis is more appropriate. We do not anticipate that this proposed rule will add any incremental costs to the regulatory costs dialysis providers already incur to comply with the new program rules under the Budget Act of 2018 because our requirements closely track CMS program rules. We seek public comment on the proposed rule's effects on in-home dialysis.

Given the information we have, including comments we received from the OIG RFI, we believe these proposals present the best approach to removing potential barriers to designing care coordination and other value-based arrangements that result in greater efficiency and improved care outcomes,

while minimizing the potential for the costs associated with fraud, waste, and abuse. We believe that the proposed rule would, on average, result in a net benefit to the healthcare industry, beneficiaries, and Federal health care programs and could alleviate the concerns expressed above. We believe there would be no incremental costs to providers and suppliers that already spend resources reviewing arrangements for compliance with fraud and abuse laws. Moreover, by adding flexibility to engage in certain innovative business arrangements without risk of liability under the statutes, we believe that these proposed regulations reduce the stringency of the existing regulatory scheme as it would otherwise apply to certain value-based arrangements; in addition, by offering new pathways to protect value-based arrangements, the proposed regulations would reduce inefficient behaviors, particularly industry behaviors that drive volume-based healthcare.

We would benefit from public input and information during the comment period regarding whether these proposals likely would have a net benefit on the industry and whether different or modified proposals would better facilitate the goals outlined in this proposed rule.

H. Alternatives Considered

We carefully considered the option of not pursuing regulatory action. However, based on comments to the OIG RFI, responses to OIG's annual Solicitation of New Safe Harbors and Special Fraud Alerts, and other industry feedback, we believe a need for regulatory reform exists in order to provide stakeholders with the flexibility necessary for innovative care delivery and payment redesign.

We also considered several other alternative approaches to the proposed safe harbors, revisions to safe harbors, and proposed exception as explained in great detail in the preceding preamble. For example, our proposals endeavor to distinguish between beneficial care coordination arrangements and payment-for-referral schemes that do not serve, and may be contrary to, the goals of coordinated care and the shift to value. We considered, and would benefit from public comment on, the benefits of our proposals and efficient ways we may distinguish payments to reward or induce referrals from remuneration provided to promote or support legitimate care coordination activities.

We also considered not using the value-based terms, definitions, and framework for proposed safe harbors (ee), (ff), (gg), and (hh), but we concluded that the fraud and abuse risks of protecting arrangements without the guardrails created by the value-based framework were too high. We believe these risks are significant because our proposed safe harbors in (ee) and (hh) could potentially protect arrangements under which providers and suppliers are paid on a fee-for-service basis by Medicare, which rewards the volume of services performed and items furnished.

VI. Paperwork Reduction Act

This document does not impose information collection and recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995.

List of Subjects

42 CFR Part 1001

Administrative practice and procedure, Fraud, Grant programs—health, Health facilities, Health professions, Maternal and child health, Medicaid, Medicare, Social Security.

42 CFR Part 1003

Fraud, Grant programs—health, Health facilities, Health professions, Medicaid, Reporting and recordkeeping.

For the reasons set forth in the preamble, the Office of Inspector General, Department of Health and Human Services, proposes to amend 42 CFR parts 1001 and 1003 as follows:

PART 1001—PROGRAM INTEGRITY—MEDICARE AND STATE HEALTH CARE PROGRAMS

■ 1. The authority citation for part 1001 continues to read as follows:

Authority: 42 U.S.C. 1302, 1320a–7, 1320a–7a, 1320a–7b, 1320a–7d, 1395u(j), 1395u(k), 1395w–104(e)(6), 1395y(d), 1395y(e), 1395cc(b)(2)(D), (E) and (F), and 1395hh; and sec. 2455, Pub. L. 103–355, 108 Stat. 3327 (31 U.S.C. 6101 note).

■ 2. Section 1001.952 is amended by:
■ a. Revising paragraphs (d), (g) introductory text, (g)(1), (g)(3)(i), and (g)(4);
■ b. Adding paragraphs (g)(5) and (6) before the undesignated text at the end of paragraph (g);
■ c. Designating the undesignated text at the end of paragraph (g) as paragraph (g)(7) and revising it;
■ d. Revising paragraph (y) introductory text, the second sentence of paragraph (y)(2), and paragraph (y)(3);
■ e. Removing and reserving paragraphs (y)(7) and (13);
■ f. Designating the note to paragraph (y) as paragraph (y)(14) and revising it;
■ g. Revising paragraphs (bb)(1)(iv)(B) and (bb)(2)(iii);
■ h. Designating the note to paragraph (bb) as paragraph (bb)(3) and revising it;
■ i. Adding reserved paragraphs (cc) and (dd); and
■ j. Adding paragraphs (ee), (ff), (gg), (hh), (ii), (jj), and (kk).

The revisions and additions read as follows:

§ 1001.952 Exceptions.

* * * * *

(d) *Personal services and management contracts and outcomes-based payment arrangements.*

(1) As used in section 1128B of the Act, ''remuneration'' does not include any payment made by a principal to an agent as compensation for the services of the agent, as long as all of the following standards are met:

(i) The agency agreement is set out in writing and signed by the parties.

(ii) The agency agreement covers all of the services the agent provides to the principal for the term of the agreement and specifies the services to be provided by the agent.

(iii) The term of the agreement is not less than 1 year.

(iv) The methodology for determining the compensation paid to the agent over the term of the agreement is set in advance, is consistent with fair market value in arm's-length transactions and is not determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made in whole or in part under Medicare, Medicaid, or other Federal health care programs.

(v) The services performed under the agreement do not involve the counseling or promotion of a business arrangement or other activity that violates any State or Federal law.

(vi) The aggregate services contracted for do not exceed those which are reasonably necessary to accomplish the commercially reasonable business purpose of the services.

(2) As used in section 1128B of the Act, ''remuneration'' does not include any outcomes-based payment as long as all of the standards in paragraphs (d)(2)(i) through (ix) of this section are met:

(i) The outcomes-based payment is made between or among parties that are collaborating to:

(A) Measurably improve (or maintain improvement in) quality of patient care; or

(B) Appropriately and materially reduce costs to, or growth in expenditures of, payors while improving, or maintaining the improved, quality of care for patients.

(ii) To receive an outcomes-based payment, the agent satisfies one or more specific evidence-based, valid outcome measures that are:

(A) Related to:

(*1*) Measurably improving, or maintaining the improved, quality of patient care;

(*2*) Appropriately and materially reducing costs to, or growth in expenditures of, payors while improving, or maintaining the improved quality of care for patients; or

(*3*) Both; and

(B) Selected based upon clinical evidence or credible medical support.

(iii) The methodology for determining the aggregate compensation (including any outcomes-based payments) paid between or among the parties over the term of the agreement is: Set in advance; commercially reasonable; consistent with fair market value; and not determined in a manner that directly takes into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made in whole or in part by a Federal health care program.

(iv) The agreement neither limits any party's ability to make decisions in their patients' best interest nor induces any party to reduce or limit medically necessary items or services.

(v) The term of the agreement is not less than 1 year.

(vi) The services performed under the agreement do not involve the counseling or promotion of a business arrangement or other activity that violates any State or Federal law.

(vii) For each outcome measure under the agreement, the parties:

(A) Regularly monitor and assess the agent's performance, including the impact of the outcomes-based payment arrangement on patient quality of care; and

(B) Periodically rebase during the term of the agreement, to the extent applicable.

(viii) The parties set forth in a signed writing, in advance of, or contemporaneous with, the commencement of the terms of the outcomes-based payment arrangement. The writing states, at a minimum: The services to be performed by the parties for the term of the agreement; the outcome measure(s) the agent must satisfy to receive an outcomes-based payment; the clinical evidence or credible medical support relied upon by the parties to select the outcome measure(s); and the schedule for the parties to regularly monitor and assess the outcome measure(s).

(ix) The principal has policies and procedures to promptly address and correct identified material performance failures or material deficiencies in quality of care resulting from the outcomes-based payment arrangement.

(3) For purposes of this paragraph (d):

(i) An agent of a principal is any person, other than a *bona fide* employee of the principal, who has an agreement to perform services for, or on behalf of, the principal.

(ii) Outcomes-based payments are limited to payments from a principal to an agent that:

(A) Reward the agent for improving (or maintaining improvement in) patient or population health by achieving one or more outcome measures that effectively and efficiently coordinate care across care settings; or

(B) Achieve one or more outcome measures that appropriately reduce payor costs while improving, or maintaining the improved quality of care for patients.

(iii) Outcomes-based payments exclude any payments:

(A) Made, directly or indirectly, by a pharmaceutical manufacturer; a manufacturer, distributor, or supplier of durable medical equipment, prosthetics, orthotics, or supplies; or a laboratory; or

(B) That relate solely to the achievement of internal cost savings for the principal.

* * * * *

(g) *Warranties.* As used in section 1128B of the Act, ''remuneration'' does not include any payment or exchange of anything of value under a warranty provided by a manufacturer or supplier of one or more items and services (provided the warranty covers at least one item) to the buyer (such as a healthcare provider or beneficiary) of the items and services, as long as the buyer complies with all of the following standards in paragraphs (g)(1) and (2) of this section and the manufacturer or supplier complies with all of the following standards in paragraphs (g)(3) through (6) of this section:

(1) The buyer (unless the buyer is a Federal health care program beneficiary) must fully and accurately report any price reduction of an item or service (including a free item or service) that was obtained as part of the warranty, in the applicable cost reporting mechanism or claim for payment filed with the Department or a State agency.

* * * * *

(3) * * *

(i) The manufacturer or supplier must fully and accurately report any price reduction of an item or service (including free items and services) that the buyer obtained as part of the warranty on the invoice or statement submitted to the buyer and inform the buyer of its obligations under paragraphs (g)(1) and (2) of this section.

* * * * *

(4) The manufacturer or supplier must not pay any remuneration to any individual (other than a beneficiary) or entity for any medical, surgical, or hospital expense incurred by a beneficiary other than for the cost of the items and services subject to the warranty.

(5) If a manufacturer or supplier offers a warranty for more than one item or one or more items and related services, the federally reimbursable items and services subject to the warranty must be reimbursed by the same Federal health care program and in the same Federal health care program payment.

(6) The manufacturer or supplier must not condition a warranty on a buyer's exclusive use of, or a minimum purchase of, any of the manufacturer's or supplier's items or services.

(7) For purposes of this paragraph (g), the term *warranty* means:

(i) Any written affirmation of fact or written promise made in connection with the sale of an item or bundle of items, or services in combination with one or more related items, by a manufacturer or supplier to a buyer, which affirmation of fact or written promise relates to the nature of the quality or workmanship and affirms or promises that such quality or workmanship is defect free or will meet a specified level of performance over a specified period of time;

(ii) Any undertaking in writing in connection with the sale by a manufacturer or supplier of an item or bundle of items, or services in combination with one or more related items, to refund, repair, replace, or take other remedial action with respect to such item or bundle of items in the event that such item or bundle of items, or services in combination with one or more related items, fails to meet the specifications set forth in the undertaking, which written affirmation, promise, or undertaking becomes part of the basis of the bargain between a seller and a buyer for purposes other than resell of such item or bundle of items; or

(iii) A manufacturer's or supplier's agreement to replace another manufacturer's or supplier's defective item or bundle of items (which is covered by an agreement made in accordance with this paragraph (g)), on terms equal to the agreement that it replaces.

* * * * *

(y) *Electronic health records items and services.* As used in section 1128B

of the Act, ''remuneration'' does not include nonmonetary remuneration (consisting of items and services in the form of software or information technology and training services, including certain cybersecurity software and services) necessary and used predominantly to create, maintain, transmit, receive, or protect electronic health records, if all of the conditions in paragraphs (y)(1) through (13) of this section are met:

* * * * *

(2) * * * For purposes of this paragraph (y)(2), software is deemed to be interoperable if, on the date it is provided to the recipient, it is certified by a certifying body authorized by the National Coordinator for Health Information Technology to electronic health record certification criteria identified in 45 CFR part 170.

(3) The donor (or any person on the donor's behalf) does not engage in a practice constituting information blocking, as defined in 45 CFR part 171, in connection with the donated items or services.

* * * * *

(7) [Reserved]

* * * * *

(13) [Reserved]

* * * * *

(14) For purposes of this paragraph (y), the following definitions apply:

(i) *Cybersecurity* means the process of protecting information by preventing, detecting, and responding to cyberattacks;

(ii) *Health plan* shall have the meaning set forth at § 1001.952(l)(2);

(iii) *Interoperable* shall mean able to:

(A) Securely exchange data with, and use data from other health information technology without special effort on the part of the user;

(B) Allow for complete access, exchange, and use of all electronically accessible health information for authorized use under applicable State or Federal law; and

(C) Does not constitute information blocking as defined in 45 CFR part 171; and

(iv) *Electronic health record* shall mean a repository of electronic health information that:

(A) Is transmitted by or maintained in electronic media; and

(B) Relates to the past, present, or future health or condition of an individual or the provision of healthcare to an individual.

* * * * *

(bb) * * *

(1) * * *

(iv) * * *

(B) Within 25 miles of the healthcare provider or supplier to or from which the patient would be transported, or within 75 miles if the patient resides in a rural area, as defined in this paragraph (bb), except that, if the patient is being discharged from an inpatient facility and transported to the patient's residence, or another residence of the patient's choice, the mileage limits in this paragraph (bb)(1)(iv)(B) shall not apply; and

* * * * *

(2) * * *

(iii) The eligible entity makes the shuttle service available only within the eligible entity's local area, meaning there are no more than 25 miles from any stop on the route to any stop at a location where healthcare items or services are provided, except that if a stop on the route is in a rural area, the distance may be up to 75 miles between that stop and any providers or suppliers on the route;

* * * * *

(3) For purposes of this paragraph (bb), the following definitions apply:

(i) An *eligible entity* is any individual or entity, except for individuals or entities (or family members or others acting on their behalf) that primarily supply healthcare items;

(ii) An *established patient* is a person who has selected and initiated contact to schedule an appointment with a provider or supplier, or who previously has attended an appointment with the provider or supplier;

(iii) A *shuttle service* is a vehicle that runs on a set route, on a set schedule;

(iv) A *rural area* is an area that is not an urban area, as defined in paragraph (bb)(3)(v) of this section; and

(v) An *urban area* is:

(A) A Metropolitan Statistical Area (MSA) or New England County Metropolitan Area (NECMA), as defined by the Executive Office of Management and Budget; or

(B) The following New England counties, which are deemed to be parts of urban areas under section 601(g) of the Social Security Amendments of 1983 (Pub. L. 98–21, 42 U.S.C. 1395ww (note)): Litchfield County, Connecticut; York County, Maine; Sagadahoc County, Maine; Merrimack County, New Hampshire; and Newport County, Rhode Island.

(cc)–(dd) [Reserved]

(ee) *Care coordination arrangements to improve quality, health outcomes, and efficiency.* As used in section 1128B of the Act, ''remuneration'' does not include the exchange of anything of value pursuant to a value-based arrangement if all of the standards in paragraphs (ee)(1) through (12) of this section are met:

(1) The VBE participants establish one or more specific evidence-based, valid outcome measures against which the recipient will be measured and which the parties reasonably anticipate will advance the coordination and management of care of the target patient population.

(2) The value-based arrangement is commercially reasonable, considering both the arrangement itself and all value-based arrangements within the VBE.

(3) In advance of, or contemporaneous with, the commencement of the value-based arrangement or any material change to the value-based arrangement, the offeror of the remuneration and any recipient(s) of such remuneration have set forth the terms of the value-based arrangement in a signed writing. The writing states, at a minimum:

(i) The value-based activities to be undertaken by the parties to the value-based arrangement;

(ii) The term of the value-based arrangement;

(iii) The target patient population;

(iv) A description of the remuneration;

(v) The offeror's cost for the remuneration;

(vi) The percentage of the offeror's cost contributed by the recipient;

(vii) If applicable, the frequency of the recipient's contribution payments for ongoing costs; and

(viii) The specific evidence-based, valid outcome measure(s) against which the recipient will be measured.

(4) The remuneration exchanged:

(i) Is in-kind;

(ii) Is used primarily to engage in value-based activities that are directly connected to the coordination and management of care for the target patient population;

(iii) Does not induce VBE participants to furnish medically unnecessary items or services or reduce or limit medically necessary items or services furnished to any patient; and

(iv) Is not funded by, and does not otherwise result from the contributions of, any individual or entity outside of the applicable VBE.

(5) The offeror of the remuneration does not take into account the volume or value of, or condition the remuneration on:

(i) Referrals of patients who are not part of the target patient population; or

(ii) Business not covered under the value-based arrangement.

(6) The recipient pays at least 15 percent of the offeror's cost for the in-kind remuneration. If a one-time cost, the recipient makes such contribution in advance of receiving the in-kind

remuneration. If an ongoing cost, the recipient makes such contribution at reasonable, regular intervals.

(7) The value-based arrangement:

(i) Is directly connected to the coordination and management of care of the target patient population;

(ii) Does not place any limitation on VBE participants' ability to make decisions in the best interest of their patients;

(iii) Does not direct or restrict referrals to a particular provider, practitioner, or supplier if:

(A) A patient expresses a preference for a different practitioner, provider, or supplier;

(B) The patient's payor determines the provider, practitioner, or supplier; or

(C) Such direction or restriction is contrary to applicable law or regulations under titles XVIII and XIX of the Act; and

(iv) Does not include marketing to patients of items or services or engaging in patient recruitment activities.

(8) The VBE, a VBE participant in the value-based arrangement acting on the VBE's behalf, or the VBE's accountable body or responsible person monitors and assesses, and reports such monitoring and assessment to the VBE's accountable body or responsible person as applicable, no less frequently than annually or at least once during the term of the value-based arrangement for arrangements with terms of less than 1 year:

(i) The coordination and management of care for the target population in the value-based arrangement;

(ii) Any deficiencies in the delivery of quality care under the value-based arrangement; and

(iii) Progress toward achieving the evidence-based, valid outcome measure(s) in the value-based arrangement.

(9) The parties terminate the arrangement within 60 days if the VBE's accountable body or responsible person determines that the value-based arrangement:

(i) Is unlikely to further the coordination and management of care for the target patient population;

(ii) Has resulted in material deficiencies in quality of care; or

(iii) Is unlikely to achieve the evidence-based, valid outcome measure(s).

(10) The offeror does not, and should not, know that the remuneration is likely to be diverted, resold, or used by the recipient for an unlawful purpose.

(11) The VBE or VBE participant makes available to the Secretary, upon request, all materials and records sufficient to establish compliance with the conditions of this paragraph (ee).

(12) For purposes of this paragraph (ee), the following definitions apply:

(i) *Coordination and management of care (or coordinating and managing care)* means, for purposes of the anti-kickback statute safe harbors at § 1001.952, the deliberate organization of patient care activities and sharing of information between two or more VBE participants or VBE participants and patients, tailored to improving the health outcomes of the target patient population, in order to achieve safer and more effective care for the target patient population.

(ii) *Target patient population* means an identified patient population selected by the VBE or its VBE participants using legitimate and verifiable criteria that:

(A) Are set out in writing in advance of the commencement of the value-based arrangement; and

(B) Further the value-based enterprise's value-based purpose(s).

(iii) *Value-based activity*

(A) Means any of the following activities, provided that the activity is reasonably designed to achieve at least one value-based purpose of the value-based enterprise:

(1) The provision of an item or service;

(2) The taking of an action; or

(3) The refraining from taking an action.

(B) Does not include the making of a referral.

(iv) *Value-based arrangement* means an arrangement for the provision of at least one value-based activity for a target patient population between or among:

(A) The value-based enterprise and one or more of its VBE participants; or

(B) VBE participants in the same value-based enterprise.

(v) *Value-based enterprise* or *VBE* means two or more VBE participants:

(A) Collaborating to achieve at least one value-based purpose;

(B) Each of which is a party to a value-based arrangement with the other or at least one other VBE participant in the value-based enterprise;

(C) That have an accountable body or person responsible for financial and operational oversight of the value-based enterprise; and

(D) That have a governing document that describes the value-based enterprise and how the VBE participants intend to achieve its value-based purpose(s).

(vi) *Value-based enterprise participant* or *VBE participant* means an individual or entity that engages in at least one value-based activity as part of a value-based enterprise. VBE participant does not include a pharmaceutical manufacturer; a manufacturer, distributor, or supplier of durable medical equipment, prosthetics, orthotics, or supplies; or a laboratory.

(vii) *Value-based purpose* means:

(A) Coordinating and managing the care of a target patient population;

(B) Improving the quality of care for a target patient population;

(C) Appropriately reducing the costs to, or growth in expenditures of, payors without reducing the quality of care for a target patient population; or

(D) Transitioning from healthcare delivery and payment mechanisms based on the volume of items and services provided to mechanisms based on the quality of care and control of costs of care for a target patient population.

(ff) *Value-based arrangements with substantial downside financial risk.* As used in section 1128B of the Act, ''remuneration'' does not include the exchange of payments or anything of value between a VBE and a VBE participant pursuant to a value-based arrangement if all of the standards in paragraphs (ff)(1) through (8) of this section are met:

(1) The VBE (directly or through a VBE participant acting on the VBE's behalf) has assumed (or is contractually obligated to assume in the next 6 months) substantial downside financial risk (as defined in this paragraph (ff)) from a payor for providing or arranging for the provision of items and services for a target patient population.

(2) Under the value-based arrangement, the VBE participant meaningfully shares in the VBE's substantial downside financial risk for providing or arranging for the provision of items and services for the target patient population. For purposes of this paragraph (ff), a VBE participant meaningfully shares in the VBE's substantial downside financial risk if the value-based arrangement provides that the VBE participant is subject to risk under one of the following three methodologies:

(i) A risk-sharing payment pursuant to which the VBE participant is at risk for 8 percent of the amount for which the VBE is at risk under its agreement with the applicable payor;

(ii) A partial or full capitation payment or similar payment methodology, excluding the Medicare inpatient prospective payment system or other like payment methodology; or

(iii) In the case of a VBE participant that is a physician, a payment that meets the requirements of the regulatory exception for value-based arrangements with meaningful downside financial risk at § 411.357(aa)(2) of this title.

(3) The remuneration provided by, or shared among, the VBE and VBE participant:

(i) Is used primarily to engage in value-based activities that are directly connected to the items and services for which the VBE is at substantial downside financial risk and that are set forth in writing pursuant to paragraph(ff)(4) of this section;

(ii) Is directly connected to one or more of the VBE's value-based purposes, at least one of which must be the coordination and management of care for the target patient population;

(iii) Does not induce VBE participants to reduce or limit medically necessary items or services furnished to any patient;

(iv) Does not include the offer or receipt of an ownership or investment interest in an entity or any distributions related to such ownership or investment interest; and

(v) Is not funded by, and does not otherwise result from the contributions of, any individual or entity outside of the VBE.

(4) In advance of, or contemporaneous with, the commencement of the value-based arrangement or any material change to the value-based arrangement, the VBE and VBE participant set forth in a signed writing the terms of the value-based arrangement. The writing states all material terms of the value-based arrangement, including: A description of the nature and extent of the VBE's substantial downside financial risk for the target patient population; a description of the manner in which the recipient meaningfully shares in the VBE's substantial downside financial risk; the value-based activities; the target patient population; and the type and the offeror's cost of the remuneration.

(5) The VBE or VBE participant offering the remuneration does not take into account the volume or value of, or condition the remuneration on:

(i) Referrals of patients who are not part of the target patient population; or

(ii) Business not covered under the value-based arrangement.

(6) The value-based arrangement does not:

(i) Place any limitation on VBE participants' ability to make decisions in the best interest of their patients;

(ii) Direct or restrict referrals to a particular provider, practitioner, or supplier if:

(A) A patient expresses a preference for a different practitioner, provider, or supplier;

(B) The patient's payor determines the provider, practitioner, or supplier; or

(C) Such direction or restriction is contrary to applicable law or regulations under titles XVIII and XIX of the Act; or

(iii) Include marketing to patients of items or services or engaging in patient recruitment activities.

(7) The VBE or VBE participant makes available to the Secretary, upon request, all materials and records sufficient to establish compliance with the conditions of this paragraph (ff).

(8) For purposes of this paragraph (ff), the following definitions apply:

(i) *Substantial downside financial risk* means risk, for the entire term of the value-based arrangement, in the form of:

(A) Shared savings with a repayment obligation to the payor of at least 40 percent of any shared losses, where loss is determined based upon a comparison of costs to historical expenditures, or to the extent such data is unavailable, evidence-based, comparable expenditures;

(B) A repayment obligation to the payor under an episodic or bundled payment arrangement of at least 20 percent of any total loss, where loss is determined based upon a comparison of costs to historical expenditures, or to the extent such data is unavailable, evidence-based, comparable expenditures;

(C) A prospectively paid population-based payment for a defined subset of the total cost of care of a target patient population, where such payment is determined based upon a review of historical expenditures, or to the extent such data is unavailable, evidence-based, comparable expenditures; or

(D) A partial capitated payment from the payor for a set of items and services for the target patient population, where such capitated payment reflects a discount equal to at least 60 percent of the total expected fee-for-service payments based on historical expenditures, or to the extent such data is unavailable, evidence-based, comparable expenditures of the VBE participants to the value-based arrangement.

(ii) *Coordination and management of care, target patient population, value-based activity, value-based arrangement, value-based enterprise, value-based purpose,* and *VBE participant* shall have the meaning set forth in paragraph (ee) of this section.

(gg) *Value-based arrangements with full financial risk.* As used in section 1128B of the Act, ''remuneration'' does not include the exchange of payments or anything of value between the VBE and a VBE participant pursuant to a value-based arrangement if all of the standards in paragraphs (gg)(1) through (8) of this section are met:

(1) The VBE (directly or through a VBE participant acting on behalf of the VBE) has assumed (or is contractually obligated to assume in the next 6 months) full financial risk from a payor and has a signed writing with the payor that specifies the target patient population and contains terms evidencing that the VBE is at full financial risk for that population for a period of at least 1 year.

(2) The value-based arrangement is set out in a writing signed by the parties that specifies the material terms of the value-based arrangement, including the value-based activities to be undertaken by the parties, and is for a period of at least 1 year.

(3) The VBE participant does not claim payment in any form directly or indirectly from a payor for items or services covered under the value-based arrangement.

(4) The remuneration exchanged between the VBE and a VBE participant:

(i) Is used primarily to engage in the value-based activities set forth in writing pursuant to paragraph (gg)(2) of this section;

(ii) Is directly connected to one or more of the VBE's value-based purposes, at least one of which must be the coordination and management of care for the target patient population;

(iii) Does not induce the VBE or VBE participants to reduce or limit medically necessary items or services furnished to any patient;

(iv) Does not include the offer or receipt of an ownership or investment interest in an entity or any distributions related to such ownership or investment interest; and

(v) Is not funded by, and does not otherwise result from the contributions of, any individual or entity outside of the VBE.

(5) The VBE or VBE participant does not take into account the volume or value of, or condition the remuneration on:

(i) Referrals of patients who are not part of the target patient population; or

(ii) Business not covered under the value-based arrangement.

(6) The VBE provides or arranges for:

(i) An operational utilization review program; and

(ii) A quality assurance program that protects against underutilization and specifies patient goals, including measurable outcomes, where appropriate.

(7) The value-based arrangement does not include marketing to patients of items or services or engaging in patient recruitment activities.

(8) The VBE or VBE participant makes available to the Secretary, upon request,

all materials and records sufficient to establish compliance with the conditions of this paragraph (gg).

(9) For purposes of this paragraph (gg), the following definitions apply:

(i) *Full financial risk* means the VBE is financially responsible for the cost of all items and services covered by the applicable payor for each patient in the target patient population and is prospectively paid by the applicable payor;

(ii) *Items and services* shall have the meaning set forth in § 1001.952(t)(2)(iv); and

(iii) *Coordination and management of care, target patient population, value-based activity, value-based arrangement, value-based enterprise, value-based purpose,* and *VBE participant* shall have the meaning set forth in paragraph (ee) of this section.

(hh) *Arrangements for patient engagement and support to improve quality, health outcomes, and efficiency.* As used in section 1128B of the Act, ''remuneration'' does not include a patient engagement tool or support furnished by a VBE participant to a patient in a target patient population if all of the conditions in paragraphs (hh)(1) through (6) of this section are met:

(1) The patient engagement tool or support is furnished directly to the patient by a VBE participant.

(2) No individual or entity outside of the applicable VBE funds or otherwise contributes to the provision of the patient engagement tool or support.

(3) The patient engagement tool or support:

(i) Is an in-kind preventive item, good, or service, or an in-kind item, good, or service such as health-related technology, patient health-related monitoring tools and services, or supports and services designed to identify and address a patient's social determinants of health;

(ii) That has a direct connection to the coordination and management of care of the target patient population;

(iii) Does not include any gift card, cash, or cash equivalent;

(iv) Does not include any in-kind item, good, or service used for patient recruitment or marketing of items or services to patients;

(v) Does not result in medically unnecessary or inappropriate items or services reimbursed in whole or in part by a Federal health care program;

(vi) Is recommended by the patient's licensed healthcare provider; and

(vii) Advances one or more of the following goals:

(A) Adherence to a treatment regimen determined by the patient's licensed healthcare provider.

(B) Adherence to a drug regimen determined by the patient's licensed healthcare provider.

(C) Adherence to a follow-up care plan established by the patient's licensed healthcare provider.

(D) Management of a disease or condition as directed by the patient's licensed healthcare provider.

(E) Improvement in measurable evidence-based health outcomes for the patient or for the target patient population.

(F) Ensuring patient safety.

(4) The offeror does not, and should not, know that the remuneration is likely to be diverted, sold, or utilized by the patient other than for the express purpose for which the patient engagement tool or support is provided.

(5) The aggregate retail value of patient engagement tools and supports furnished to a patient by a VBE participant on an annual basis does not exceed $500 unless such patient engagement tools and supports are furnished to patients based on a good faith, individualized determination of the patient's financial need.

(6) The VBE participant makes available to the Secretary, upon request, all materials and records sufficient to establish that the patient engagement tool or support was distributed in a manner that meets the conditions of this paragraph (hh).

(7) For purposes of this paragraph (hh), *coordination and management of care, target patient population, value-based purpose, VBE,* and *VBE participant* shall have the meaning set forth in paragraph (ee) of this section.

(ii) *CMS-sponsored model arrangements and CMS-sponsored model patient incentives.*

(1) As used in section 1128B of the Act, ''remuneration'' does not include an exchange of anything of value between or among CMS-sponsored model parties under a CMS-sponsored model arrangement in a model for which CMS has determined that this safe harbor is available if all of the following conditions are met:

(i) The CMS-sponsored model parties reasonably determine that the CMS-sponsored model arrangement will advance one or more goals of the CMS-sponsored model;

(ii) The exchange of value does not induce CMS-sponsored model parties or other providers or suppliers to furnish medically unnecessary items or services or reduce or limit medically necessary items or services furnished to any patient;

(iii) The CMS-sponsored model parties do not offer, pay, solicit, or receive remuneration in return for, or to induce or reward, any Federal health care program referrals or other Federal health care program business generated outside of the CMS-sponsored model;

(iv) The CMS-sponsored model parties, in advance of, or contemporaneous with the commencement of, the CMS-sponsored model arrangement, set forth the terms of the CMS-sponsored model arrangement in a signed writing. The writing must specify, at a minimum, the activities to be undertaken by the CMS-sponsored model parties and the nature of the remuneration to be exchanged under the CMS-sponsored model arrangement;

(v) The parties to the CMS-sponsored model arrangement make available to the Secretary, upon request, all materials and records sufficient to establish whether the remuneration was exchanged in a manner that meets the conditions of this safe harbor; and

(vi) The CMS-sponsored model parties satisfy such programmatic requirements as may be imposed by CMS in connection with the use of this safe harbor.

(2) As used in section 1128B of the Act, ''remuneration'' does not include a CMS-sponsored model patient incentive under a model for which CMS has determined that this safe harbor is available, if all of the conditions of paragraph (ii)(2)(i) through (v) are met of this section:

(i) The CMS-sponsored model participant reasonably determines that the CMS-sponsored model patient incentive will advance one or more goals of the CMS-sponsored model;

(ii) The CMS-sponsored model patient incentive has a direct connection to the patient's healthcare;

(iii) The CMS-sponsored model participant makes available to the Secretary, upon request, all materials and records sufficient to establish whether the CMS-sponsored model patient incentive was distributed in a manner that meets the conditions of this paragraph; and

(iv) The CMS-sponsored model participant satisfies such programmatic requirements as may be imposed by CMS in connection with the use of this safe harbor.

(v) For purposes of this paragraph (ii)(2), a patient may retain any incentives received prior to the termination or expiration of the participation documentation of the CMS-sponsored model participant.

(3) For purposes of this paragraph (ii), the following definitions apply:

(i) *CMS-sponsored model* means:

(A) A model being tested under section 1115A(b) of the Act or a model

expanded under section 1115A(c) of the Act; or

(B) The Medicare shared savings program under section 1899 of the Act;

(ii) *CMS-sponsored model arrangement* means an arrangement between or among CMS-sponsored model parties to engage in activities under the CMS-sponsored model and that is consistent with, and is not a type of arrangement prohibited by, the participation documentation;

(iii) *CMS-sponsored model participant* means an individual or entity that is subject to, and is operating under, participation documentation with CMS to participate in a CMS-sponsored model;

(iv) *CMS-sponsored model party* means:

(A) A CMS-sponsored model participant; or

(B) Other individual or entity who the participation documentation specifies may enter into a CMS-sponsored model arrangement;

(v) *CMS-sponsored model patient incentive* means remuneration not of a type prohibited by the participation documentation and is furnished consistent with the CMS-sponsored model by a CMS-sponsored model participant (or by an agent of the CMS-sponsored model participant under the CMS-sponsored model participant's direction and control) directly to a patient under the CMS-sponsored model; and

(vi) *Participation documentation* means the participation agreement, cooperative agreement, regulations, or model-specific addendum to an existing contract with CMS that:

(A) Is currently in effect, and

(B) Specifies the terms of a CMS-sponsored model.

(jj) *Cybersecurity technology and related services.* As used in section 1128B of the Act, ''remuneration'' does not include nonmonetary remuneration (consisting of certain types of cybersecurity technology and services), if all of the conditions in paragraphs (jj)(1) through (5) of this section are met:

(1) The technology and services are necessary and used predominantly to implement and maintain effective cybersecurity.

(2) The donor does not:

(i) Directly take into account the volume or value of referrals or other business generated between the parties when determining the eligibility of a potential recipient for the technology or services, or the amount or nature of the technology or services to be donated; or

(ii) Condition the donation of technology or services, or the amount or nature of the technology or services to be donated, on future referrals.

(3) Neither the recipient nor the recipient's practice (or any affiliated individual or entity) makes the receipt of technology or services, or the amount or nature of the technology or services, a condition of doing business with the donor.

(4) The arrangement is set forth in a written agreement that:

(i) Is signed by the parties;

(ii) Describes the technology and services being provided and the amount of the recipient's contribution, if any; and

(5) The donor does not shift the costs of the technology or services to any Federal health care program.

(6) For purposes of this paragraph (jj) the following definitions apply:

(i) *Cybersecurity* means the process of protecting information by preventing, detecting, and responding to cyberattacks.

(ii) *Technology* means any software or other types of information technology, other than hardware.

(kk) *ACO Beneficiary Incentive Program.* As used in section 1128B of the Act, ''remuneration'' does not include an incentive payment made by an ACO to an assigned beneficiary under a beneficiary incentive program established under section 1899(m) of the Act, as amended by Congress from time to time, if the incentive payment is made in accordance with the requirements found in such subsection.

PART 1003—CIVIL MONEY PENALTIES, ASSESSMENTS AND EXCLUSIONS

■ 3. The authority citation for part 1003 continues to read as follows:

Authority: 42 U.S.C. 262a, 1302, 1320–7, 1320a–7a, 1320b–10, 1395u(j), 1395u(k), 1395cc(j), 1395w–141(i)(3), 1395dd(d)(1), 1395mm, 1395nn(g), 1395ss(d), 1396b(m), 11131(c), and 11137(b)(2).

■ 4. Section 1003.110 is amended by adding paragraph (10) to the definition of ''remuneration'' and adding in alphabetical order a definition for ''telehealth technologies'' to read as follows:

§ 1003.110 Definitions.

* * * * *

Remuneration * * *

* * * * *

(10) The provision of telehealth technologies by a provider of services or a renal dialysis facility (as such terms are defined for purposes of title XVIII of the Act) to an individual with end stage renal disease who is receiving home dialysis for which payment is being made under part B of such title, if—

(i) The telehealth technologies are furnished to the individual by the provider of services or the renal dialysis facility that is currently providing the in-home dialysis, telehealth visits, or other end stage renal disease care to the patient;

(ii) The telehealth technologies are not offered as part of any advertisement or solicitation;

(iii) The telehealth technologies contribute substantially to the provision of telehealth services related to the individual's end stage renal disease, is not of excessive value, and is not duplicative of technology that the beneficiary already owns if that technology is adequate for the telehealth purposes; and

(iv) The provider of services or a renal dialysis facility does not bill Federal health care programs, other payors, or individuals for the telehealth technologies, claim the value of the telehealth technologies as a bad debt for payment purposes under a Federal health care program, or otherwise shift the burden of the value of the telehealth technologies onto a Federal health care program, other payors, or individuals.

* * * * *

Telehealth technologies, for purposes of the definition of the term ''remuneration'' as set forth in this section and the telehealth technologies exception to section 50302(c) of the Bipartisan Budget Act of 2018, which adds an exception as new section 1128A(i)(6)(J) of the Act, means multimedia communications equipment that includes, at a minimum, audio and video equipment permitting two-way, real-time interactive communication between the patient and distant site physician or practitioner used in the diagnosis, intervention, or ongoing care management—paid for by Medicare Part B—between a patient and the remote healthcare provider. Telephones, facsimile machines, and electronic mail systems are not telehealth technologies.

* * * * *

Dated: September 30, 2019.

Alex M. Azar II,

Secretary.

Joanne M. Chiedi,

Acting Inspector General.

[FR Doc. 2019–22027 Filed 10–9–19; 4:15 pm]

BILLING CODE 4152–04–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 411

[CMS–1720–P]

RIN 0938–AT64

Medicare Program; Modernizing and Clarifying the Physician Self-Referral Regulations

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

SUMMARY: This proposed rule would address any undue regulatory impact and burden of the physician self-referral law. This proposed rule is being issued in conjunction with the Centers for Medicare & Medicaid Services' (CMS) Patients over Paperwork initiative and the Department of Health and Human Services' (the Department or HHS) Regulatory Sprint to Coordinated Care. This proposed rule proposes exceptions to the physician self-referral law for certain value-based compensation arrangements between or among physicians, providers, and suppliers. It would also create a new exception for certain arrangements under which a physician receives limited remuneration for items or services actually provided by the physician; create a new exception for donations of cybersecurity technology and related services; and amend the existing exception for electronic health records (EHR) items and services. This proposed rule also provides critically necessary guidance for physicians and health care providers and suppliers whose financial relationships are governed by the physician self-referral statute and regulations.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on December 31, 2019.

ADDRESSES: In commenting, please refer to file code CMS–1720–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission. You may submit comments in one of four 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–1720–P, P.O. Box 8013, 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–1720–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* Alternatively, you may deliver (by hand or courier) your written comments ONLY to the following addresses prior to the close of the comment period:

a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue SW, Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 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: Lisa O. Wilson, (410) 786–8852. Matthew Edgar, (410) 786–0698.

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.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1–800–743–3951.

Acronyms

In addition, because of the many organizations and terms to which we refer by acronym in this proposed rule, we are listing these acronyms and their corresponding terms in alphabetical order below:

ACO Accountable care organization
API Application programming interface
ASC Ambulatory surgical center
CEC Comprehensive ESRD Care Model
CFR Code of Federal Regulations
CHIP Children's Health Insurance Program
CISA Cybersecurity Information Sharing Act of 2015 (Pub. L. 114–113, enacted on December 18, 2015)
CJR Comprehensive Care for Joint Replacement Model
CMP Civil monetary penalty
CMS RFI Request for Information Regarding the Physician Self-Referral Law (83 FR 29524)
CY Calendar year
DHS Designated health services
DMEPOS Durable medical equipment, prosthetics, orthotics & supplies
DRA Deficit Reduction Act of 2005 (Pub. L. 109–171, enacted on February 8, 2006)
DRG Diagnosis-related group
EHR Electronic health records
EKG Electrocardiogram
EMTALA Emergency Medical Treatment and Labor Act (Pub. L. 99–272, enacted on April 7, 1986)
ERISA Employee Retirement Income Security Act of 1974 (Pub. L. 93–406, enacted on September 2, 1974)
ESOP Employee stock ownership plan
ESRD End-stage renal disease
FFS Fee-for-service
FQHC Federally qualified health center
FR Federal Register
FY Fiscal year
HCIC Health care industry cybersecurity
HHS [Department of] Health and Human Services
HIPAA Health Insurance Portability and Accountability Act of 1996 (Pub. L. 104–191, enacted August 21, 1996)
IPA Independent practice association
IPPS Acute Care Hospital Inpatient Prospective Payment System
IRS Internal Revenue Service
IT Information technology
MA Medicare Advantage
MIPPA Medicare Improvements for Patients and Providers Act (Pub. L. 110–275, enacted on July 15, 2008)
MMA Medicare Prescription Drug, Improvement and Modernization Act of 2003 (Pub. L. 108–173, enacted on December 8, 2003)
NIST National Institute of Standards and Technology
NPP Nonphysician practitioner
NPRM Notice of proposed rulemaking

OBRA 89 Omnibus Budget Reconciliation Act of 1989 (Pub. L. 101–239, enacted on December 19, 1989)
OBRA 90 Omnibus Budget Reconciliation Act of 1990 (Pub. L. 101–508, enacted on November 5, 1990)
OBRA 93 Omnibus Budget Reconciliation Act of 1993 (Pub. L. 103–66, enacted on August 10, 1993)
OCM Oncology Care Model
OIG [HHS] Office of Inspector General
OMB Office of Management and Budget
ONC Office of the National Coordinator for Health Information Technology
OPPS Hospital Outpatient Prospective Payment System
PFS Physician Fee Schedule
PHI Protected health information
PHSA Public Health Service Act (Pub. L. 178–410, enacted on July 1, 1944)
PPS Prospective payment system
RFI Request for information
RHC Rural health clinic
RVU Relative value unit
SNF Skilled nursing facility
SRDP CMS Voluntary Physician Self-Referral Disclosure Protocol

I. Background

A. Statutory and Regulatory History

Section 1877 of the Social Security Act (the Act), also known as the physician self-referral law: (1) Prohibits a physician from making referrals for certain designated health services payable by Medicare to an entity with which he or she (or an immediate family member) has a financial relationship, unless an exception applies; and (2) prohibits the entity from filing claims with Medicare (or billing another individual, entity, or third party payer) for those referred services. A financial relationship is an ownership or investment interest in the entity or a compensation arrangement with the entity. The statute establishes a number of specific exceptions and grants the Secretary of the Department of Health and Human Services (the Secretary) the authority to create regulatory exceptions for financial relationships that do not pose a risk of program or patient abuse. Section 1903(s) of the Act extends aspects of the physician self-referral prohibitions to Medicaid. For additional information about section 1903(s) of the Act, see 66 FR 857 through 858.

This rulemaking follows a history of rulemakings related to the physician self-referral law. The following discussion provides a chronology of our more significant and comprehensive rulemakings; it is not an exhaustive list of all rulemakings related to the physician self-referral law. After the passage of section 1877 of the Act, we proposed rulemakings in 1992 (related only to referrals for clinical laboratory services) (57 FR 8588) (the 1992 proposed rule) and 1998 (addressing referrals for all designated health services) (63 FR 1659) (the 1998 proposed rule). We finalized the proposals from the 1992 proposed rule in 1995 (60 FR 41914) (the 1995 final rule), and issued final rules following the 1998 proposed rule in three stages. The first final rulemaking (Phase I) was published in the **Federal Register** on January 4, 2001 as a final rule with comment period (66 FR 856). The second final rulemaking (Phase II) was published in the **Federal Register** on March 26, 2004 as an interim final rule with comment period (69 FR 16054). Due to a printing error, a portion of the Phase II preamble was omitted from the March 26, 2004 **Federal Register** publication. That portion of the preamble, which addressed reporting requirements and sanctions, was published on April 6, 2004 (69 FR 17933). The third final rulemaking (Phase III) was published in the **Federal Register** on September 5, 2007 as a final rule (72 FR 51012).

In addition to Phase I, Phase II, and Phase III, we issued final regulations on August 19, 2008 in the Fiscal Year (FY) 2009 Inpatient Prospective Payment System final rule with comment period (73 FR 48434) (the FY 2009 IPPS final rule). That rulemaking made various revisions to the physician self-referral regulations, including: (1) Revisions to the ''stand in the shoes'' provisions; (2) establishment of provisions regarding the period of disallowance and temporary noncompliance with signature requirements; (3) prohibitions on per unit of service (''per-click'') and percentage-based compensation formulas for determining the rental charges for office space and equipment lease arrangements; and (4) expansion of the definition of ''entity.''

After passage of the Patient Protection and Affordable Care Act of 2010 (Pub. L. 111–148) (Affordable Care Act), we issued final regulations on November 29, 2010 in the Calendar Year (CY) 2011 Physician Fee Schedule (PFS) final rule with comment period that codified a disclosure requirement established by the Affordable Care Act for the in-office ancillary services exception (75 FR 73443). We also issued final regulations on November 24, 2010 in the CY 2011 Outpatient Prospective Payment System (OPPS) final rule with comment period (75 FR 71800), on November 30, 2011 in the CY 2012 OPPS final rule with comment period (76 FR 74122), and on November 10, 2014 in the CY 2015 OPPS final rule with comment period (79 FR 66987) that established or revised certain regulatory provisions concerning physician-owned hospitals to codify and interpret the Affordable Care Act's revisions to section 1877 of the Act. On November 16, 2015, in the CY 2016 PFS final rule, we issued regulations to reduce burden and facilitate compliance (80 FR 71300 through 71341). In that rulemaking, we established two new exceptions, clarified certain provisions of the physician self-referral regulations, updated regulations to reflect changes in terminology, and revised definitions related to physician-owned hospitals. On November 15, 2016, we included in the CY 2017 PFS final rule, at § 411.357(a)(5)(ii)(B), (b)(4)(ii)(B), (l)(3)(ii), and (p)(1)(ii)(B), requirements identical to regulations that have been in effect since October 1, 2009 that the rental charges for the lease of office space or equipment are not determined using a formula based on per-unit of service rental charges, to the extent that such charges reflect services provided to patients referred by the lessor to the lessee (81 FR 80534).

On November 23, 2018, in our most recent update, the CY 2019 PFS final rule (83 FR 59715 through 59717), we incorporated into our regulations provisions at sections 1877(h)(1)(D) and (E) of the Act that were added by section 50404 of the Bipartisan Budget Act of 2018 (Pub. L. 115–123). Specifically, we codified in regulations our longstanding policy that the writing requirement in various compensation arrangement exceptions in § 411.357 can be satisfied by a collection of documents, including contemporaneous documents evidencing the course of conduct between the parties. We also amended the special rule for temporary noncompliance with signature requirements at § 411.353(g), removing the limitation on the use of the rule to once every 3 years with respect to the same physician and making other changes to conform the regulatory provision to section 1877(h)(1)(E) of the Act.

B. Health Care Delivery and Payment Reform: Transition to Value-Based Care

1. The Regulatory Sprint to Coordinated Care

The Department has identified the broad reach of the physician self-referral law, as well as the Federal anti-kickback statute and beneficiary inducements civil monetary penalty (CMP) law, sections 1128B(b) and 1128A(a)(5) of the Act, respectively, as potentially inhibiting beneficial arrangements that would advance the transition to value-based care and the coordination of care among providers in both the Federal and commercial sectors. Industry stakeholders have informed us that,

because the consequences of noncompliance with the physician self-referral law (and the anti-kickback statute) are so dire, providers, suppliers, and physicians may be discouraged from entering into innovative arrangements that would improve quality outcomes, produce health system efficiencies, and lower costs (or slow their rate of growth). To address these concerns, and to help accelerate the transformation of the health care system into one that better pays for value and promotes care coordination, HHS launched a Regulatory Sprint to Coordinated Care (the Regulatory Sprint), led by the Deputy Secretary of HHS. This Regulatory Sprint aims to remove potential regulatory barriers to care coordination and value-based care created by four key Federal health care laws and associated regulations: (1) The physician self-referral law; (2) the anti-kickback statute; (3) the Health Insurance Portability and Accountability Act of 1996 (Pub. L. 104–191) (HIPAA); and (4) the rules under 42 CFR part 2 related to opioid and substance use disorder treatment. Through the Regulatory Sprint, HHS aims to encourage and improve—

- A patient's ability to understand treatment plans and make empowered decisions;
- Providers' alignment on an end-to-end treatment approach (that is, coordination among providers along the patient's full care journey);
- Incentives for providers to coordinate, collaborate, and provide patients with tools to be more involved; and
- Information-sharing among providers, facilities, and other stakeholders in a manner that facilitates efficient care while preserving and protecting patient access to data.

The Department believes that the realization of these goals would meaningfully improve the quality of care received by all American patients. As part of the Regulatory Sprint, CMS, the HHS Office of Inspector General (OIG), and the HHS Office for Civil Rights (OCR) each issued requests for information to solicit comments that may help to inform the Department's approach to achieving the goals of the Regulatory Sprint (83 FR 29524, 83 FR 43607, and 83 FR 64302, respectively). We discuss our request for information (the CMS RFI) in this section of this proposed rule, including the specific information we requested from commenters, and how we used the information shared by commenters to inform this proposed rulemaking.

2. Policy Considerations and Other Information Relevant to the Development of This Proposed Rule

a. Medicare Payment Was Volume-Based When the Physician Self-Referral Statute Was Enacted

When the physician self-referral statute was enacted in 1989, under traditional fee-for-service (FFS) Medicare (that is, Parts A and B), the vast majority of covered services were paid based on volume. Although some services were ''bundled'' into a single payment, such as inpatient hospital services that were paid on the basis of the diagnosis-related group (DRG) that corresponded to the patient's diagnosis and the services provided (known as the Hospital Inpatient Prospective Payment System, or IPPS), in general, Medicare made a payment each time a provider or supplier furnished a service to a beneficiary. Thus, the more services a provider or supplier furnished, the more Medicare payments it would receive. Importantly, these bundled payments typically covered services furnished by a single provider or supplier, directly or by contract; payments were not bundled across multiple providers, each billing independently. This volume-based reimbursement system continues to apply under traditional Medicare to both services paid under a prospective payment system (PPS) and services paid under a retrospective FFS system.

As described in this proposed rule, the physician self-referral statute was enacted to address concerns that arose in Medicare's volume-based reimbursement system where the more designated health services that a physician ordered, the more payments Medicare would make to the entity that furnished the designated health services. If the referring physician had an ownership or investment interest in the entity furnishing the designated health services, he or she could increase the entity's revenue by referring patients for more or higher value services, potentially increasing the profit distributions tied to the physician's ownership interest. Similarly, a physician who had a service or other compensation arrangement with an entity might increase his or her aggregate compensation if he or she made referrals that resulted in more Medicare payments to the entity. The physician self-referral statute was enacted to combat the potential that financial self-interest would affect a physician's medical decision making and ensure that patients have options for quality care. The law's prohibitions were intended to prevent a patient from being referred for services that are not needed or steered to less convenient, lower quality, or more expensive health care providers because the patient's physician can improve his or her financial standing through those referrals. This statutory structure was designed for and made sense in Medicare's then largely volume-based reimbursement system.

b. The Medicare Shared Savings Program, the Center for Medicare and Medicaid Innovation, and Medicare's Transition to Value-Based Payment

Since the enactment of the physician self-referral statute in 1989, significant changes in the delivery of health care services and the payment for such services have occurred, both within the Medicare and Medicaid programs and for non-Federal payors and patients. For some time, we have engaged in efforts to align payment under the Medicare program with the quality of the care provided to our beneficiaries. Laws such as the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108–173) (MMA), the Deficit Reduction Act of 2005 (Pub. L. 109–171) (DRA), and the Medicare Improvements for Patients and Providers Act of 2008 (Pub. L. 110–275) (MIPPA) guided our early efforts to move toward health care delivery and payment reform. More recently, the Affordable Care Act required significant changes to the Medicare program's payment systems and provides the Secretary with broad authority to test innovative payment and service delivery models.

Section 3022 of the Affordable Care Act established the Medicare Shared Savings Program (Shared Savings Program). The Congress created the Shared Savings Program to promote accountability for a patient population and coordinate items and services under Medicare Parts A and B and encourage investment in infrastructure and redesigned care processes for high-quality and efficient service delivery. In essence, the Shared Savings Program would facilitate coordination among providers to improve the quality of care for Medicare FFS beneficiaries and reduce unnecessary costs. Physicians, hospitals, and other eligible providers and suppliers may participate in the Shared Savings Program by creating or participating in an accountable care organization (ACO) that agrees to be held accountable for the quality, cost, and experience of care of an assigned Medicare FFS beneficiary population. ACOs that successfully meet quality and savings requirements share a percentage of the achieved savings with Medicare. Since enactment, we have issued

numerous regulations to implement and update the Shared Savings Program.

In keeping with the Secretary's vision for achieving value-based transformation by pioneering bold new payment models, we recently finalized changes to the Shared Savings Program that allow us to take an important step forward in how Medicare pays for value. In the December 31, 2018, final rule entitled ''Medicare Shared Savings Program; Accountable Care Organizations—Pathways to Success'' (the 2018 Shared Savings Program final rule) (83 FR 67816), we recognized Shared Savings Program ACOs as an important innovation for moving our payment systems away from paying for volume and toward paying for value and outcomes, as ACOs are held accountable for the total cost of care and quality outcomes for the assigned beneficiary patient populations they serve. We made significant design changes to the Shared Savings Program that are intended to put the program on a path toward achieving a more measurable move to value, demonstrate savings to the Medicare program, and promote a competitive and accountable marketplace (83 FR 68050). Specifically, we finalized a significant redesign of the participation options available under the Shared Savings Program to encourage ACOs to transition to two-sided risk models (in which they may share in savings and are accountable for repaying shared losses), increase savings and mitigate losses for the Medicare Trust Funds, and increase program integrity. For more information about the Shared Savings Program, see *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/index.html.*

Section 1115A of the Act, as added by section 3021 of the Affordable Care Act, established the Center for Medicare and Medicaid Innovation (the Innovation Center) within CMS. The purpose of the Innovation Center is to test innovative payment and service delivery models to reduce expenditures for the care furnished to patients in the Medicare and Medicaid programs and the Children's Health Insurance Program (CHIP) while preserving or enhancing the quality of that care. Using its authority in section 1115A of the Act, the Innovation Center has tested numerous health care delivery and payment models in which providers, suppliers, and individual practitioners participate. Most Innovation Center models generally fall into three categories: Accountable care models, episode-based payment models, and primary care transformation models. The Innovation Center also tests initiatives targeted to the Medicaid and CHIP population and to Medicare-Medicaid (dual eligible) enrollees, and is focused on other initiatives to accelerate the development and testing of new payment and service delivery models, as well as to speed the adoption of best practices. We describe a few representative Innovation Center models in this section of the proposed rule.

The Innovation Center recently released financial and quality results for the second year of another of its ACO models, the Next Generation ACO model, which requires participants to assume the highest level of risk out of all CMS ACO programs and models, and in exchange for this level of risk, rewards participants with greater regulatory flexibility. The Next Generation ACO model actuarial results show that net savings to the Medicare Trust Funds from the model in 2017 were more than $164 million across 44 ACOs. The model is also showing strong performance on quality metrics. See *https://www.cms.gov/newsroom/press-releases/cms-finalizes-pathways-success-overhaul-medicares-national-aco-program.*

The Innovation Center is also testing several episode-based payment models, including the Oncology Care Model (OCM) and the Comprehensive Care for Joint Replacement (CJR) Model. The goal of OCM is to utilize appropriately aligned financial incentives to enable improved care coordination, appropriateness of care, and access to care for beneficiaries undergoing chemotherapy. Under this model, physician practices have entered into payment arrangements that include financial and performance accountability for episodes of care surrounding chemotherapy administration to cancer patients. The OCM encourages participating practices to improve care and lower costs through an episode-based payment model that financially incentivizes high-quality, coordinated care. The practices participating in OCM have committed to providing enhanced services to Medicare beneficiaries such as care coordination, navigation, and national treatment guidelines for care. The OCM provides an incentive to participating physician practices to comprehensively and appropriately address the complex care needs of the beneficiary population receiving chemotherapy treatment and heighten their focus on furnishing services that specifically improve the patient experience or health outcomes. Fourteen commercial payors are participating in OCM in alignment with Medicare to create broader incentives for care transformation at the physician practice level. Aligned financial incentives that result from engaging multiple payors leverage the opportunity to transform care for oncology patients across a broader population. Other payors benefit from savings, better outcomes for their enrollees, and greater information around care quality. Participating payors have the flexibility to design their own payment incentives to support their enrollees while aligning with the Innovation Center's specific goals for OCM of care improvement and efficiency.

In addition to the Innovation Center's overarching goal of reduced program expenditures while preserving or enhancing quality of care, like OCM, the goal of the CJR Model is to transform care delivery with the result of better and more efficient care for patients undergoing the most common inpatient surgeries for Medicare beneficiaries: Hip and knee replacements (also called lower extremity joint replacements). This model tests bundled payment and quality measurement for an episode of care associated with hip and knee replacements to encourage hospitals, physicians, and post-acute care providers to work together to improve the quality and coordination of care from the initial hospitalization through recovery.

For more information about the Innovation Center's innovative health care payment and service delivery models, see *https://innovation.cms.gov/.* Importantly, the Congress granted the Secretary broad authority to waive provisions of section 1877 of the Act and certain other Federal fraud and abuse laws when he determines it is necessary to implement the Shared Savings Program (see section 1899(f) of the Act) or test models under the Innovation Center's authority (see section 1115A(d)(1) of the Act). For more information about waivers issued using these authorities and guidance documents related to specific waivers, see *https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Fraud-and-Abuse-Waivers.html.*

c. Commercial Payor and Provider-Driven Activity

Although payments directly from a payor to a physician generally do not implicate the physician self-referral law unless the payor is itself an entity that furnishes designated health services, remuneration between physicians and other health care providers that provide care to a payor's enrolled patients (or subscribers) likely does implicate the physician self-referral law. Commercial

payors and health care providers have implemented and continue to develop numerous innovative health care payment and care delivery models that do not include or specifically relate to CMS. Even though the physicians and health care providers who participate in these initiatives do not necessarily provide designated health services payable by Medicare as part of the initiatives, financial relationships between them may nonetheless implicate the physician self-referral law, which, in turn, may restrict referrals of Medicare patients. In considering the policies proposed in this proposed rule, we examined the value-based care delivery and payment models developed by commercial payors, as well as those developed directly by health care providers, to better understand the need for exceptions to the physician self-referral law that would permit financial relationships among health care providers who provide services to patients outside the Medicare program.

CMS is aware of developments by payors, including the development of value-based care delivery and payment initiatives, that are intended to achieve the same population health goals as ACOs: Better health, affordability, and experience. The approach of these payment initiatives is to reward health care professionals for value rather than volume and promote higher quality of care and lower total medical costs. CMS is aware of numerous initiative arrangements with primary care physician groups in over 30 states. One particular program encompassed more than 2 million commercial subscribers and more than 140,000 primary care physicians and specialists. The initiative expanded on prior initiatives involving large physician groups and integrated delivery systems, which showed successes, including better-than-market quality performance, and total medical cost; 50 percent fewer unnecessary emergency room visits; better compliance with diabetes measures; and closure of 21 percent more gaps in care.

Also of note, another payor has developed plans that promote care coordination measures by providing financial incentives to their hospital networks for reaching Integrated Care Certification from The Joint Commission. This payor's initiative was developed to evaluate the ability of identified health care settings to provide collaborative, coordinated services. The certification is a 3-year recognition of an organization's ability to provide clinically integrated care. (See *https://www.jointcommission.org/assets/1/18/ICC_eligibility_12-14.pdf.*) This type of care coordination is similar to the goals set forth in CMS' ACO programs and models, as well as our Bundled Payments for Care Improvement initiatives.

In response to the CMS RFI mentioned in section I.B.1. of this proposed rule and in more detail in section I.B.2.d. of this proposed rule, commenters shared information regarding alternative payment models and other innovative programs sponsored by commercial payors. One commenter described its value-based contracting with physicians and health care providers as a move away from traditional volume-driven practices. This payor reimburses physicians for care coordination activities with incentive payments to facilitate better care; shares savings with physicians where their efforts helped achieve the cost savings; pays bundled rates for surgical procedures performed in ambulatory surgical centers (ASCs); and makes incentive payments to encourage the use of certain sites of service for particular cases. This commenter also noted that pharmaceutical manufacturers and other service providers are part of its value-based models. According to this commenter, its efforts will help align financial incentives with patient health outcomes and help prepare physicians and other providers to deliver care that improves patient outcomes but at lower cost, all while assuming greater financial risk. Other commenters described the breadth of their involvement in value-based health care delivery and payment. One of these commenters noted that 61 million (60 percent) of its subscribers have access to value-based providers and, in 2017, its value-based reimbursement accounted for 31 percent of total claims spending. Another commenter stated that it has 1,000 ACOs, with 15 million subscribers who access care from over 110,000 physicians and 1,100 hospitals participating in this value-based care program. These commenters stressed that their achievements in programs where the physician self-referral law is not implicated or does not impose an absolute prohibition on physician referrals could be expanded to benefit the Medicare program and its beneficiaries with meaningful reform of the physician self-referral regulations.

d. Request for Information Regarding the Physician Self-Referral Law (CMS–1720–NC)

As described previously, the Secretary identified four priorities for HHS, the first of which is transforming our health care system into one that pays for value. Dramatically different from the system that existed when the physician self-referral statute was enacted, a value-driven health care system pays for health and outcomes rather than sickness and procedures. We believe that a successful value-based system requires integration and coordination among physicians and other health care providers and suppliers. The Secretary has laid out four areas of emphasis for building a system that delivers value: maximizing the promise of health information technology (IT), improving transparency in price and quality, pioneering bold new models in Medicare and Medicaid, and removing government burdens that impede care coordination. This proposed rule focuses primarily on the final two areas of emphasis for value-based transformation—pioneering new models in Medicare and Medicaid and removing regulatory barriers that impede care coordination.

As the Secretary and the Administrator of CMS (the Administrator) have made clear, we are well aware of the burden that regulations, including the physician self-referral regulations, place on health care professionals and organizations, especially with respect to care coordination. In 2017, through the annual payment rules, CMS requested comments on improvements that could be made to the health care delivery system that would reduce unnecessary burdens for clinicians, other providers, and patients and their families. In response, commenters shared information regarding the barriers to participation in health care delivery and payment reform efforts, both public and private, as well as the burdens of compliance with the physician self-referral statute and regulations as they exist today. As a result of our review of these comments, and with a goal of reducing regulatory burden and dismantling barriers to value-based care transformation while also protecting the integrity of the Medicare program, on June 25, 2018, we published in the **Federal Register** a Request for Information Regarding the Physician Self-Referral Law (as noted previously, the CMS RFI) seeking recommendations and input from the public on how to address any undue impact and burden of the physician self-referral statute and regulations (83 FR 29524). In the CMS RFI, we stated that we are particularly interested in input on issues that include the structure of arrangements between parties that participate in alternative payment models or other

novel financial arrangements, the need for revisions or additions to exceptions to the physician self-referral regulations, and terminology related to alternative payment models and the physician self-referral statute and regulations in general (83 FR 29525).

We received approximately 375 comments in response to the CMS RFI. A wide range of stakeholders, including physicians and associations representing physicians, hospitals and associations representing hospitals, integrated health care delivery systems, non-Federal payors, individuals, rural stakeholders, and other components of the health care industry submitted comments. Commenters indicated that they appreciated the opportunity to submit feedback and recognized that the health care system is moving away from paying based on volume and toward payments based on value. Although most commenters believed that changes to the physician self-referral regulations are needed to support the move to a value-based payment system, many recognized that the potential for program integrity vulnerability or other abuses continues to be a significant threat that CMS should not ignore. We received comments on most of the issues for which we requested information. We appreciate the detailed comments submitted, and found them extremely informative and helpful in developing our proposals.

Comments fell within five general themes. First, commenters requested new exceptions to the physician self-referral law to protect a variety of compensation arrangements between and among parties in CMS-sponsored alternative payment models and also those models that are sponsored by other payors. Commenters also requested protection for care coordination arrangements. Generally, commenters recognized the need for appropriate safeguards. Second, commenters requested a new exception to permit entities to donate cybersecurity technology and services to physicians. Third, commenters provided helpful feedback on terminology and concepts critical to the physician self-referral law, such as commercial reasonableness, fair market value, and compensation that ''takes into account'' the volume or value of referrals and is ''set in advance.'' Fourth, some commenters expressed concerns that new exceptions or easing current restrictions could exacerbate overutilization and other harms. For example, some commenters indicated that financial gain should never be permitted to influence medical decision making, and some expressed concern that value-based payment systems drive industry consolidation and reduce competition. Finally, a few commenters provided feedback on issues that were not covered by the CMS RFI, such as requests to eliminate or keep the statutory restrictions for physician-owned hospitals and requests to eliminate, expand, or limit the scope and availability of the in-office ancillary services exception.

C. Application and Scope of the Physician Self-Referral Law—Generally

Our intent in interpreting and implementing section 1877 of the Act has always been ''to interpret the [referral and billing] prohibitions narrowly and the exceptions broadly, to the extent consistent with statutory language and intent,'' and we have not vacillated from this position (66 FR 860). Our 1998 proposed rule was informed by our review of the legislative history of section 1877 of the Act, consultation with our law enforcement partners about their experience implementing and enforcing the Federal fraud and abuse laws, and empirical studies of physicians' referral patterns and practices, which concluded that a physician's financial relationship with an entity can affect a physician's medical decision-making and lead to overutilization. At the time of our earliest rulemakings, we did not have as much experience in administering the physician self-referral law or working with our law enforcement partners on investigations and actions involving violations of the physician self-referral law. Thus, despite our stated intention to interpret the law's prohibitions narrowly and the exceptions broadly, we proceeded with great caution when designing exceptions.

Over the past decade, in particular, we have vastly expanded our knowledge of the aspects of financial relationships that result in Medicare program or patient abuse. Our administration of the CMS Voluntary Self-Referral Disclosure Protocol (SRDP), which has received over 1,100 submissions since its inception in 2010, has provided us insight into thousands of financial relationships—most of which were compensation arrangements—that ran afoul of the physician self-referral law but posed no real risk of Medicare program or patient abuse. We made revisions to our regulations and shared policy clarifications in the CY 2016 and 2019 PFS rulemakings to address many issues related to the documentation requirements in the statutory and regulatory exceptions to the physician self-referral law, but we have not, to date, addressed other requirements in the regulatory exceptions that stakeholders, including CMS RFI commenters, have identified as adding unnecessary complexity without increasing safeguards for program integrity. In this proposed rule, we are proposing to delete certain requirements in our regulatory exceptions that may be unnecessary at this time. We are also proposing to revise existing exceptions or propose new exceptions for nonabusive arrangements that we identified through our administration of the SRDP and the CMS RFI comments, and for which there is currently no applicable exception to the physician self-referral law's referral and billing prohibitions. In sections II.D. and E. of this proposed rule, we describe our specific proposals.

D. Purpose of the Proposed Rule

In 2017, CMS launched the Patients over Paperwork initiative, a cross-cutting, collaborative process that evaluates and streamlines regulations with a goal to reduce unnecessary burden, increase efficiencies, and improve the beneficiary experience. This effort emphasizes a commitment to removing regulatory obstacles to providers spending time with patients. Reducing unnecessary burden generally is a shared goal of the Patients over Paperwork initiative and the Regulatory Sprint. The Regulatory Sprint is focused specifically on identifying regulatory requirements or prohibitions that may act as barriers to coordinated care, assessing whether those regulatory provisions are unnecessary obstacles to coordinated care, and issuing guidance or revising regulations to address such obstacles and, as appropriate, encouraging and incentivizing coordinated care. As requested by the Administrator and the Deputy Secretary, we reexamined the physician self-referral statute and our regulations in order to identify ways to address any undue impact and burden of the law. Informed by the responses to the CMS RFI and our own experience in administering the physician self-referral law, we are proposing numerous revisions to modernize and clarify the physician self-referral regulations.

The proposals set forth in section II.A. of this proposed rule are intended to alleviate the undue impact of the physician self-referral statute and regulations on parties that participate in alternative payment models and other novel financial arrangements and to facilitate care coordination among such parties. As part of the Regulatory Sprint, OIG is concurrently developing proposals under the anti-kickback statute and CMP law to address similar

concerns. Because many of the compensation arrangements between parties that participate in alternative payment models and other novel financial arrangements implicate both the physician self-referral law and the anti-kickback statute, we coordinated closely with OIG in developing some of the proposals in this proposed rule. Where appropriate, our aim is to promote alignment across our agencies' proposed rules to ease the compliance burden on the regulated industry. In some cases, CMS' proposals may be different in application or potentially more restrictive than OIG's comparable proposals, in recognition of the differences in statutory structures, authorities, and penalties. In other cases, OIG's proposals may be more restrictive. For some arrangements, it may be appropriate for the anti-kickback statute, which is an intent-based criminal law, to serve as ''backstop'' protection for arrangements that might be protected by an exception to the strict liability physician self-referral law. Given the close nexus between our proposals and OIG's proposals, we encourage stakeholders to review and submit comments on both proposed rules. However, we may consider comments received only by OIG on its proposed rule if the comments address issues relevant to our proposals.

Our proposals that do not directly address value-based arrangements are set forth in sections II.B., C., D., and E. of this proposed rule and seek to balance genuine program integrity concerns against the considerable burden of the physician self-referral law's billing and claims submission prohibitions by reassessing the appropriate scope of the statute's reach; establishing exceptions for common nonabusive compensation arrangements between physicians and the entities to which they refer Medicare beneficiaries for designated health services; and providing critically necessary guidance for physicians and health care providers and suppliers whose financial relationships are governed by the physician self-referral statute and regulations.

II. Provisions of the Proposed Regulations

A. Facilitating the Transition to Value-Based Care and Fostering Care Coordination

1. Background

Transforming our health care system into one that pays for value is one of the Secretary's priorities. Based on the comments to the CMS RFI, it is clear that there is broad consensus throughout the health care industry regarding the urgent need for a movement away from legacy systems that pay for care on a FFS basis. Identifying and dismantling regulatory barriers to value-based care transformation is a critical step in this movement. We are aware of the effect the physician self-referral law may have on parties participating or considering participation in integrated care delivery models, alternative payment models, and arrangements to incent improvements in outcomes and reductions in cost, and we share the optimism of commenters that the changes to the physician self-referral regulations proposed here will unlock innovation and enable HHS to realize its goal of transforming the health care system into one that pays for value.

The health care landscape when the physician self-referral law was enacted bears little resemblance to the landscape of today. As some CMS RFI commenters highlighted, the physician self-referral law was enacted at a time when the goals of the various components of the health care system were not merely unaligned but often in conflict, with each component competing for a bigger share of the health care dollar without regard to the inefficiencies that resulted for the system as a whole—in other words, a volume-based system. According to several commenters, the current physician self-referral regulations—intended to combat overutilization in a volume-based world—are outmoded because, by their nature, integrated care models protect against overutilization by aligning clinical and economic performance as the benchmarks for value. And, in general, the greater the economic risk that providers assume, the greater the economic disincentive to overutilize services. According to more than one of these commenters, the current prohibitions are even antithetical to the stated goals of policy makers both in the Congress and within HHS for health care delivery and payment reform. Although we agree in concept, we continue to operate substantially in a volume-based payment system. Thus, we must proceed with caution, even as we propose the significant changes outlined in this proposed rule.

The vast majority of CMS RFI commenters requested that CMS revise existing exceptions or develop one or more new exceptions to the physician self-referral law to address the concerns noted previously. (We consider commenters' requests for ''waivers'' of the physician self-referral law's prohibitions to be requests for new exceptions, as they have the same result; that is, if the conditions of the waiver or exception are met, the arrangement will be outside the ambit of the physician self-referral law's prohibitions.) Commenters urged us to exercise our authority to the broadest extent possible and focus on how the physician self-referral law should apply to the emerging models likely to dominate in the near future and beyond. Commenters also urged us not to limit the application of new policies to Medicare-sponsored models and payment methodologies. We intend for our proposals to facilitate an evolving health care delivery system, and endeavor here to strike the appropriate balance between ensuring program integrity and designing policies that will stand the test of time.

A few commenters stressed that a multi-faceted approach that establishes multiple new exceptions would only add more burden and complexity to the law. These commenters requested that we establish a single exception, similar to the Shared Savings Program Participation Waiver (80 FR 66726), that would apply to any compensation arrangement, regardless of the type of arrangement, payment model, or level of risk undertaken by the parties to the arrangement. Although we appreciate the commenters' concerns about complexity, we are cognizant of the need to ensure the integrity of the Medicare program and believe that the approach advocated by the commenters would not adequately protect the program and its beneficiaries. We believe that the proposals described in this section of the rule achieve the right balance between ensuring program integrity, making compliance with the physician self-referral law readily achievable, and providing the flexibility required by participants in value-based health care delivery and payment systems. As noted previously, in developing the proposed exceptions, definitions, and related policies, we coordinated closely with OIG. Where possible and feasible, we have aligned with OIG's proposals to ease the compliance burden on the regulated industry.

2. Proposed Definitions and Exceptions

We are proposing at § 411.357(aa) new exceptions to the physician self-referral law for compensation arrangements that satisfy specified requirements based on the characteristics of the arrangement and the level of financial risk undertaken by the parties to the arrangement or the value-based enterprise of which they are participants. The exceptions would apply regardless of whether the

arrangement relates to care furnished to Medicare beneficiaries, non-Medicare patients, or a combination of both. Although we believe that revisions to the physician self-referral regulations are crucial to facilitating the transition to a value-based health care delivery and payment system, nothing in our proposals is intended to suggest that many value-based arrangements, such as pay-for-performance arrangements or certain risk-sharing arrangements, do not satisfy the requirements of existing exceptions to the physician self-referral law.

For purposes of applying the proposed exceptions, we are proposing new definitions at § 411.351 for the following terms: Value-based activity; value-based arrangement; value-based enterprise; value-based purpose; VBE participant; and target patient population. The definitions are essential to the application of the exceptions. The proposed exceptions apply only to compensation arrangements that qualify as value-based arrangements. Thus, the exceptions may be accessed only by those parties that qualify as VBE participants in the same value-based enterprise. We intend for the definitions and exceptions together to create the set of requirements for protection from the physician self-referral law's referral and claims submission prohibitions.

To facilitate readers' review of our proposals, we discuss the proposed definitions first.

a. Proposed Definitions

The proposed ''value-based'' definitions are interconnected and, for the best understanding, should be read together. For purposes of applying the proposed exceptions at § 411.357(aa), we are proposing the following definitions at § 411.351:

- *Value-based activity* would mean any of the following activities, provided that the activity is reasonably designed to achieve at least one value-based purpose of the value-based enterprise: (1) The provision of an item or service; (2) the taking of an action; or (3) the refraining from taking an action. The making of a referral is not a value-based activity.
- *Value-based arrangement* would mean an arrangement for the provision of at least one value-based activity for a target patient population between or among: (1) The value-based enterprise and one or more of its VBE participants; or (2) VBE participants in the same value-based enterprise.
- *Value-based enterprise* would mean two or more VBE participants: (1) Collaborating to achieve at least one value-based purpose; (2) each of which is a party to a value-based arrangement with the other or at least one other VBE participant in the value-based enterprise; (3) that have an accountable body or person responsible for financial and operational oversight of the value-based enterprise; and (4) that have a governing document that describes the value-based enterprise and how the VBE participants intend to achieve its value-based purpose(s).
- *Value-based purpose* would mean: (1) Coordinating and managing the care of a target patient population; (2) improving the quality of care for a target patient population; (3) appropriately reducing the costs to, or growth in expenditures of, payors without reducing the quality of care for a target patient population; or (4) transitioning from health care delivery and payment mechanisms based on the volume of items and services provided to mechanisms based on the quality of care and control of costs of care for a target patient population.
- *VBE participant* would mean an individual or entity that engages in at least one value-based activity as part of a value-based enterprise.
- *Target patient population* would mean an identified patient population selected by a value-based enterprise or its VBE participants based on legitimate and verifiable criteria that are set out in writing in advance of the commencement of the value-based arrangement and further the value-based enterprise's value-based purpose(s).

The activities that serve as the basis for the compensation arrangements are key to qualifying as a value-based arrangement to which the proposed exceptions at § 411.357(aa) would apply. We are proposing to identify these activities as ''value-based activities'' and propose at § 411.351 to define ''value-based activity'' to include the provision of an item, the provision of a service, the taking of an action, or the refraining from taking an action, provided that the value-based activity is reasonably designed to achieve at least one value-based purpose of the value-based enterprise of which the parties are participants. Sometimes value-based activities are easily identifiable as the provision of items or services to a patient; other times, identifying a specific activity responsible for an outcome in a value-based health care system can be difficult. We appreciate that remuneration paid in furtherance of the objectives of a value-based health care system does not always involve one-to-one payments for items or services provided by a party to an arrangement. For example, a shared savings payment distributed by an entity to a downstream physician who joined with other providers and suppliers to achieve the savings represents the physician's agreed upon share of such savings rather than a payment for specific items or services furnished by the physician to the entity (or on the entity's behalf). And, when payments are made to encourage a physician to adhere to a redesigned care protocol, such payments are made, in part, in consideration of the physician refraining from following his or her past patient care practices rather than for direct patient care items or services furnished by the physician. On the other hand, the act of referring patients for designated health services is itself not a value-based activity. As a general matter, referrals are not items or services for which a physician may be compensated under the physician self-referral law, and payments for referrals are antithetical to the purpose of the statute (69 FR 16096). We discuss this in further detail in section II.D.2.c. of this proposed rule.

Value-based activities must be reasonably designed to achieve at least one value-based purpose of the value-based enterprise. For example, if the value-based purpose of the enterprise is to coordinate and manage the care of patients who undergo lower extremity joint replacement procedures, a value-based arrangement might require routine post-discharge meetings between a hospital and the physician primarily responsible for the care of the patient following discharge from the hospital. However, if the value-based purpose of the enterprise is to reduce costs to, or growth in expenditures of, payors while improving or maintaining the improved quality of care for the target patient population, providing patient care services (the purported value-based activity) without monitoring their utilization would not appear to be reasonably designed to achieve that purpose.

The definition of ''value-based arrangement'' is key to our proposals aimed at facilitating the transition to value-based care and fostering care coordination, as the proposed exceptions apply only to arrangements that qualify as value-based arrangements. Under our proposal, an arrangement between a value-based enterprise and one or more of its VBE participants (if the enterprise is an ''entity'' as defined at § 411.351 and the VBE participants are physicians), or between VBE participants in the same value-based enterprise, for the provision of at least one value-based activity for a target patient population would qualify as a value-based arrangement. Because

our proposed exceptions at § 411.357(aa) would apply only to compensation arrangements (as defined at § 411.354(c)), the value-based arrangement must be a compensation arrangement and not another type of financial relationship to which the physician self-referral law applies. Effectively, the parties to a value-based arrangement would be an entity furnishing designated health services and a physician; otherwise, the physician self-referral law's prohibitions would not be implicated. We discuss the other terminology used in the proposed definition of ''value-based arrangement'' in this section of the proposed rule.

Patient care coordination and management are the foundation of a value-based health care delivery system. Reform of the delivery of health care through better care coordination—including more efficient transitions for patients moving between and across care settings and providers,[1] reduction of orders for duplicative items and services, and open sharing of medical records and other important health data across care settings and among a patient's providers (consistent with privacy and security rules)—is integrally connected to reforming health care payment systems to shift from volume-driven to value-driven payment models. We expect that most value-based arrangements would involve activities that coordinate and manage the care of a target patient population, but have not proposed to limit the universe of compensation arrangements that would qualify as value-based arrangements to those arrangements specifically for the coordination and management of patient care. We seek comment regarding whether this approach—designed to provide needed flexibility for parties participating in alternative payment models (including those sponsored by CMS) to succeed in the transition to value-based payment—poses a risk of program or patient abuse that should be addressed through a revised definition of ''value-based arrangement'' that requires care coordination and management in order to qualify as a value-based arrangement.

The exceptions proposed at § 411.357(aa) apply only to value-based arrangements, which, as described previously, must be between a value-based enterprise and one or more of its VBE participants or between parties in the same value-based enterprise. We intend the definition of ''value-based enterprise'' to include only organized groups of health care providers, suppliers, and other components of the health care system collaborating to achieve the goals of a value-based health care system. An ''enterprise'' may be a distinct legal entity—such as an ACO—with a formal governing body, operating agreement or bylaws, and the ability to receive payment on behalf of its affiliated health care providers. An ''enterprise'' may also consist only of the two parties to a value-based arrangement with the written documentation recording the arrangement serving as the required governing document that describes the enterprise and how the parties intend to achieve its value-based purpose(s). (We note, as described below, that a value-based arrangement need not be reduced to writing to satisfy the requirements of the exceptions proposed at § 411.357(aa)(1) and (2).) Whatever its size and structure, a value-based enterprise is essentially a network of participants (such as clinicians, providers, and suppliers) that have agreed to collaborate with regard to a target patient population to put the patient at the center of care through care coordination, increase efficiencies in the delivery of care, and improve outcomes for patients. We have proposed our definition of ''value-based enterprise'' in terms of the functions of the enterprise as it is not our intention to dictate or limit the appropriate legal structures for qualifying as a value-based enterprise.

To qualify as a value-based enterprise, among other things, each participant in the network, whom we refer to as VBE participants, must be a party to at least one value-based arrangement with at least one other participant in the network or with the value-based enterprise (if the enterprise is an ''entity'' as defined at § 411.351). (If the network is comprised of only two VBE participants, they must have at least one value-based arrangement with each other in order for the network to qualify as a value-based enterprise.) We describe the proposed definition of VBE participant in more detail in this section of the proposed rule. In addition, the network seeking to qualify as a value-based enterprise must have an accountable body or person that is responsible for the financial and operational oversight of the enterprise. This may be the governing board, a committee of the governing board, or a corporate officer of the legal entity that is the value-based enterprise, or this may be the party to a value-based arrangement that is designated as being responsible for the financial and operational oversight of the arrangement between the parties (if the ''enterprise'' is a network consisting of just the two parties). Finally, the network must have a governing document that describes the network (that is, the value-based enterprise) and how the VBE participants intend to achieve its value-based purpose(s). Implicit in this definition is that the value-based enterprise must have at least one value-based purpose.

Also critical to qualifying as a value-based arrangement is the purpose of the arrangement. As noted previously, only arrangements reasonably designed to achieve at least one value-based purpose may potentially qualify as a value-based arrangement to which the exceptions proposed at § 411.357(aa) would apply. Our proposed definition of ''value-based purpose'' identifies four core goals related to a target patient population. These are: coordinating and managing the care of the target patient population; improving the quality of care for the target patient population; appropriately reducing the costs to, or the growth in expenditures of, payors without reducing the quality of care for the target patient population; and transitioning from health care delivery and payment mechanisms based on the volume of items and services provided to mechanisms based on the quality of care and control of costs of care for the target patient population. One or more of these purposes must anchor every compensation arrangement that qualifies as a value-based arrangement to which our proposed new exceptions would apply. Some of these goals are recognizable as part of the successor frameworks to the ''triple aim'' that are integral to CMS' value-based programs and our larger quality strategy to reform how health care is delivered and reimbursed. Although we expect that stakeholders will be familiar with these concepts, we seek comment regarding whether additional interpretation is necessary. Specifically, with respect to the value-based purpose of appropriately reducing the costs to, or the growth in expenditures of, payors without reducing the quality of care for the target patient population, we are considering whether to require that the purpose of the value-based enterprise is to improve quality or maintain the already-improved quality of care for the target patient population (in addition to appropriately reducing the costs to or the growth of expenditures of payors). That is, the value-based purpose identified at proposed § 411.351

[1] For purposes of this section, the term ''providers'' includes both providers and suppliers as those terms are defined in 42 CFR 400.202, as well as other components of the health care system. The term is used generically unless otherwise noted.

(definition of value-based purpose, paragraph (3)) would state: Appropriately reducing the costs to, or the growth in expenditures of, payors while improving or maintaining the improved quality of care for the target patient population. If we adopt such a policy, a value-based enterprise could not select this value-based purpose until after it has already achieved some improvement in the quality of care for the target patient population that is the subject of the value-based arrangement. We seek comment regarding this proposal.

We are seeking comment whether it is desirable or necessary to express in regulation text what is meant by ''coordinating and managing care'' and, if so, whether ''coordinating and managing care'' should be defined to mean the deliberate organization of patient care activities and sharing of information between two or more VBE participants, tailored to improving the health outcomes of the target patient population, in order to achieve safer and more effective care for the target patient population. We note that this would align closely with the definition of ''coordinating and managing care'' under consideration by OIG. We also seek comment regarding permissible ways to determine whether quality of care has improved, a methodology for determining whether costs are reduced or expenditure growth has been stopped, or what parties must do to show they are transitioning from health care delivery and payment mechanisms based on the volume of items and services provided to mechanisms based on the quality of care and control of costs of care. The transitioning from volume-based to value-based health care delivery and payment mechanisms is the fourth goal identified in our proposed definition of value-based purpose. We interpret ''transitioning from health care delivery and payment mechanisms based on the volume of items and services provided to mechanisms based on the quality of care and control of costs of care for the target patient population'' as a category that includes the integration of VBE participants in team-based coordinated care models; establishing the infrastructure necessary to provide patient-centered coordinated care; and accepting (or preparing to accept) increased levels of financial risk from payors or other VBE participants in value-based arrangements. We are cognizant that this goal may lack the precision desired in the physician self-referral regulations. Specifically, without clear boundaries as to what qualifies as ''transitioning from health care delivery and payment mechanisms based on the volume of items and services provided to mechanisms based on the quality of care and control of costs of care for the target patient population,'' it may be difficult to know whether the underlying purpose of an arrangement qualifies as a value-based purpose that triggers the availability of the proposed new exceptions at § 411.357(aa). We seek comment with respect to this concern and the proposed definition of value-based purpose generally. We believe that reducing costs to patients is a laudable objective of a value-based arrangement when the reduction in costs relates to services that are unnecessary for the patient and does not inappropriately shift costs to the payor or another participant in the health care system. Due to our concerns about gaming and the inappropriate shifting of costs, we did not propose to include the reduction of costs to patients as a value-based purpose. We seek comment on this policy determination.

As noted previously, we proposed to define VBE participant (that is, a participant in a value-based enterprise) to mean an individual or entity that engages in at least one value-based activity as part of a value-based enterprise, as described in this section II.A.2.a. We note that the word ''entity,'' as used in the proposed definition of ''VBE participant,'' is not limited to non-natural persons that qualify as ''entities'' as defined at current § 411.351. Our proposed definition of ''VBE participant'' is intended to align with the definition under consideration by OIG. We seek comment regarding whether the use of the word ''entity'' in this definition would cause confusion due to the fact that the universe of non-natural persons (that is, entities) that could qualify as VBE participants is greater than the universe of non-natural persons that qualify as ''entities'' as defined at current § 411.351 and, if so, alternatives for defining ''VBE participant'' for purposes of section 1877 of the Act and the physician self-referral regulations.

Based on the experience of our law enforcement partners, including their oversight experience, we are also concerned about protecting potentially abusive arrangements between certain types of entities that furnish designated health services for purposes of the physician self-referral law. Specifically, we are concerned about compensation arrangements between physicians and laboratories or suppliers of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) that may be intended to improperly influence or capture referrals without contributing to the better coordination of care for patients. (See the 2013 EHR final rule (78 FR 78751), issued on December 27, 2013, for a discussion of our concerns regarding the donation of EHR items and services by laboratories (78 FR 78757 through 78762).) We are considering whether to also exclude laboratories and DMEPOS suppliers from the definition of VBE participant or, in the alternative, whether to include in the exceptions at § 411.357(aa), if finalized, a requirement that the arrangement is not between a physician (or immediate family member of a physician) and a laboratory or DMEPOS supplier. In particular, it is not clear to us that laboratories and DMEPOS suppliers have the direct patient contacts that would justify their inclusion as parties working under a protected value-based arrangement to achieve the type of patient-centered care that is a core tenet of care coordination and a value-based health care system. We solicit public comment on the role laboratories and DMEPOS suppliers play in care coordination for patients and value-based delivery and payment models. We are interested in learning more about how laboratories or DMEPOS suppliers may be important or necessary to foster care coordination for patients, as well as roles they may play that raise an undue risk of program or patient abuse. We note that, regardless of whether we exclude these suppliers (or any other providers or suppliers) from the definition of ''VBE participant,'' they may nevertheless be part of a value-based enterprise.

Due to our (and our law enforcement partners') ongoing program integrity concerns with certain other components of the health care system and to maintain consistency with policies under consideration by OIG, we are also considering whether to exclude the following providers, suppliers, and other persons from the definition of ''VBE participant'': Pharmaceutical manufacturers; manufacturers and distributors of DMEPOS; pharmacy benefit managers (PBMs); wholesalers; and distributors. We believe that aligning our policies, if finalized, would minimize complexity for parties whose arrangements implicate both the physician self-referral law and the anti-kickback statute. The exclusion from the definition of ''VBE participant'' would, in operation, serve to exclude a compensation arrangement between a physician and the party that is not a VBE participant from the application of the proposed exceptions for value-based

arrangements. Therefore, in the alternative, we are considering whether to include in the exceptions at § 411.357(aa) for value-based arrangements, if finalized, a requirement that the arrangement is not between a physician (or immediate family member of a physician) and a: Pharmaceutical manufacturer; manufacturer or distributor of DMEPOS; pharmacy benefit manager; wholesaler; or distributor. We note that pharmacy benefit managers, manufacturers, and distributors usually are not entities furnishing designated health services for purposes of the physician self-referral law and, for the most part, serve only as persons in unbroken chains of financial relationships that may establish an indirect ownership or investment interest or an indirect compensation arrangement under the regulations at § 411.354(b) and (c). Finally, even if we exclude pharmaceutical manufacturers, manufacturers and distributors of DMEPOS, pharmacy benefit managers, wholesalers, distributors, or other parties from the definition of ''VBE participant,'' no person, whether or not a provider or supplier in the Medicare program, would be precluded from participating in and contributing to a value-based enterprise. We seek comment on which persons and entities should qualify as VBE participants; our alternative proposals regarding protection for arrangements involving physicians (or their immediate family members) and the specified persons or organizations; and, in particular, whether other providers or suppliers, such as health technology companies, should be excluded from the definition of VBE participant or the application of the proposed exceptions due to similar program integrity concerns. We note that we intend to align our policies with policies under consideration by OIG where possible and appropriate, and will consider comments submitted to OIG regarding its proposed definition of ''VBE participant'' as we develop policies in any final rule.

We are proposing to define the target patient population for which VBE participants undertake value-based activities to mean the identified patient population selected by a value-based enterprise or its VBE participants using legitimate and verifiable criteria that are set out in writing in advance of the commencement of the value-based arrangement and further the value-based enterprise's value-based purpose(s). Legitimate and verifiable criteria may include medical or health characteristics (for example, patients undergoing knee replacement surgery or patients with newly diagnosed type 2 diabetes), geographic characteristics (for example, all patients in an identified county or set of zip codes), payor status (for example, all patients with a particular health insurance plan or payor), or other defining characteristics. Selecting a target patient population consisting of only lucrative or adherent patients (cherry-picking) and avoiding costly or noncompliant patients (lemon-dropping) would not be permissible under most circumstances, as we would not consider the selection criteria to be legitimate (even if verifiable). Generally speaking, choosing a target patient population in a manner driven primarily by a profit motive or purely financial concerns would not be legitimate. We seek comment regarding the requirement that selection criteria be legitimate and verifiable, as well as any additional or substitute criteria that we might include in the definition of target patient population. We also seek comment on additional selection criteria that should or should not be considered ''legitimate and verifiable'' and on whether we should specify in regulation text a non-exhaustive list of selection criteria that would or would not be ''legitimate and verifiable.''

b. Proposed Exceptions

The physician self-referral law (along with other Federal fraud and abuse laws) provides critical protection against a range of troubling patient and program abuses that may result from volume-driven, FFS payment. These abuses include unnecessary utilization, increased costs to payors and patients, inappropriate steering of patients, corruption of medical decision making, and competition based on buying referrals instead of delivering quality, convenient care. While value-based payment models hold promise for addressing these abuses, they may pose risks of their own, including risks of stinting on care (underutilization), cherry-picking, lemon-dropping, and manipulation or falsification of data used to verify outcomes. Moreover, during the transformation to value-based payment, many new delivery and payment models include both FFS and value-based payment mechanisms in the same model, subjecting providers to mixed incentives, and presenting the possibility of arrangements that pose both traditional FFS risk and emerging value-based payment risks.

In removing regulatory barriers to innovative care coordination and value-based arrangements, we are faced with the challenge of designing protection for emerging health care arrangements, the optimal form, design, and efficacy of which remains unknown or unproven. This is a fundamental challenge of regulating during a period of innovation and experimentation. In addition, the health care industry is experiencing very rapid change, and there is a lack of predictability of desired future arrangements. Matters are further complicated by the substantial variation in care coordination and value-based arrangements contemplated by the health care industry, variation among patient populations and providers, emerging health technologies and data capabilities, and our desire not to chill beneficial innovations. Thus, the one-size-fits-all approach to protection from the physician self-referral law's prohibitions that was recommended by many commenters may be less than optimal.

The design and structure of our proposed exceptions are intended to further several complementary goals. First, we have endeavored to remove regulatory barriers, real or perceived, to create space and flexibility for industry-led innovation in the delivery of better and more efficient coordinated health care for patients and improved health outcomes. Second, consistent with the Secretary's priorities, the historical trend toward improving health care through better care coordination, and the increasing adoption of value-based models in the health care industry, we are proposing a set of exceptions that, as a whole, may create additional incentives for the industry to move away from volume-based health care delivery and payment and toward population health and other non-FFS payment models. In this regard, our proposed exception structure incorporates additional flexibilities for compensation arrangements between parties that have increased their participation in mature value-based payment models and their assumption of downside financial risk under such models. As discussed in more detail in this section of the proposed rule, our expectation is that meaningful assumption of downside financial risk would not only serve the overall transformation of industry payment systems, but could also curb, at least to some degree, FFS incentives to order medically unnecessary or overly costly items and services, key patient and program harms addressed by the physician self-referral law (and other Federal fraud and abuse laws).

As described in this proposed rule and in the CMS RFI, the current exceptions to the physician self-referral law include requirements that may create significant challenges for parties that wish to develop novel financial

arrangements to facilitate their successful participation in health care delivery and payment reform efforts. Most of the commonly relied upon exceptions to the physician self-referral law include requirements related to compensation that may be difficult to satisfy where the arrangement is designed to foster the behavior shaping necessary for the provision of high-quality patient care that is not reimbursed on a traditional FFS basis. Requirements that compensation be set in advance, fair market value, and not take into account the volume or value of a physician's referrals or the other business generated between the parties may inhibit the innovation necessary to achieve well-coordinated care that results in better health outcomes and reduced expenditures (or reduced growth in expenditures). For example, depending on their structure, arrangements for the distribution of shared savings or repayment of shared losses, gainsharing arrangements, and pay-for-performance arrangements that provide for payments to refrain from ordering unnecessary care, among others, may be unable to satisfy the requirements of an existing exception to the physician self-referral law. According to one commenter, a typical shared savings payment inherently takes into account the volume or value of referrals for hospital services and other designated health services, but does so by creating an inverse correlation between the volume or value of referrals and the amount of the shared savings payment. As another commenter suggested, many stakeholders simply do not possess a degree of risk tolerance sufficient to participate in new models of health care delivery and payment if they have to apply the requirements of the existing exceptions to their financial arrangements, even when such arrangements do not have the characteristics that the physician self-referral law was intended to constrain. Thus, rather than being a check on bad actors, in the context of value-based care models, the physician self-referral law may actually be having a chilling effect on models and arrangements designed to ''bend the cost curve and improve quality of care to patients.''

We have carefully considered the CMS RFI comments and anecdotal information shared by stakeholders regarding the impact of the specific requirements that compensation be set in advance, fair market value, and not determined in any manner that takes into account the volume or value of a physician's referrals or the other business generated between the parties, law enforcement and judicial activity related to these requirements, and our own observations from our work (including our work on fraud and abuse waivers for CMS accountable care and other models). We are concerned that the inclusion of such requirements in the exceptions for value-based arrangements proposed at § 411.357(aa) would conflict with our goal of addressing regulatory barriers to value-based care transformation. As one commenter stated, these requirements simply may not be suited to the collaborative models that reward value and outcomes.

We note that two of the exceptions for value-based arrangements that we are proposing are available to protect arrangements even when payments from the payor are made on a FFS basis. Even so, we are not proposing to require that remuneration is consistent with fair market value and not determined in any manner that takes into account the volume or value of a physician's referrals or the other business generated by the physician for the entity. Instead, we are proposing a carefully woven fabric of safeguards, including requirements incorporated through the applicable value-based definitions. We believe that the disincentives for overutilization, stinting on patient care, and other harms the physician self-referral law was intended to address that are built into the proposed value-based definitions will operate in tandem with the requirements included in the proposed exceptions and be sufficient to protect against program and patient abuse. This is especially true where full or meaningful downside financial risk is assumed. We are, however, including in two of the proposed exceptions for value-based arrangements that the methodology used to determine the amount of the remuneration—but not the actual amount of the remuneration itself—is set in advance of the undertaking of value-based activities for which the remuneration is provided. We seek comment on our approach. We are especially interested in comments regarding whether the safeguards provided by the combination of the proposed definitions and the requirements of the proposed exceptions would be adequate to protect against program or patient abuse and, if not, whether it would be appropriate or necessary to include requirements in any final exceptions that remuneration: (1) Not take into account the volume or value of a physician's referrals or the other business generated by the physician for the entity; and (2) is consistent with the fair market value of the value-based activities provided under the arrangement. We are also interested in comments regarding whether we should include a requirement that the value-based arrangement is commercially reasonable as defined in our alternative proposals described in section II.B.2. of this proposed rule.

Because the proposed exceptions for value-based arrangements do not include a requirement that the remuneration is not determined in any manner that takes into account the volume or value of referrals, the special rule at current § 411.354(d)(4) would not apply to arrangements protected under the exceptions. (See section II.B. of this proposed rule for a more fulsome discussion of the history of the special rule at § 411.354(d)(4).) This special rule permits the entity of which the physician is a *bona fide* employee, independent contractor, or party to a managed care contract to direct the physician's referrals to a particular provider, practitioner, or supplier, provided that the compensation arrangement meets specified conditions designed to preserve the physician's judgment as to the patient's best medical interests, avoid interfering in an insurer's operations, and, importantly, protect patient choice.

The right to freedom of choice of providers is expressed and reinforced in almost every aspect of the Medicare program. We believe that a patient's control over who provides his or her care directly contributes to improved health outcomes and patient satisfaction, enhanced quality of care and efficiency in the delivery of care, increased competition among providers, and reduced medical costs, all of which are aims of the Medicare program. Protection of patient choice is especially critical in the context of referrals made by a physician to an entity with which the physician has a financial relationship, as the physician's financial self-interest may impact, if not infringe on, a patient's right to control who furnishes his or her care. For this reason, we are proposing to make compliance with § 411.354(d)(4)(iv) a requirement of the exceptions that apply to employment arrangements, personal service arrangements, or managed care contracts that purport to restrict or direct physician referrals, including the proposed exceptions at § 411.357(aa) for value-based arrangements. (We are not proposing to include this requirement in the exception for group practice arrangements with a hospital at § 411.357(g) because the statute does not authorize the Secretary to impose additional requirements by regulation

beyond those included in the statute at section 1877(e)(7) of the Act.) As described in section II.B. of this proposed rule, we are also proposing clarifying revisions to current § 411.354(d)(4). In the alternative, rather than reference § 411.354(d)(4)(iv), we are proposing to include at § 411.357(aa) a separate requirement applicable specifically to value-based arrangements to ensure that, regardless of the nature of the value-based arrangement and its value-based purpose(s), the regulation adequately protects a patient's choice of health care provider, the physician's medical judgment, and the ability of health insurers to efficiently provide care to their members. We seek comment on the best approach to address our concerns.

Finally, we have endeavored to be as neutral as possible with respect to the types of value-based enterprises and value-based arrangements the proposed exceptions would cover in order to allow for innovation and experimentation in the health care marketplace and so that compliance with the physician self-referral law is not the driver of innovation or the barrier to innovation. One CMS RFI commenter asserted that, in their current state, the physician self-referral regulations discourage the development and adoption of rewards that encourage change on a broad scale, across all patient populations and payor types, and over indefinite periods of time. It is for this reason also that we are not proposing to limit the exceptions to CMS-sponsored models or establish separate exceptions with different criteria for arrangements that exist outside of CMS-sponsored models.

When the physician self-referral law was expanded in 1993 to apply to designated health services beyond the clinical laboratory services to which the original 1989 law applied, according to the sponsor of the legislation, the Honorable Fortney ''Pete'' Stark, the physician self-referral law was intended to address physician referrals that drive up health care costs and result in unnecessary utilization of services. (*See* Opening Statement of the Honorable Pete Stark, Physician Ownership and Referral Arrangements and H.R. 345, ''The Comprehensive Physician Ownership and Referral Act of 1993,'' House of Representatives, Committee on Ways and Means, Subcommittee on Health, April 20, 1993, p. 144.) Mr. Stark went on to emphasize the importance of a physician's ability to offer patients neutral advice about whether or not services are necessary, which services are preferable, and who should provide them. He noted that the physician self-referral law would improve consumers' confidence in their physicians and the health care system generally. In other words, the legislation was proposed (and the law ultimately enacted) to counter the effects of physician decision making driven by financial self-interest—overutilization of health care services, the suppression of patient choice, and the impact on the medical marketplace.

As discussed previously in this proposed rule, in 1989 and 1993, the vast majority of Medicare services were reimbursed based on volume under a retrospective FFS system. The statutory exceptions to the physician self-referral law's referral and billing prohibitions were developed during this time of FFS, volume-based payment, with conditions which, if met, would allow the physician's ownership or investment interest or compensation arrangement to proceed without triggering the ban on the physician's referrals or the entity's claims submission. We believe that the exceptions in section 1877 of the Act indicate the Congress' stance on what safeguards are necessary to protect against program or patient abuse in a system where Medicare payment is available for each service referred by a physician and furnished by a provider or supplier. To date, the exceptions for compensation arrangements issued under section 1877(b)(4) of the Act, which grants the Secretary authority to establish exceptions for financial relationships that the Secretary determines do not pose a risk of program or patient abuse, have generally followed the blueprint established by the Congress for compensation arrangements that exist in a FFS system.

Value-based health care delivery and payment shifts the paradigm of our analysis under section 1877(b)(4) of the Act. When no longer operating in a volume-based system, or operating in a system that reduces the amount of FFS payment by combining it with some level of value-based payment, we believe that our exceptions need fewer ''traditional'' requirements to ensure the arrangements they protect do not pose a risk of program or patient abuse. This is because a value-based health care delivery and payment system itself provides safeguards against harms such as overutilization, care stinting, patient steering, and negative impacts on the medical marketplace. Using the Secretary's authority under section 1877(b)(4) of the Act, we are proposing three exceptions for compensation arrangements that we believe do not pose a risk of program or patient abuse when considered in concert with: (1) The program integrity and other requirements integrated in the proposed definitions used to apply the exceptions only to compensation arrangements that qualify as ''value-based arrangements;'' and (2) the disincentives to perpetrate the harms the physician self-referral law was intended to deter that are intrinsic in the assumption of substantial downside financial risk and meaningful participation in value-based health care delivery and payment models. Specifically, at proposed § 411.357(aa)(1), we are proposing an exception that would apply to a value-based arrangement where a value-based enterprise has, during the entire term of the arrangement, assumed full financial risk from a payor for patient care services for a target patient population. At proposed § 411.357(aa)(2), we are proposing an exception that would apply to a value-based arrangement under which the physician is at meaningful downside financial risk for failure to achieve the value-based purposes of the value-based enterprise during the entire term of the arrangement. Finally, at proposed § 411.357(aa)(3), we are proposing an exception that would apply to any value-based arrangement, provided that the arrangement satisfies specified requirements. The proposed exceptions include fewer requirements where a value-based enterprise has assumed full financial risk for the cost of the target patient population's health care (that is, the value-based enterprise and its VBE participants receive no FFS payments in addition to the capitated payments or global budget payment made to the value-based enterprise from the payor), with the requirements increasing and changing as the level of financial risk in the value-based arrangement diminishes.

The exceptions proposed at § 411.357(aa) and described in detail in this section of the proposed rule would be applicable to the compensation arrangements between parties in a CMS-sponsored model, program, or other initiative (provided that the compensation arrangement at issue qualifies as ''value-based arrangement''), and we believe that compensation arrangements between parties in a CMS-sponsored model, program, or other initiative can be structured to satisfy the requirements of at least one of the proposed exceptions at § 411.357(aa). We intend that this suite of value-based exceptions, if finalized, would eliminate the need for any new waivers of section 1877 of the Act for value-based arrangements. (We note that, even if the proposed exceptions are finalized, parties may elect to use the waivers

applicable to the CMS-sponsored models, programs, or initiatives in which they participate.) Even so, we are interested in learning whether stakeholders view our proposals as leaving gaps in protection from the physician self-referral law's prohibitions for certain arrangements that are permissible under a CMS-sponsored model, program, or other initiative. We are soliciting comments regarding the structure and scope of our proposed exceptions; specific compensation arrangements that are permissible under a CMS-sponsored model, program, or other initiative but might not be able to satisfy the requirements of one of the proposed value-based exceptions; and suggested modifications to our proposals that would bridge any perceived or actual gaps in the protection of the exceptions at proposed § 411.357(aa)(1), (2) and (3). We are also interested in comments that address what safeguards would be appropriate to include in such a ''gap-filler'' exception in order to protect against program or patient abuse. We remind potential commenters that an exception issued using the authority at section 1877(b)(4) of the Act may protect only those financial relationships that the Secretary determines do not pose a risk of program or patient abuse.

We are mindful that value-based enterprises and parties to value-based arrangements may assume other types of risk, including operational risk, contractual risk, and investment risk. For example, the adopter of EHR technology and the developer of a medical office building assume business risk that the investment in the EHR technology and the buildout of office space, respectively, does not result in profit. For our purposes, we are focused on the financial risk because we believe such risk can directly influence the incentives physicians and other providers have to order items and services for patients, the conduct at the core of the physician self-referral law (and other Federal fraud and abuse laws). We are not persuaded other types of risk would operate similarly to counter volume-based payment incentives; however, we solicit comments on this issue.

Several CMS RFI commenters requested that we keep in place existing exceptions that may protect certain value-based arrangements, regardless of any proposed new exceptions and policies. We are not at this time proposing any substantive changes to the exception at § 411.355(c) for services furnished by an organization (or its contractors or subcontractors) to enrollees or the exception at § 411.357(n) for risk-sharing arrangements. However, see section II.D.13. of this proposed rule for our proposal to update the exception at § 411.355(c) to eliminate an out-of-date reference. Many commenters discussed the difficulty specialty physicians have in participating in alternative payment models, especially advanced alternative payment models, and requested that we deem certain financial relationships to qualify as alternative payment models. Our proposals do not turn on whether the parties to an arrangement are participating in alternative payment models or whether arrangements themselves qualify as alternative payment models. We believe that the approach discussed in this proposed rule, under which the proposed exceptions are available for compensation arrangements designed to achieve the value-based purpose(s) of an enterprise consisting of at least the physician and the entity to which he or she refers designated health services, is the better approach. Physician self-referral law policy is not the appropriate place to define or identify alternative payment models. Our focus here is to remove the regulatory barriers that inhibit the transformation to value-based care.

(1) Full Financial Risk (Proposed § 411.357(aa)(1))

We are proposing at § 411.357(aa)(1) an exception to the physician self-referral law (the ''full financial risk exception'') that would apply to value-based arrangements between VBE participants in a value-based enterprise that has assumed ''full financial risk'' for the cost of all patient care items and services covered by the applicable payor for each patient in the target patient population for a specified period of time; that is, the value-based enterprise is financially responsible (or is contractually obligated to be financially responsible within the 6 months following the commencement date of the value-based arrangement) on a prospective basis for the cost of all patient care items and services covered by the applicable payor for each patient in the target patient population for a specified period of time. For Medicare beneficiaries, we would interpret this requirement to mean that the value-based enterprise, at a minimum, is responsible for all items and services covered under Parts A and B. We seek comments regarding the proposed definition of ''full financial risk'' described here and in proposed § 411.357(aa)(1)(viii). Specifically, we seek comment regarding whether a value-based enterprise should be considered to be at full financial risk if it is responsible for the cost of only a defined set of patient care services for a target patient population and whether we should require a minimum period of time during which the value-based enterprise is at full financial risk (for example, 1 year).

Full financial risk may take the form of capitation payments (that is, a predetermined payment per patient per month or other period of time) or global budget payment from a payor that compensates the value-based enterprise for providing all patient care items and services for a target patient population for a predetermined period of time. The proposed exception would not prohibit other approaches to full financial risk, and we seek comment regarding other types of full financial risk payment models that may exist currently or that stakeholders anticipate as the transition to a value-based health care delivery and payment system progresses. As described elsewhere in this section, a value-based enterprise need not be a separate legal entity with the power to contract on its own. Rather, networks of physicians, entities furnishing designated health services, and other components of the health care system collaborating to achieve the goals of a value-based health care system, organized with legal formality or not, may qualify as a value-based enterprise. A value-based enterprise may assume legal obligations in any number of ways. For example, all VBE participants in a value-based enterprise could each sign the contract for the value-based enterprise to assume full financial risk from a payor. Or, the VBE participants in a value-based enterprise could have contractual arrangements among themselves that assign risk jointly and severally. Or, similar to physicians in an independent practice association (IPA), VBE participants could vest the authority to bind all VBE participants in the value-based enterprise with a designated person who contracts for the assumption of full financial risk on behalf of the value-based enterprise and its VBE participants. We do not purport to prescribe in this proposal a specific manner for the assumption of full financial risk.

The financial risk must be prospective; that is, the contract between the value-based enterprise and the payor may not allow for any additional payment to compensate for costs incurred by the value-based enterprise in providing specific patient care items and services to the target patient population, nor may any VBE participant claim payment from the payor for such items or services. Our

proposed definition of ''full financial risk'' would not prohibit a payor from making payments to a value-based enterprise to offset losses incurred by the enterprise above those prospectively agreed to by the parties. The payment of shared savings or other incentive payments for achieving quality, performance, or other benchmarks also would not be prohibited. We are proposing to also protect value-based arrangements entered into in preparation for the implementation of the value-based enterprise's full financial risk payor contract where such arrangements begin after the value-based enterprise is contractually obligated to assume full financial risk for the cost of patient care items and services for the target patient population but prior to the date the provision of patient care items and services under the contract begin. We are proposing to limit this period to the 6 months prior to the effective date of the full financial risk payor contract. In other words, the value-based enterprise must be at full financial risk within the 6 months following the commencement of the value-based arrangement. We seek comment whether this is a sufficient period of time for parties to construct arrangements and begin preparations for the implementation of the value-based enterprise's full financial risk payor contract.

We believe that full financial risk is one defining characteristic of a mature value-based payment system. When a value-based enterprise is at full financial risk for the cost of all patient care services, the incentives to order unnecessary services or steer patients to higher-cost sites of service are diminished. Even when downstream contractors are paid on something other than a full-risk basis, the value-based enterprise itself is incented to monitor for appropriate utilization, referral patterns, and quality performance, which we believe helps to reduce the risk of program or patient abuse. As one CMS RFI commenter noted, where there is a finite amount of payment, if costs go up, participating providers may incur direct financial losses. According to the commenter, these kinds of payment limitations provide stronger and more effective guardrails against increases in the volume and costs of services than the fraud and abuse laws ever placed on the FFS system. As a precaution, we are including several important safeguards in the proposed exception.

One requirement of the proposed exception is that the value-based enterprise must be at full financial risk during the entire duration of the value-based arrangement for which the parties to the arrangement seek protection. The proposed exception would not protect arrangements that begin at some point during a period when the safeguards intrinsic to full-risk value-based payment are in place, but that continue into a timeframe when such safeguards no longer exist. However, one or both of the other proposed exceptions at § 411.357(aa) may be available to protect value-based arrangements that exist during a period when the value-based enterprise is not at full financial risk for the cost of all patient care items and services covered by the applicable payor for each patient in the target patient population.

As described throughout this proposed rule, we believe that well-coordinated and managed patient care is the cornerstone of a value-based health care system. We are soliciting comments regarding whether it is necessary to include in the full financial risk exception, as well as the other exceptions for value-based arrangements at § 411.357(aa), a requirement that the parties to a value-based arrangement engage in value-based activities that include, at a minimum, the coordination and management of the care of the target patient population or that the value-based arrangement be reasonably designed, at a minimum, to coordinate and manage the care of the target patient population. We believe that such a requirement would be the most direct way to further the goals of the Regulatory Sprint. On the other hand, we also believe that, by their nature, arrangements that qualify as ''value-based arrangements'' would have care coordination and management at their heart, and we question whether an explicit requirement is necessary. Moreover, we are concerned that requiring every value-based arrangement to include the coordination and management of care of the target patient population could leave beneficial value-based arrangements that do not directly coordinate or manage the care of the target patient population without access to any of the exceptions at proposed § 411.357(aa) and potentially unable to meet the requirements of any existing exception to the physician self-referral law.

We are also proposing a requirement that the remuneration under the value-based arrangement is for or results from value-based activities undertaken by the recipient of the remuneration for patients in the target patient population. We recognize that payments under certain incentive payment arrangements, such as gainsharing arrangements, may be difficult to tie to specific items or services furnished by a VBE participant. We would not interpret the requirement at proposed § 411.357(aa)(1)(ii) as mandating a one-to-one payment for an item or service (or other value-based activity). Gainsharing payments, shared savings distributions, and similar payments may result from value-based activities undertaken by the recipient of the payment for patients in the target patient population. We believe that the requirement that the remuneration is for or results from value-based activities undertaken by the recipient of the remuneration for patients in the target patient population adequately addresses this issue; however, we are considering whether to require that the remuneration also or instead relates to the value-based purpose(s) of the value-based enterprise or value-based arrangement. Also, we intend for this to be an objective standard; that is, the remuneration must, in fact, be for or result from value-based activities undertaken by the recipient of the remuneration for patients in the target patient population. The proposed exception, therefore, would not protect payments for referrals or any other actions or business unrelated to the target patient population, such as general marketing or sales arrangements. With respect to in-kind remuneration, essentially, the remuneration must be necessary and not simply duplicate technology or other infrastructure that the recipient already has. Finally, although the remuneration must be for or result from value-based activities undertaken by the recipient of the remuneration for patients in the target patient population, parties would not be prohibited from using the remuneration for the benefit of patients who are not part of the target patient population.

Integrated into most of the CMS-sponsored models is a requirement that any remuneration between parties to an allowable financial arrangement is not provided as an inducement to reduce or limit medically necessary items or services to any patient in the assigned patient population. We believe this is an important safeguard for patient safety and quality of care, regardless of whether Medicare is the ultimate payor for the services, and propose to include it in the full financial risk exception by requiring at proposed § 411.357(aa)(1)(iii) that remuneration is not provided as an inducement to reduce or limit medically necessary items or services to any patient, whether in the target patient population or not. Remuneration that leads to a reduction in medically necessary services would be inherently suspect and could

implicate sections 1128A(b)(1) and (2) of the Act.

In addition, we are proposing to protect only those value-based arrangements under which remuneration is not conditioned on referrals of patients who are not part of the target patient population or business not covered under the value-based arrangement. Although this requirement is similar to the requirement that remuneration is for or results from value-based activities undertaken by the recipient of the remuneration for patients in the target patient population, it is intended to address a different concern. The exception would not protect arrangements where one or both parties have made referrals or other business not covered by the value-based arrangement a condition of the remuneration. By way of example, if the value-based enterprise is at full financial risk for the total cost of care for all of a commercial payor's enrollees in a particular county, the exception would not protect a value-based arrangement between an entity and a physician that are VBE participants in the value-based enterprise if the entity required the physician to refer Medicare patients who are not part of the target patient population for designated health services furnished by the entity. Similarly, the exception would not protect a value-based arrangement related to knee replacement services furnished to Medicare beneficiaries if the arrangement required that the physician perform all his or her other orthopedic surgeries at the hospital. (Our examples relate to value-based arrangements between entities furnishing designated health services and physicians because the physician self-referral law's prohibitions would not be implicated if the arrangement was not between an entity furnishing designated health services and a physician (or the physician organization in whose shoes the physician stands under § 411.354(c)(2).)

We are also proposing requirements at § 411.357(aa)(1)(v) and (vi) related to requiring a physician to refer to a particular provider, practitioner, or supplier and price transparency. We refer to our description of these requirements in sections II.B.4. and II.A.2.b., of this proposed rule, respectively.

Finally, we are proposing to require that records of the methodology for determining and the actual amount of remuneration paid under the value-based arrangement be maintained for a period of at least 6 years and made available to the Secretary upon request. Requirements similar to this are found in our existing regulations in the group practice rules at § 411.352(d)(2) and (i), the exception for physician recruitment at § 411.357(4)(iv), and the exception for assistance to compensate a nonphysician practitioner at § 411.357(x)(2). We expect that parties are familiar with these requirements and that the maintenance of such records is part of their routine business practices.

We consider the exception at proposed § 411.357(aa)(1) comparable, in some respects, to the exception at § 411.357(n) for risk-sharing arrangements, which is intended to be a broad exception with maximum flexibility, covering all risk-sharing compensation paid to a physician by an entity downstream of any type of health plan, insurance company, or health maintenance organization (that is, any ''managed care organization'') or independent practice association, provided the arrangement relates to enrollees and meets the conditions set forth in the exception (69 FR 16114). All downstream entities are included within the scope of the exception for risk-sharing arrangements. We endeavored to structure a similar exception here, given the underlying parallels between a managed care organization and a value-based enterprise at full financial risk for the cost of all patient care items and services covered by the applicable payor for each patient in the target patient population. Although the proposed exception at § 411.357(aa)(1) is not limited to ''risk-sharing compensation'' paid to a physician, but, rather, covers any type of remuneration paid under a value-based arrangement that is for or results from value-based activities undertaken by the recipient of the remuneration, for the reasons discussed throughout this section II.A. of this proposed rule, we believe that the type of flexibility provided in the exception for risk-sharing arrangements is also warranted here. Finally, like the exception at § 411.357(n) for risk-sharing arrangements, there are no documentation requirements proposed for the full financial risk exception. Nevertheless, we believe that reducing to writing any arrangement between referral sources is a good business practice that allows the parties to monitor and confirm that the arrangement is operating as intended.

(2) Value-Based Arrangements With Meaningful Downside Financial Risk to the Physician (Proposed § 411.357(aa)(2))

A few CMS RFI commenters opined that the health care industry is in the infancy of its transition to value-based health care delivery and payment. Although we believe that our efforts described in section I.B.2. of this proposed rule, as well as those of non-Federal payors and a significant segment of the health care industry, have advanced us beyond ''infancy,'' we acknowledge that most physicians and providers are not yet prepared or willing to be responsible for the total cost of patient care services for a target patient population. However, some physicians are participating in or considering participating in alternative payment models that provide for potential financial gain in exchange for the undertaking of downside financial risk.

We believe that financial risk assumed directly by a physician will affect his or her practice and referral patterns in a way that curbs the influence of traditional FFS, volume-based payment. When that financial risk is tied to the failure to achieve value-based purposes, we believe there is great potential for the type of behavior-shaping necessary to transform our health care delivery system into one that improves patient outcomes, eliminates waste and inefficiencies, and reduces costs to or the growth in expenditures of payors. Arrangements under which a physician is at meaningful downside financial risk for failure to achieve predetermined cost, quality, or other performance benchmarks contain certain inherent protections against program or patient abuse.

We are proposing an exception at § 411.357(aa)(2) that would protect remuneration paid under a value-based arrangement where the physician is at meaningful downside financial risk for failure to achieve the value-based purpose(s) of the value-based enterprise (the ''meaningful downside financial risk exception''). (As noted previously, for purposes of our proposed exceptions, the parties to a value-based arrangement would be an entity furnishing designated health services and a physician; otherwise, the physician self-referral law's prohibitions would not be implicated.) Although the physician must be at meaningful downside financial risk for the entire term of the value-based arrangement, the remuneration could be paid to or from the physician. We seek comment regarding whether the physician would have the same incentive to modify his or her practice and referral patterns in a manner designed to achieve the important goals described in this proposed rule if the party that has assumed the meaningful downside financial risk and is paying remuneration under the arrangement is the entity furnishing designated health

services. We expect that, in such a case, the entity would be appropriately motivated to monitor and respond to a physician's practice and referral patterns if such patterns could negatively impact the entity's financial position, but we are not convinced that such motivation to monitor would be sufficient to safeguard against program or patient abuse.

For purposes of the exception, we are proposing to define ''meaningful downside financial risk'' to mean that the physician is responsible to pay the entity no less than 25 percent of the value of the remuneration the physician receives under the value-based arrangement. We believe that this level of financial risk is high enough to curb the influence of traditional FFS, volume-based payment and achieve the type of behavior-shaping necessary to facilitate achievement of the goals set forth in this proposed rule. Defining meaningful downside financial risk in this way would establish consistency with the 25 percent threshold determined by the Secretary for the statutory and regulatory exceptions for physician incentive plans at section 1877(e)(3)(B) of the Act and § 411.357(d)(2), respectively, which reference ''substantial financial risk'' to a physician (or physician group). For purposes of those exceptions, the Secretary has defined ''substantial financial risk'' to mean the risk for referral services that exceeds the risk threshold, which is currently set at 25 percent (see § 422.208). We have proposed to require that the financial risk be ''downside'' risk for clarity. Because we are not proposing to limit the type of remuneration that may be provided, we require the risk of repayment to be for no less than 25 percent of the *value* of the remuneration to account for remuneration that may be provided in-kind, such as infrastructure or care coordination services.

Meaningful downside financial risk would also include full financial risk. That is, for purposes of the meaningful downside financial risk exception, we are proposing to define ''meaningful downside financial risk'' to also mean that the physician is financially responsible to the payor or the entity on a prospective basis for the cost of all or a defined set of items and services covered by the applicable payor for each patient in the target patient population for a specified period of time. Thus, a physician would be at meaningful downside financial risk when he or she is at ''full'' financial risk; that is, when the physician is paid a capitated payment, global budget payment, or some other payment for all or a defined set of patient care services for the target patient population. We are, however, concerned about the potential for gaming if the parties established too narrow a set of patient care services for which the physician is at meaningful downside financial risk. We are considering an approach that defines meaningful downside financial risk only to mean that the physician is responsible to pay the entity no less than 25 percent of the value of the remuneration the physician receives under the value-based arrangement and exclude a specific reference to total cost of care. We seek comment on our approaches as to how we might appropriately define meaningful downside financial risk for purposes of proposed § 411.357(aa)(2). Specifically, we seek comment on whether the proposed 25 percent threshold is appropriate, and whether downside risk for 25 percent of only a nominal amount of remuneration would be sufficient to curb the influence of traditional FFS, volume-based payment.

As we discussed previously, under the full financial risk exception, we are proposing to protect value-based arrangements entered into in preparation for the implementation of the value-based enterprise's full financial risk payor contract where such arrangements begin after the value-based enterprise is contractually obligated to assume full financial risk for the cost of patient care items and services for the target patient population but prior to the date the provision of patient care items and services under the contract begin. We are proposing to limit this period to the 6 months prior to the effective date of the full financial risk payor contract. We seek comment whether we should include an analogous provision in the meaningful downside financial risk exception and, if so, whether 6 months is an appropriate period of time for parties to construct arrangements and begin preparations for the physician's assumption of meaningful downside financial risk.

Because the exception proposed at § 411.357(aa)(2) does not require the type of global risk to the value-based enterprise as our proposed full financial risk exception, we believe that additional or different requirements are necessary to protect against program or patient abuse. We are proposing a requirement at § 411.357(aa)(2)(i) that the physician must be at meaningful downside financial risk for the entire term of the value-based arrangement. We believe this is important to curtail any gaming that could occur by adding meaningful downside financial risk to a physician during only a short portion of the term of an arrangement.

To buttress our oversight ability and that of our law enforcement partners, we are proposing at § 411.357(aa)(2)(ii) a requirement that the nature and extent of the physician's financial risk is set forth in writing. This is also, of course, a good business practice that allows the parties to monitor their value-based arrangements and ensure that they are operating as intended. For similar reasons, but also as a safeguard against manipulating a value-based arrangement to reward referrals, we are proposing a requirement that the methodology used to determine the amount of the remuneration is set in advance of the furnishing of the items or services for which the remuneration is provided. The special rule on compensation at § 411.354(d)(1) that deems compensation to be set in advance when certain conditions are met would apply. However, that provision is merely a deeming provision and parties would be free to confirm satisfaction of the proposed requirement another way.

Integrated into most of the CMS-sponsored models is a requirement that any remuneration between parties to an allowable financial arrangement is not provided as an inducement to reduce or limit medically necessary items or services to any patient in the assigned patient population. We believe this is an important safeguard for patient safety and quality of care, regardless of whether Medicare is the ultimate payor for the services, and propose to include it in the meaningful downside financial risk exception by requiring at proposed § 411.357(aa)(2)(v) that remuneration is not provided as an inducement to reduce or limit medically necessary items or services to any patient, whether in the target patient population or not. Remuneration that leads to a reduction in medically necessary services would be inherently suspect and could implicate sections 1128A(b)(1) and (2) of the Act.

For the reasons discussed in section II.A.2.b.(1). of this proposed rule, we are also proposing to include in the meaningful downside financial risk exception requirements that the remuneration is for or results from value-based activities undertaken by the recipient of the remuneration for patients in the target patient population; remuneration is not provided as an inducement to reduce or limit medically necessary items or services to any patient, whether in the target patient population or not; remuneration is not conditioned on referrals of patients who are not part of the target patient population or business not covered

under the value-based arrangement; and that records of the methodology for determining and the actual amount of remuneration paid under the value-based arrangement must be maintained for a period of at least 6 years and made available to the Secretary upon request. We would interpret these requirements as described in section II.A.2.b.(1). of this proposed rule and seek comments as requested. We are also proposing requirements at § 411.357(aa)(2)(vii) and (viii) related to requiring a physician to refer to a particular provider, practitioner, or supplier and price transparency.

(3) Value-Based Arrangements (Proposed § 411.357(aa)(3))

One CMS RFI commenter stated that, because physician decisions drive the overwhelming majority of all health care spending and patient outcomes, it is not possible to transform health care without a strong, aligned shared partnership between entities furnishing designated health services and physicians. According to other commenters, alignment of parties' financial interests is key to the behavior shaping necessary to succeed in a value-based payment system. Another commenter, a commercial payor, asserted that permitting physicians and physician groups (especially smaller practices that are not used to risk-sharing or are too small to absorb downside financial risk) to assume only upside risk—or, for that matter, no financial risk—would encourage more physicians to participate in care coordination activities now while they continue to build towards being able to enter into two-sided risk-sharing arrangements. In consideration of these and similar comments, as well as our belief that bold reforms to the physician self-referral regulations are necessary to foster the delivery of coordinated patient care and achieve the Secretary's vision of transitioning to a truly value-based health care delivery and payment system, we are proposing an exception at § 411.357(aa)(3) for compensation arrangements that qualify as value-based arrangements, regardless of the level of risk undertaken by the value-based enterprise or any of its VBE participants (the ''value-based arrangement exception''). As proposed, the exception would permit both monetary and nonmonetary remuneration between the parties. We are considering whether to limit the scope of the proposed exception to nonmonetary remuneration only and seek comment regarding the impact such a limitation may have on the transition to a value-based health care delivery and payment system.

We are proposing to include in the value-based arrangement exception certain requirements that are included in the proposed meaningful downside financial risk exception, some of which are also included in the proposed full financial risk exception. We would interpret these requirements as described in section II.A.2.b.(1). of this proposed rule, and include them in the value-based arrangement exception for the same reasons articulated with respect to our other proposed exceptions. We also seek comments as requested previously in sections II.A.2.b.(1). and II.A.2.b.(2). of this proposed rule. These requirements are: The remuneration is for or results from value-based activities undertaken by the recipient of the remuneration for patients in the target patient population; remuneration is not provided as an inducement to reduce or limit medically necessary items or services to a patient in the target patient population; remuneration is not conditioned on referrals of patients who are not part of the target patient population or business not covered by the value-based arrangement; the methodology used to determine the amount of the remuneration is set in advance of the furnishing of the items or services for which the remuneration is provided; and records of the methodology for determining and the actual amount of remuneration paid under the value-based arrangement must be maintained for a period of at least 6 years and made available to the Secretary upon request. We are also proposing requirements at § 411.357(aa)(2)(vii) and (viii) related to requiring a physician to refer to a particular provider, practitioner, or supplier and price transparency.

Because the exception proposed at § 411.357(aa)(3) would be applicable even to value-based arrangements where neither party, but especially not the physician, has undertaken any downside financial risk, we believe that safeguards beyond those included in the proposed meaningful downside financial risk exception are necessary to protect against program or patient abuse. Specifically, we are proposing, as an alternative to the requirement that remuneration is not conditioned on referrals of patients who are not part of the target patient population or business not covered by the value-based arrangement, a requirement that remuneration is not conditioned on the volume or value of referrals of *any patients* to the entity or the volume or value of *any other business generated* by the physician for the entity. We note that, as described in section II.A.2.b. of this proposed rule, we are not proposing to include in the value-based arrangement exception a requirement that the remuneration is not determined in any manner that takes into account the volume or value of a physician's referrals or the other business generated by the physician. The alternative proposal described here would prohibit remuneration that is *conditioned on* the volume or value of referrals of *any patients* to the entity or the volume or value of *any other business generated* by the physician for the entity. We seek comments regarding this alternative proposal; the interplay of the proposed alternative requirement with our longstanding policy that the entity of which the physician is a *bona fide* employee or independent contractor, or that is a party to a managed care contract with the physician, may direct the physician's referrals to a particular provider, practitioner, or supplier, as long as the compensation arrangement meets specified conditions designed to preserve the physician's judgment as to the patient's best medical interests, avoid interfering in an insurer's operations, and protect patient choice; and whether including such an alternative requirement would impede parties' ability to achieve the value-based purposes on which their value-based arrangement is premised if the entity cannot direct referrals as historically permitted.

In addition, we are proposing additional requirements in the exception proposed at § 411.357(aa)(3) that the value-based arrangement is set forth in writing and signed by the parties, and that the writing includes a description of: The value-based activities to be undertaken under the arrangement; how the value-based activities are expected to further the value-based purpose(s) of the value-based enterprise; the target patient population for the arrangement; the type or nature of the remuneration; the methodology used to determine the amount of the remuneration; and the performance or quality standards against which the recipient of the remuneration will be measured, if any. We believe that the documentation requirements are self-explanatory. Although we expect that parties would plan to satisfy the writing requirement in advance of the commencement of the value-based arrangement, the special rule at proposed § 411.354(e)(3) (modified, in part, from existing § 411.353(g)(1)(ii)) would apply. We highlight that we intend that the value-based purpose of the arrangement must relate to the value-based enterprise as a

whole (which, as noted previously in section II.A.2.a. of this proposed rule, may be the two parties to the value-based arrangement). The exception would not protect a ''side'' arrangement between two VBE participants that is unrelated to the goals and objectives (that is, the value-based purposes) of the value-based enterprise of which they are participants, even if the arrangement itself serves a value-based purpose, as defined at proposed § 411.351. We seek comment whether we should specifically include this policy in the proposed value-based arrangement exception as a requirement separate from the writing requirement.

In addition, we are proposing to require that the performance or quality standards against which the recipient of the remuneration will be measured, if any, are objective and measurable. Such standards must be determined prospectively, and any changes to the performance or quality standards must be set forth in writing and apply only prospectively. We recognize that performance or quality standards may not be applicable to all value-based arrangements—for example, an arrangement under which a hospital provides needed infrastructure to a physician in the same value-based enterprise may not require the physician to achieve specific performance or quality goals in order to receive or keep the infrastructure items or services. However, if the value-based arrangement does include performance or quality standards that relate to the receipt of the remuneration—for example, an arrangement to share the internal cost savings achieved if the physician meaningfully participates in the hospital's quality and outcomes improvement program and reaches or exceeds predetermined benchmarks for his or her personal performance or quality measurement—such performance or quality standards must be determined in advance of their implementation. The exception would not protect arrangements where the performance or quality standards are set retrospectively. Moreover, any performance or qualify standards against which the recipient of the remuneration will be measured should not simply reflect the status quo. We are considering whether to require that performance or quality standards be designed to drive meaningful improvements in physician performance, quality, health outcomes, or efficiencies in care delivery. We seek comment regarding whether we should include this as a requirement of the proposed value-based arrangement exception and the burden or cost of including such a requirement.

We expect that, as a prudent business practice, parties would monitor their arrangements to determine whether they are operating as intended and serving their intended purposes, regardless of whether the arrangements are value-based, and have in place mechanisms to address identified deficiencies, as appropriate. In fact, there is an implicit ongoing obligation for an entity to monitor its financial relationship with a physician for compliance with an applicable exception.

In general, if a physician has a financial relationship with an entity that does not satisfy all requirements of an applicable exception (after applying any special rules), section 1877(a)(1)(A) of the Act prohibits the physician from making a referral to the entity for the furnishing of designated health services for which payment may otherwise be made under Medicare, section 1877(a)(1)(B) of the Act prohibits the entity from presenting or causing to present a claim under Medicare for the designated health services furnished pursuant to a prohibited referral, and section 1877(g)(1) of the Act prohibits Medicare from making payment for a designated health service that is provided pursuant to a prohibited referral. Parties must ensure the compliance of their financial relationship with an applicable exception at the time the physician makes a referral for designated health service(s).

To illustrate, assume a hospital donates EHR items and services to Physician A, including ongoing software upgrades, maintenance, and services, for which the vendor charges the hospital monthly in advance of providing the EHR items and services. The regulation at § 411.357(w)(4) requires that, before the receipt of the items and services, the physician pays 15 percent of the donor's cost for the items and services. The parties agree that Physician A will pay 15 percent of the monthly cost of the EHR items and services prior to the beginning of each month. If Physician A fails to make the July 31st payment as scheduled, the arrangement would no longer satisfy the requirements of § 411.357(w)(4), and Physician A would be prohibited from making referrals for designated health services to the hospital as of August 1st and the hospital would be prohibited from submitting claims to the Medicare program for any improperly referred designated health services. If the arrangement is later brought back into compliance with the requirements of the exception, the physician would again be permitted to make referrals for designated health services to the hospital, and the hospital could submit claims for such designated health services (but not the designated health services referred during the period of noncompliance). The hospital has an obligation to ensure that the claims it submits to Medicare for designated health services referred by a physician are permissible and, in fact, explicitly certifies compliance with the physician self-referral law on each claim form and cost report it submits. We note that the arrangement described would also implicate the Federal anti-kickback statute, and the parties must also ensure compliance with that statute.

With respect to arrangements that would qualify for protection under the exception for value-based arrangements as proposed at § 411.357(aa)(3), there would also exist an implicit ongoing obligation to monitor for compliance with the exception. To illustrate, assume a hospital revised its care protocol for screening for a certain type of cancer to incorporate newly issued guidelines from a nationally recognized organization. The new guidelines, and the revised protocol, no longer support a single screening modality for the disease. Instead, the organization recommends screening by combining two modalities to achieve more accurate results. The revised guidelines and hospital care protocol are intended to improve the quality of care for patients by detecting more cancers and avoiding potential unnecessary overtreatment of false positive results (which can be frequent for single-modality screening for the disease). The hospital observes that most community physicians continue to refer patients to the hospital for single-modality screening. To align referring physician practices with the hospital's revised care protocol, the hospital offers to pay physicians $10 for each instance that they order dual-modality screening in accordance with the revised care protocol during a 2-year period. The hospital expects that it would take approximately 2 years to shape physician behavior to always follow the recommended care protocol (except when not medically appropriate for the particular patient). Assume that both single-modality and dual-modality screening are designated health services payable by Medicare.

The exception at proposed § 411.357(aa)(3) is applicable only to arrangements that qualify as ''value-based arrangements,'' as proposed at § 411.351. The arrangement must be for the provision of at least one value-based activity for a target patient population and must be between a value-based

enterprise and one or more of its VBE participants or between VBE participants in the same value-based enterprise. The value-based activity must be reasonably designed to achieve at least one value-based purpose of the value-based enterprise that is a party to the arrangement or is the value-based enterprise in which the parties to the arrangement are each VBE participants. In this illustration, the value-based enterprise is the hospital and identified community physicians. (The hospital and the community physicians could also be part of a larger value-based enterprise.) The target patient population is patients in the hospital's service area that receive screening for the particular disease. The value-based activity is adherence with the hospital's revised care protocol by ordering dual-modality screening instead of single-modality screening. The value-based purpose of the value-based enterprise is to improve the quality of care for patients in the hospital's service area by detecting more cancers and avoiding potential unnecessary overtreatment of false positive results.

At its inception, provided that an arrangement between the hospital and Physician B satisfies all requirements of proposed § 411.357(aa)(3), Physician B's referrals of designated health services to the hospital and the hospital's submission of claims to Medicare for the designated health services referred by Physician B would not violate the physician self-referral law. However, assume that one year into the arrangement, the hospital's data analysis indicates that the use of dual-modality screening not only does not result in earlier detection of cancer, but results in more false positive results, invasive biopsies, and unnecessary treatment than single-modality screening. As a result, the hospital determines that the use of dual-modality screening, despite the nationally-recognized recommendations, will not achieve its goal to improve the quality of care for patients in the hospital's service area by detecting more cancers and avoiding potential unnecessary overtreatment of false positive results. At that point, because the value-based activities under the arrangement would no longer be reasonably designed to achieve the value-based purpose of improving the quality of care for patients in the hospital's service area by detecting more cancers and avoiding potential unnecessary overtreatment of false positive results, the arrangement would no longer qualify as a ''value-based arrangement'' and would no longer qualify for protection under the exception at proposed § 411.357(aa)(3). Absent modification of the arrangement to ensure qualification as a ''value-based arrangement'' and compliance with the requirements of the exception at proposed § 411.357(aa)(3), Physician B would be prohibited from making future referrals of any designated health services to the hospital unless the arrangement satisfies the requirements of another applicable exception to the physician self-referral law (which it likely would not). In addition, the hospital would be prohibited from submitting claims to Medicare for any improperly referred designated health services.

As described previously, parties must ensure the compliance of their financial relationship with an applicable exception at the time of the physician's referral for the designated health service(s). The failure to monitor for or a lack of knowledge of such compliance does not nullify the prohibition. If the hospital did not monitor the arrangement for progress toward the value-based purpose of the value-based enterprise, Physician B's future referrals would nevertheless be prohibited due to the fact that adherence to the revised care protocol could not, in fact, achieve the value-based purpose of the value-based enterprise and would no longer be a ''value-based activity'' as that term is defined at proposed § 411.351. In turn, the arrangement would not qualify as a ''value-based arrangement'' and the exception at proposed § 411.357(aa)(3) would no longer be available to protect Physician B's referrals.

As illustrated, implicit in the physician self-referral law, as applied, is a requirement that one or both parties monitor the compliance of their value-based arrangement with an applicable exception, including whether the value-based activities under the arrangement are furthering (or could further) the value-based purpose(s) of the value-based enterprise. Even so, as additional program integrity safeguards, we are considering whether to require that: (1) The value-based enterprise or the VBE participant providing the remuneration must monitor to determine whether the value-based activities under the arrangement are furthering the value-based purpose(s) of the value-based enterprise; and (2) if the value-based activities will be unable to achieve the value-based purpose(s) of the arrangement, the physician must cease referring designated health services to the entity, either immediately upon the determination that the value-based purpose(s) will not be achieved through the value-based activities or within 60 days of such determination. We seek comment regarding whether we should include these as requirements of the proposed value-based arrangement exception, how parties could monitor for achievement of value-based purposes, and the burden or cost of including such a requirement. Specifically, we seek comment regarding whether we should require that monitoring should occur at specified intervals and, if so, what the intervals should be. Recognizing that cost savings, in particular, may take an extended period of time to achieve, we also seek comment regarding whether to impose time limits with respect to a value-based enterprise's or VBE participant's determination that the value-based purpose of the enterprise will not be achieved through the value-based activities required under the arrangement; that is, require that the value-based purpose must be achieved within a certain timeframe, such as 3 years and, if it is not, the value-based purpose would be deemed not achievable through the value-based activities requirement under the arrangement. We also seek comment regarding the types of monitoring activities that parties to value-based arrangements are currently performing.

We are also considering whether to require the recipient of any nonmonetary remuneration under a value-based arrangement to contribute at least 15 percent of the donor's cost of the nonmonetary remuneration. We would require that the 15 percent contribution is made: (1) Within 90 calendar days of the donation of the nonmonetary remuneration if the donation is a one-time cost to the donor; and (2) at reasonable, regular intervals if the donation of the nonmonetary remuneration is an ongoing cost to the donor. As we stated with respect to the 15 percent contribution required under the current exception at § 411.357(w) for EHR items and services, parties should use a reasonable and verifiable method for allocating costs and are strongly encouraged to maintain contemporaneous and accurate documentation (71 FR 45161 through 45162). Requiring financial participation by a recipient of nonmonetary remuneration under a value-based arrangement would help ensure that the nonmonetary remuneration is appropriate and beneficial for the achievement the value-based purpose(s) of the value-based enterprise, as well as that the recipient will actually use the nonmonetary remuneration. However, we are concerned that such a requirement could inhibit the adoption

of value-based arrangements. As discussed in section II.D.11.d.(1) of this proposed rule, many commenters to the CMS RFI expressed that the 15 percent contribution requirement under the existing exception for EHR items and services is burdensome to some recipients and acts as a barrier to adoption of EHR technology. We are concerned that the burden of a 15 percent contribution requirement would prove similarly burdensome under value-based arrangements, particularly with respect to small and rural physicians, providers, and suppliers that cannot afford the contribution. We seek comment regarding whether we should include a recipient contribution requirement in the proposed value-based arrangement exception and the burden or cost of including such a requirement. Specifically, we seek comment regarding the appropriate level for any required contribution (if 15 percent is not an appropriate level) and whether certain recipients (for example, small or rural physicians, providers, and suppliers) should be exempt from compliance with the requirement.

Finally, as discussed throughout sections I. and II.A. of this proposed rule, where possible and feasible, we aim to align our policies with those under consideration by OIG to ease the compliance burden on the regulated industry by minimizing complexity for parties whose arrangements implicate both the physician self-referral law and the anti-kickback statute. For this reason, we are considering whether to adopt any other requirements included in the safe harbor at proposed § 1001.952(ee) and not specifically proposed in this section II.A.2.b.(3). We will consider comments received by OIG on its proposals when developing any final policies for the value-based arrangement exception to the physician self-referral law.

(4) Indirect Compensation Arrangements to Which the Exceptions at Proposed § 411.357(aa) are Applicable (Proposed § 411.354(c)(4))

The prohibitions of section 1877 of the Act apply if a physician (or an immediate family member of a physician) has an ownership or investment interest in an entity or a compensation arrangement with an entity. For purposes of the physician self-referral law, a compensation arrangement is any arrangement involving direct or indirect remuneration between a physician (or an immediate family member of the physician) and an entity, and remuneration means any payment or other benefit made directly, indirectly, overtly, covertly, in cash, or in kind. (*See* §§ 411.351 and 411.354(c).) In Phase I, we finalized regulations that define when an indirect compensation arrangement exists between a physician and the entity to which he or she refers designated health services. For purposes of applying these regulations, in the FY 2008 IPPS final rule, we finalized additional regulations that deem a physician to stand in the shoes of his or her physician organization if the physician has an ownership or investment interest in the physician organization that is not merely a titular interest. These regulations are found at § 411.354(c)(2) and (3).

Under our current regulations, if an indirect compensation arrangement exists, the exception for indirect compensation arrangements at § 411.357(p) is available to protect the compensation arrangement. If all of the requirements of the exception are satisfied, the physician would not be barred from referring patients to the entity for designated health services and the entity would not be barred from submitting claims for the referred services. No other exception in § 411.357 is applicable to indirect compensation arrangements. However, the parties may elect to protect individual referrals of and claims for designated health services using an applicable exception in § 411.355 of our regulations.

We anticipate that an unbroken chain of financial relationships described in current § 411.354(c)(2)(i) may include a value-based arrangement, as that term is proposed to be defined at § 411.351. Thus, an unbroken chain of financial relationships that includes a value-based arrangement could form an ''indirect compensation arrangement'' for purposes of the physician self-referral law if the circumstances described in § 411.354(c)(2)(ii) and (iii) also exist. In such an event, despite the existence of the value-based arrangement in the unbroken chain of financial relationships, under our current regulations, the only exception available to ensure the permissibility of *all* the physician's referrals to the entity (assuming no other financial relationships exist between the parties) would be the exception for indirect compensation arrangements at § 411.357(p), which includes requirements not found in the proposed exceptions for value-based arrangements at § 411.357(aa). (If the parties elect to utilize a ''services'' exception at § 411.355, designated health services are protected only on a service-by-service basis and satisfaction of the requirements of an applicable exception permits only the referral of and claim submission for the particular designated health service that satisfied the requirements of the exception.) For the reasons discussed previously in this section II.A.2.b. of this proposed rule, it is possible that an indirect compensation arrangement that includes a value-based arrangement in the unbroken chain of financial relationships that forms the indirect compensation arrangement could not satisfy the requirements of § 411.357(p) because the compensation to the physician could take into account the volume or value of referrals or other business generated by the physician for the entity or may not be fair market value for specific items or services provided by the physician to the entity.

In this section II.A.2.b. of this proposed rule, we are proposing exceptions available only to compensation arrangements that qualify as value-based arrangements. Although our proposals do not limit the applicability of the exceptions to value-based arrangements directly between a physician and the entity to which he or she refers designated health services, the definition of ''value-based arrangement'' proposed at § 411.351 requires that the compensation arrangement is ''between'' (or ''among,'' if there are more than two parties to the arrangement) specified parties. We are proposing here to identify the circumstances under which the proposed exceptions at § 411.357(aa) would apply to an indirect compensation arrangement that includes a value-based arrangement in the unbroken chain of financial relationships described in § 411.354(c)(2)(i). Specifically, we are proposing that, when the value-based arrangement is the link in the chain closest to the physician—that is, the physician is a direct party to the value-based arrangement—the indirect compensation arrangement would qualify as a ''value-based arrangement'' for purposes of applying the proposed exceptions at § 411.357(aa). To be clear, the link closest to the physician may not be an ownership interest; it must be a compensation arrangement that meets the definition of value-based arrangement at proposed § 411.351. For purposes of determining whether the indirect compensation arrangement satisfies the requirements of an applicable exception at proposed § 411.357(aa), we would look at the value-based arrangement to which the physician is a party. For the reasons described in section II.A.2.a. of this proposed rule, we are considering

whether to exclude an unbroken chain of financial relationships between an entity and a physician from the definition of ''indirect value-based arrangement'' if the link closest to the physician (that is, the value-based arrangement to which the physician is a party) is a compensation arrangement between the physician and a: Pharmaceutical manufacturer; manufacturer, distributor, or supplier of DMEPOS; laboratory; pharmacy benefit manager; wholesaler; or distributor. In the alternative, we are considering whether to exclude an unbroken chain of financial relationships between an entity and a physician from the definition of ''indirect value-based arrangement'' if one of these persons or organizations is a party to any financial relationship in the chain of financial relationships. We are also considering whether to include health technology companies in any such exclusion in order to align our policies with policies under consideration by OIG where possible and appropriate. We seek comment on these approaches and their effectiveness in enhancing program integrity.

Under this proposal, parties would first determine if an indirect compensation arrangement exists and, if it does, determine whether the compensation arrangement to which the physician is a direct party qualifies as a value-based arrangement. If so, the exceptions at proposed § 411.357(aa) for value-based arrangements would be applicable. To illustrate, assume an unbroken chain of financial relationships between a hospital and a physician that runs: Hospital—(owned by)—parent organization—(owns)—physician practice—(employs)—physician. Thus, the links in the unbroken chain are ownership or investment interest—ownership or investment interest—compensation arrangement. For purposes of determining whether an indirect compensation exists between the physician and the hospital, under § 411.354(c)(2)(ii), we analyze the compensation arrangement between the physician practice and the physician. Assume also that the compensation paid to the physician under her employment arrangement varies with the volume or value of her referrals to the hospital because she is paid a bonus for each referral for designated health services furnished by the hospital provided that she adheres to redesigned care protocols intended to further one or more value-based purposes (as defined at proposed § 411.351). Finally, assume that the hospital has actual knowledge that the physician receives aggregate compensation that varies with the volume or value of her referrals to the hospital. The unbroken chain of financial relationships establishes an indirect compensation arrangement; therefore, in order for the physician to refer patients to the hospital for designated health services and for the hospital to submit claims to Medicare for the referred designated health services, the indirect compensation arrangement must satisfy the requirements of an applicable exception. Under this alternative proposal, if the compensation arrangement between the physician practice and the physician qualifies as a value-based arrangement (as defined at proposed § 411.351), the exceptions at proposed § 411.357(aa) would be available to protect the value-based arrangement (that is, the indirect compensation arrangement) between the hospital and the physician. (The parties could also utilize an applicable exception in § 411.355 to protect individual referrals for designated health services or the exception at § 411.357(p) to protect the indirect compensation arrangement between the hospital and the physician, but it is unlikely that all requirements of § 411.357(p) would be satisfied in this hypothetical fact pattern.)

In the alternative, we are proposing to define ''indirect value-based arrangement'' and specify in regulation that the exceptions proposed at § 411.357(aa) would be available to protect the arrangement. Under this alternate proposal, an indirect value-based arrangement would exist if: (1) Between the physician and the entity there exists an unbroken chain of any number (but not fewer than one) of persons (including but not limited to natural persons, corporations, and municipal organizations) that have financial relationships (as defined at § 411.354(a)) between them (that is, each person in the unbroken chain is linked to the preceding person by either an ownership or investment interest or a compensation arrangement); (2) the financial relationship between the physician and the person with which he or she is directly linked is a value-based arrangement; and (3) the entity has actual knowledge of the value-based arrangement in subparagraph (2). Under our alternative proposal, if an unbroken chain of financial relationships between a physician and an entity qualifies as an ''indirect value-based arrangement,'' the three exceptions proposed at § 411.357(aa) would be applicable and the requirements of at least one of the applicable exceptions must be satisfied in order for the physician to refer patients to the hospital for designated health services and for the hospital to submit claims to Medicare for the referred designated health services. For purposes of determining whether the indirect value-based arrangement satisfies the requirements of an applicable exception at proposed § 411.357(aa), we would look at the value-based arrangement to which the physician is a party. (The parties could also utilize an applicable exception in § 411.355 to protect individual referrals for designated health services or the exception at § 411.357(p) to protect the indirect compensation arrangement between the hospital and the physician, but it is unlikely that all requirements of § 411.357(p) would be satisfied in this hypothetical fact pattern.)

To illustrate this alternative proposal, assume the same unbroken chain of financial relationships. The first step in the analysis would be to determine whether the compensation arrangement between the physician practice and the physician is a value-based arrangement (irrespective of whether the compensation to the physician varies with the volume or value of her referrals to the hospital). If so, and the hospital has actual knowledge of the value-based arrangement, the unbroken chain of financial relationships would constitute an indirect value-based arrangement that must satisfy the requirements of an applicable exception at proposed § 411.357(aa) in order for the physician to refer patients to the hospital for designated health services and for the hospital to submit claims to Medicare for the referred designated health services. (The parties could also utilize an applicable exception in § 411.355 to protect individual referrals for designated health services.)

We seek comment on the best approach to address value-based arrangements that are part of an unbroken chain of financial relationships between a physician and an entity to which he or she refers patients for designated health services. Specifically, we are interested in whether one of the approaches described here is preferable. We are also soliciting comments on whether it is necessary to establish new regulations at all; that is, whether we should simply apply our existing regulations at § 411.354(c) to determine whether an unbroken chain of financial relationships that includes a value-based arrangement establishes an indirect compensation arrangement. If so, the parties could rely on the exception at current § 411.357(p) for

indirect compensation arrangements or any applicable exception in § 411.355 to protect individual referrals from the physician to the entity and claims for the referred designated health services.

(5) Price Transparency

Price transparency is a critical component of a health care system that pays for value and aligns with our desire to reinforce and support patient freedom of choice. We believe that transparency in pricing can empower consumers of health care services to make more informed decisions about their care and lower the rate of growth in health care costs. Health care consumers today lack meaningful and timely access to pricing information that could, if available, help them choose a lower-cost setting or a higher-value provider. Patients are often unaware of site-of-care cost differentials until it is too late (see Aparna Higgins & German Veselovskiy, *Does the Cite of Care Change the Cost of Care,* Health Affairs (June 2, 2016), *https://www.healthaffairs.org/do/10.1377/hblog20160602.055132/full/*). Multiple surveys and studies have revealed that patients want their health care providers to engage in cost discussions, and one recent national survey found that a majority of physicians want to have cost of care discussions with their patients (see Caroline E. Sloan, MD & Peter A. Ubel, MD, *The 7 Habits of Highly Effective Cost-of-Care Conversations,* Annals of Internal Medicine (May 7, 2019), *https://annals.org/aim/issue/937992,* and *Let's Talk About Money,* The University of Utah (2018), *https://uofuhealth.utah.edu/value/lets-talk-about-money.php*). The point of referral presents an ideal opportunity to have such cost-of-care discussions.

In the CMS RFI, we solicited comment on the role of transparency in the context of the physician self-referral law. In particular, we solicited comment on whether, if provided by the referring physician to a beneficiary, transparency about a physician's financial relationships, price transparency, or the availability of other data necessary for informed consumer purchasing (such as data about quality of services provided) would reduce or eliminate the harms to the Medicare program and its beneficiaries that the physician self-referral law is intended to address. Many commenters replied that making a physician's financial relationships and cost of care information available could be useful. One commenter suggested that providing clear and transparent information was vital in the health care industry where patients are often vulnerable, confused, and unsure of their options. This commenter further opined that informed patients are empowered to take charge of their health care and better assist their providers in fulfilling their health care needs. Several commenters shared similar support for transparency efforts. Another commenter stated that transparency of a physician's financial relationships along with price and quality of care information would be valuable to patients in choosing providers and care pathways. This commenter maintained that these actions would also engage patients in protecting against possible unintended consequences of value-based arrangements. Other commenters raised concerns that information on price transparency and a physician's financial relationships with other health care providers, in combination with already-required disclosures under HIPAA, informed consent information and forms, insurance payment authorization forms, and other paperwork that patients receive or must complete would serve only to inundate patients with paperwork that they will find confusing or simply not read. These commenters contended that, although transparency is an appealing concept, requiring additional disclosures would result in more burden than benefit.

The June 24, 2019 Executive Order on Improving Price and Quality Transparency in American Healthcare to Put Patients First recognizes the importance of price transparency. The Executive Order directs Federal agencies to take historic steps toward getting patients the information they need and when they need it to make well-informed decisions about their health care. CMS has already acted on the Executive Order through its proposals in the CY 2020 OPPS proposed rule to improve the availability of meaningful pricing information to the public. We believe that all consumers need price and quality information in advance to make an informed decision when they choose a good or service, including at the point of a referral for such goods or services. By making meaningful price and quality information more broadly available, we can protect patients and increase competition, innovation, and value in the health care system.

As discussed elsewhere in this section of the proposed rule, we are committed to ensuring that physician self-referral law policies do not infringe on patient choice and the ability of physicians and patients to make health care decisions that are in the patient's best interest. We believe it is important for patients to have timely access to information about all aspects of their care, including information about the factors that may affect the cost of services for which they are referred. A patient who is made aware, for example, that costs may differ based on the site of service where the referred services are furnished, may become a more conscious consumer of health care services. Access to such information may also spark important conversations between patients and their physicians, promoting patient choice and the ability of physicians and patients to make health care decisions that are in the patient's best interest. In conjunction with their physicians' determination of the need for recommended health care services and the urgency of that need, information on the factors that may affect the cost of such services could ensure that patients have the information they need to shop and seek out high-quality care at the lowest possible cost.

We seek to establish policies that facilitate consumers' ability to participate actively and meaningfully in decisions relating to their care. At the same time, we are cognizant that including requirements regarding price transparency in the exceptions to the physician self-referral law raises certain challenges for the regulated industry. We seek comments on how to pursue our price transparency objectives in the context of the physician self-referral law, both in the context of a value-based health care system and otherwise, and how to overcome the technical, operational, legal, cultural, and other challenges to including price transparency requirements in the physician self-referral regulations. Specifically, we are interested in comments regarding the availability of pricing information and out-of-pocket costs to patients (including information specific to a particular patient's insurance, such as the satisfaction of the patient's applicable deductible, copayment, and coinsurance obligations); the appropriate timing for the dissemination of information (that is, whether the information should be provided at the time of the referral, the time the service is scheduled, or some other time); and the burden associated with compliance with a requirement in an exception to the physician self-referral law to provide information about the factors that may affect the cost of services for which a patient is referred. Finally, we seek comment whether the inclusion of a price transparency requirement in a value-based exception would provide additional protections against program or patient abuse through the active

participation of patients in selecting their health care providers and suppliers.

In furtherance of our goal of price transparency for all patients, we are considering whether to include a requirement related to price transparency in every exception for value-based arrangements at proposed § 411.357(aa). For instance, we are considering whether to require that a physician provide a notice or have a policy regarding the provision of a public notice that alerts patients that their out of pocket costs for items and services for which they are referred by the physician may vary based on the site where the services are furnished and based on the type of insurance that they have. Because of limits on currently available pricing data, we believe such a requirement could be an important first step in breaking down barriers to cost-of-care discussions that play a beneficial role in a value-based health care system. The public notice provided or reflected in the policy could be made in any form or manner that is accessible to patients. For example, a notice on the physician's website, a poster on the wall in the physician's office, or a notice in a patient portal used by the physician's patients would all be acceptable. We expect that any notice would be written in plain language that would be understood by the general public. We refer readers to the Plain Writing Act of 2010 (Pub. L. 111–274, enacted on October 13, 2010) for further information. We seek comment on whether, if we finalize such a requirement, it would be helpful for CMS to provide a sample notice and, if we provide a sample notice, whether we should deem such a notice to satisfy the requirement described. We note that we would not require public notice in advance of referrals for emergency hospital services to avoid delays in urgently needed care. We seek comment on other options for price transparency requirements in the value-based exceptions to the physician self-referral law that we are proposing in this proposed rule, as well as whether we should consider for a future rulemaking the inclusion of price transparency requirements in exceptions to the physician self-referral law included in our existing regulations.

B. Fundamental Terminology and Requirements

1. Background

As described in greater detail in this section of the proposed rule, many of the statutory and regulatory exceptions to the physician self-referral law include one, two, or all of the following requirements: The compensation arrangement itself is commercially reasonable; the amount of the compensation is fair market value; and the compensation paid under the arrangement is not determined in a manner that takes into account the volume or value of referrals (or, in some cases, other business generated between the parties). These requirements are presented in various ways within the statutory and regulatory exceptions, but it is clear that they are separate and distinct requirements, each of which must be satisfied when present in an exception. Nonetheless, the regulated industry and its complementary parts, such as the health care valuation community, continue to seek additional guidance from CMS. For example, many CMS RFI commenters shared a common belief that, if compensation is not fair market value, CMS would automatically consider it to take into account the volume or value of referrals. Or, under the current definition of fair market value at § 411.351, if compensation takes into account the volume or value of referrals, it cannot be fair market value. (Although this is not the case, we note that failure to meet even a single requirement of an applicable exception leaves a compensation arrangement subject to the physician self-referral law's referral and claims submission prohibitions; failure to satisfy multiple requirements of an exception does not result in ''additional'' noncompliance with the law's prohibitions.) We provide examples of such guidance below in sections II.B.3 and II.B.5. Moreover, although commercial reasonableness is a core requirement of many exceptions to the physician self-referral law, the only guidance we have provided to date is in a proposed rule (63 FR 1700). False Claims Act case law has exacerbated the challenge of complying with these three fundamental requirements, according to commenters.

Over the years, stakeholders have approached CMS with requests for clarification on our policy with respect to when an arrangement is considered commercially reasonable, under what circumstances compensation is considered to take into account the volume or value of referrals or other business generated between the parties, and how to determine the fair market value of compensation. In light of the current Regulatory Sprint, we included in the CMS RFI specific questions regarding these issues. A large number of commenters responded to these specific requests. Although the commenters suggested varying ways we could provide clearer guidance, uniformly, they requested that we establish bright-line, objective regulations for each of these fundamental requirements. Our overall intention in this proposed rule is to reduce the burden of compliance with the physician self-referral law, provide clarification where possible, and revise regulations as necessary to achieve these goals and the goals of the Regulatory Sprint. We reviewed the statute and our regulations in a fresh light, and believe that clear, bright-line rules would enhance both stakeholder compliance efforts and our enforcement capability. We have endeavored here to provide the clarity that will benefit the regulated industry, CMS, and our law enforcement partners.

In developing our proposals for guidance on the fundamental terminology and requirements described previously, we considered three basic questions—

- Does the arrangement make sense as a means to accomplish the parties' goals?
- How did the parties calculate the remuneration?
- Did the calculation result in compensation that is fair market value for the asset, item, service, or rental property?

These questions relate, respectively, to the definition of commercial reasonableness, the volume or value standard and the other business generated standard, and the definition of fair market value. In this section of the proposed rule, we provide detailed descriptions of our proposed definitions and special rules. Importantly, our proposals relate only to the application of section 1877 of the Act and our physician self-referral regulations. Although other laws and regulations, including the anti-kickback statute and CMP law, may utilize the same or similar terminology, the interpretations proposed here would not affect OIG's (or any other governmental agency's) interpretation or ability to interpret such terms for purposes of laws or regulations other than the physician self-referral law. In addition, our interpretation of these key terms does not relate to and in no way binds the Internal Revenue Service with respect to its rulings and interpretation of the Internal Revenue Code or State agencies with respect to any State law or regulation that may utilize the same or similar terminology. We note further that, to the extent terminology is the same as or similar to terminology used in the Quality Payment Program within the PFS, our proposals would not affect

or apply to the Quality Payment Program.

2. Commercially Reasonable (§ 411.351)

We are proposing to include at § 411.351 a definition for the term ''commercially reasonable.'' As described previously, many of the statutory and regulatory exceptions to the physician self-referral law include a requirement that the compensation arrangement is commercially reasonable. For example, the exception at section 1877(e)(2) of the Act for *bona fide* employment relationships requires that the remuneration provided to the physician is pursuant to an arrangement that would be commercially reasonable (even if no referrals were made to the employer). The exception at section 1877(e)(3)(A) of the Act for personal service arrangements uses slightly different language to describe this general concept, and requires that the aggregate services contracted for do not exceed those that are reasonable and necessary for the legitimate business purposes of the arrangement. The exception at § 411.357(l) for fair market value compensation, which the Secretary established in regulation using his authority at section 1877(b)(4) of the Act, requires that the arrangement is commercially reasonable (taking into account the nature and scope of the transaction) and furthers the legitimate business purposes of the parties. Despite the prevalence of this requirement (in one form or another), we addressed the concept of commercial reasonableness only once—in our 1998 proposed rule—where we stated that we are interpreting ''commercially reasonable'' to mean that an arrangement appears to be a sensible, prudent business agreement, from the perspective of the particular parties involved, even in the absence of any potential referrals (63 FR 1700). The physician self-referral regulations themselves lack a codified definition for the term commercially reasonable.

As discussed previously, we believe that the key question to ask when determining whether an arrangement is commercially reasonable is simply whether the arrangement makes sense as a means to accomplish the parties' goals. We continue to believe that this determination should be made from the perspective of the particular parties involved in the arrangement. The determination of commercial reasonableness is not one of valuation. Nor does the determination that an arrangement is commercially reasonable turn on whether the arrangement is profitable. It is apparent from our review of the CMS RFI comments that there is a widespread misconception about our position on the nexus between the commercial reasonableness of an arrangement and its profitability. We wish to clarify that compensation arrangements that do not result in profit for one or more of the parties may nonetheless be commercially reasonable.

CMS RFI commenters shared numerous examples of compensation arrangements that they believed would be commercially reasonable despite the fact that the party paying the remuneration does not recognize an equivalent or greater financial benefit from the items or services purchased in the transaction, or that the party receiving the remuneration incurs costs in furnishing the items or services that are greater than the amount of the remuneration received. Commenters also explained that, even knowing in advance that an arrangement may result in losses to one or more parties, it may be reasonable, if not necessary, to nevertheless enter into the arrangement. These commenters explained some of the reasons why parties would enter into such transactions, such as community need, timely access to health care services, fulfillment of licensure or regulatory obligations, including those under the Emergency Medical Treatment and Labor Act (EMTALA), the provision of charity care, and the improvement of quality and health outcomes. One commenter suggested that entire hospital service lines, with their needed management and other physician-provided services, are illustrative for operating at a loss and identified psychiatric and burn units as examples of such service lines. According to this commenter, with changes in reimbursement, more service lines will operate at a loss in the future. The commenter urged that these services are of vital need to communities and, unless CMS addresses the definition of ''commercial reasonableness,'' health care providers may be prohibited from providing these services to their communities as a result of a fear of violating the commercial reasonableness standard. We find these comments and the concerns they highlight compelling.

We are proposing two alternative definitions for the term ''commercially reasonable.'' First, we are proposing to define ''commercially reasonable'' to mean that the particular arrangement furthers a legitimate business purpose of the parties and is on similar terms and conditions as like arrangements. In the alternative, we are proposing to define ''commercially reasonable'' to mean that the arrangement makes commercial sense and is entered into by a reasonable entity of similar type and size and a reasonable physician of similar scope and specialty. We seek comment on each of these proposed definitions as well as input from stakeholders regarding other possible definitions that would provide clear guidance to enable parties to structure their arrangements in a manner that ensures compliance with the requirement that their particular arrangement is commercially reasonable. We are also proposing to clarify in regulation text that an arrangement may be commercially reasonable even if it does not result in profit for one or more of the parties.

In developing our proposals, we reviewed the Internal Revenue Service (IRS) Revenue Ruling 97–21, which considered whether a hospital violates the requirements for exemption from federal income tax as an organization described in section 501(c)(3) of the Internal Revenue Code (Title 26 of the United States Code) when it provides incentives to recruit private practice physicians to join its medical staff or to provide medical services in the community. The IRS identified several activities that would support a hospital's charitable purposes, all of which were mentioned in the CMS RFI comments. As described previously, the arrangements identified by commenters on the CMS RFI may further a legitimate business purpose of the parties or make commercial sense as well. However, arrangements that, on their face, appear to further a legitimate business purpose of the parties may not be commercially reasonable if they merely duplicate other facially legitimate arrangements. For example, a hospital may enter into an arrangement for the personal services of a physician to oversee its oncology department. If the hospital needs only one medical director for the oncology department, but later enters into a second arrangement with another physician for oversight of the department, the second arrangement merely duplicates the already-obtained medical directorship services and may not be commercially reasonable. Although the evaluation of compliance with the physician self-referral law always requires a review of the facts and circumstances of the financial relationship between the parties, the commercial reasonableness of multiple arrangements for the same services is questionable.

Also important to our consideration of the best way to define and interpret ''commercially reasonable'' was the IRS's conclusion that a hospital may not engage in substantial unlawful activities and maintain its tax-exempt status

because the conduct of an unlawful activity is inconsistent with charitable purposes. The IRS explained that an organization conducts an activity that is unlawful, and therefore not in furtherance of a charitable purpose, if the organization's property is to be used for an objective that is in violation of the criminal law. We are similarly taking the position that an activity that is in violation of criminal law would not be a legitimate business purpose of the parties, nor would it make commercial sense, and, therefore, would not be commercially reasonable for purposes of the physician self-referral law. We note that the absence of a criminal violation would not, in and of itself, establish that an arrangement is commercially reasonable. We seek comment on our alternate proposals for the definition of ''commercially reasonable'' and its interpretation, including how parties could determine whether an arrangement is on similar terms and conditions as like arrangements.

We note that many of the exceptions to the physician self-referral law require that an arrangement is commercially reasonable ''even if no referrals were made between the parties'' or ''even if no referrals were made to the employer.'' The exceptions use varying phrasing to describe this requirement and we do not repeat each iteration here. We are not proposing to eliminate this requirement from the exceptions where it appears. For example, under our first alternative proposal, an employment arrangement must further a legitimate business purpose of the parties and be on similar terms and conditions as like arrangements, even if no referrals were made to the employer, as well as satisfy the other requirements of the exception, in order for the physician to refer patients to the employing entity for designated health services and for the employing entity to submit claims to Medicare for the referred designated health services. Under our second alternative proposal, an employment arrangement must make commercial sense and be entered into by a reasonable entity of similar type and size and a reasonable physician of similar scope and specialty, even if no referrals were made to the employer, as well as satisfy the other requirements of the exception. To emphasize, a compensation arrangement must satisfy the ''even if no referrals were made'' requirement if it is included as a requirement of the relevant exception under which the parties seek protection from the physician self-referral law's referral and claims submission prohibitions.

3. The Volume or Value Standard and the Other Business Generated Standard (§ 411.354(d)(5) and (6))

Many of the exceptions at section 1877(e) of the Act (''Exceptions Relating to Other Compensation Arrangements'') and in our regulations include a requirement that the compensation paid under the arrangement is not determined in a manner that takes into account the volume or value of referrals by the physician who is a party to the arrangement, and some exceptions also include a requirement that the compensation is not determined in a manner that takes into account other business generated between the parties. We refer to these as the ''volume or value standard'' and the ''other business generated standard,'' respectively. Throughout the regulatory history of the physician self-referral law, we have shared our interpretation of these standards and responded to comments as they arose. Despite our attempt at establishing clear guidance regarding the application of the volume or value standard and the other business generated standard, commenters to several requests for information, including the CMS RFI, identified their lack of a clear understanding as to when compensation will be considered to take into account the volume or value of referrals or other business generated by the physician as one of the greatest risks they face when structuring arrangements between entities furnishing designated health services and the physicians who refer to them. They stated that, not only do they face the risk of penalties under the physician self-referral law, but, because a violation of the physician self-referral law may be the predicate for liability under the Federal False Claims Act (31 U.S.C. 3729 through 3733), entities are susceptible to both government and whistleblower actions that can result in significant penalties through litigation or settlement. Commenters and other stakeholders have long expressed frustration that, from their perspective, the guidance from CMS has been too limited and left them without an objective standard against which to judge their financial relationships. Our proposals here are intended to provide objective tests for determining whether compensation takes into account the volume or value of referrals or the volume or value of other business generated by the physician. Before describing our proposals, we provide a brief history of the guidance to date on the volume or value standard and the other business generated standard.

In the 1998 proposed rule, we discussed the volume or value standard as it pertains to the criteria that a physician practice must meet to qualify as a ''group practice'' (63 FR 1690). We also stated that we would apply this interpretation of the volume or value standard throughout our regulations (63 FR 1699). In the discussion of group practices, we stated that we believe that the volume or value standard precludes a group practice from paying physician members for each referral they personally make or based on the volume or value of the referred services (63 FR 1690). We went on to state that the most straightforward way for a physician practice to demonstrate that it is meeting the requirements for group practices would be for the practice to avoid a link between physician compensation and the volume or value of any referrals, regardless of whether the referrals involve Medicare or Medicaid patients (63 FR 1690). However, because our definition of ''referral'' at § 411.351 includes only referrals for designated health services, we also noted that a physician practice that wants to compensate its members on the basis of non-Medicare and non-Medicaid referrals would be required to separately account for revenues and distributions related to referrals for designated health services for Medicare and Medicaid patients (63 FR 1690). (See section II.C. of this proposed rule for a discussion of the inclusion of Medicaid referrals in the existing regulation and our proposed revisions to the group practice rules.) Outside of the group practice context, these principles apply generally to compensation from an entity to a physician. We also addressed the other business generated standard in the 1998 proposed rule, stating that we believe that the Congress may not have wished to except arrangements that include additional compensation for other business dealings and that, if a party's compensation contains payment for other business generated between the parties, we would expect the parties to separately determine if this extra payment falls within one of the exceptions (63 FR 1700).

In Phase I, we finalized our policy regarding the volume or value standard and the other business generated standard, responding to comments on our proposals in the 1998 proposed rule. Most importantly, we revised the scope of the volume or value standard to permit time-based or unit of service-based compensation formulas (66 FR 876). We also stated that the phrase ''does not take into account other

business generated between the parties'' means that the fixed, fair market value payment cannot take into account, or vary with, referrals of designated health services payable by Medicare or Medicaid or any other business generated by the referring physician, including other Federal and private pay business (66 FR 877), noting that the phrase ''generated between the parties'' means business generated *by the referring physician* for purposes of the physician self-referral law (66 FR 876). We stated that section 1877 of the Act establishes a straightforward test that compensation should be at fair market value for the work or service performed or the equipment or [office] space leased—not inflated to compensate for the physician's ability to generate other revenue (66 FR 877). Finally, in response to an inquiry about whether the compensation paid to a physician for the purchase of his or her practice could include the value of the physician's referrals of designated health services to the practice, we stated that compensation may include the value of designated health services made by the physician to his or her practice if the designated health services referred by the selling physician satisfied the requirements of an applicable exception, such as the in-office ancillary services exception, and the purchase arrangement is not contingent on future referrals (66 FR 877). This policy would apply also to the value of the physician's referrals of designated health services to his or her practice if the compensation arrangement between the physician and the practice satisfied the requirements of an applicable exception.

Also in Phase I, we established special rules on compensation at § 411.354(d)(2) and (3) that deem compensation not to take into account the volume or value of referrals or other business generated between the parties if certain conditions are met (66 FR 876 through 877). These rules state that compensation will be deemed not to take into account the volume or value of referrals if the compensation is fair market value for services or items actually provided and does not vary during the course of the compensation arrangement in any manner that takes into account referrals of designated health services. Compensation will be deemed not to take into account the volume or value of other business generated between the parties to a compensation arrangement if the compensation is fair market value and does not vary during the term of the compensation arrangement in any manner that takes into account referrals or other business generated by the referring physician, including private pay health care business. Both special rules apply to time-based or per-unit of service-based (''per-click'') compensation formulas. However, as we noted later in Phase II, the special rules on compensation are intended to be safe harbors, and there may be some situations not described in § 411.354(d)(2) or (3) where an arrangement does not take into account the volume or value of referrals or other business generated between the parties (69 FR 16070).

In Phase II, we clarified that personally performed services are not considered other business generated by the referring physician (69 FR 16068). We also stated that fixed compensation (that is, one lump payment or several individual payments aggregated together) can take into account or otherwise reflect the volume or value of referrals (for example, if the payment exceeds the fair market value for the items or services provided) (69 FR 16059). We noted that whether the compensation does, in fact, take into account or otherwise reflect the volume or value of referrals will require a case-by-case determination based on the facts and circumstances. (We note that the language ''otherwise reflects'' was considered superfluous and removed from our regulation text in Phase III (72 FR 51027).)

To date, we have not codified any regulations defining or otherwise interpreting the volume or value standard or the other business generated standard. In this proposed rule, we are proposing to do so. The proposed special rules at § 411.354(d)(5) and (6), if finalized, will supersede our previous guidance, including guidance with which they may be (or appear to be) inconsistent. We note that, unless finalized, the proposed special rules and the policies they effect are not applicable to the determination of whether compensation takes into account the volume or value of referrals or the volume or value of other business generated between the parties (that is, by the physician).

In the CMS RFI, we solicited comments on when, in the context of the physician self-referral law and, specifically, within the context of alternative payment models and other novel financial arrangements, compensation should be considered to ''take into account the volume or value of referrals'' by a physician or ''take into account other business generated'' between parties to an arrangement (83 FR 29526). We requested that commenters share with us, by way of example or otherwise, compensation formulas that do not take into account the volume or value of referrals by a physician or other business generated between the parties. We discussed the comments related to the inclusion of the volume or value standard or the other business generated standard in new exceptions for value-based arrangements in section II.A.2.b. of this proposed rule. Our discussion in this section II.B.3. of this proposed rule relates only to these standards as they apply outside of the context of value-based arrangements; specifically, as they apply to the definition of remuneration at section 1877(h)(1)(C) of the Act and § 411.351 of our regulations, the definition of indirect compensation arrangement at § 411.354(c)(2), the special rule on compensation that is considered set in advance at § 411.354(d)(1), the special rules for per-unit compensation at § 411.354(d)(2) and (3), the exception for academic medical centers at § 411.355(e)(1)(ii), and various exceptions for compensation arrangements at section 1877(e) of the Act and in § 411.357 of our regulations (including the proposed exceptions for limited remuneration to a physician at § 411.357(z) and cybersecurity technology and related services at § 411.357(bb), if finalized). As discussed previously, the proposed exceptions for value-based arrangements do not include the volume or value standards as requirements for the remuneration between the parties.

CMS RFI commenters uniformly requested that we provide objective benchmarks for determining when compensation is considered to take into account the volume or value of referrals or take into account other business generated between the parties. Many commenters stated their belief that a provider's subjective intent is potentially relevant in determining whether the manner in which the compensation was established took into account the volume or value of referrals or other business generated. These and many other commenters requested that the regulations make clear that the volume or value standard and the other business generated standard are bright-line, objective tests; that is, by the plain terms of an arrangement, the test is whether the methodology used to set physician compensation utilizes as a variable the volume or value of the physician's referrals or the volume or value of other business generated by the physician. Other commenters shared their concerns that, under the current guidance and the position taken by the

government in certain of its enforcement actions, parties can never be sure that their determination of the compensation to be paid under an arrangement with a referring physician will be insulated from scrutiny.

We believe there is great value in having an objective test for determining whether the compensation is determined in any manner that takes into account the volume or value of referrals or takes into account other business generated between the parties. Our proposals are intended to establish such a test. We are proposing an approach that, rather than deeming compensation under certain circumstances not to have been determined in a manner that takes into account the volume or value of referrals or takes into account other business generated between the parties, defines exactly when compensation will be considered to take into account the volume or value of referrals or take into account other business generated between the parties. Under our proposed approach, which we believe creates the bright-line rule sought by commenters and other stakeholders, outside of the circumstances at proposed § 411.354(d)(5) and (6), compensation would not be considered to take into account the volume or value of referrals or take into account other business generated between the parties, respectively. In other words, only when the mathematical formula used to calculate the amount of the compensation includes as a variable referrals or other business generated, and the amount of the compensation correlates with the number or value of the physician's referrals to or the physician's generation of other business for the entity, is the compensation considered to take into account the volume or value of referrals or take into account the volume or value of other business generated. We believe our proposed approach is consistent with the position we articulated in Phase I where we stated that, in general, we believe that a compensation structure does not directly take into account the volume or value of referrals if there is no direct correlation between the total amount of a physician's compensation and the volume or value of the physician's referrals of designated health services (66 FR 908).

Although we are proposing nonsubstantive changes to standardize where possible the language used to describe the volume or value standard and the other business generated standard in our regulations, due to the varying language used throughout the statutory scheme and the language that will remain in the regulatory scheme even if our proposed changes are finalized, we find it impossible to establish a single *definition* for each standard. Therefore, instead of a definition at § 411.351, we are proposing special rules for compensation arrangements that will apply regardless of the exact language used to describe the standards. Also, because section 1877 of the Act defines a compensation arrangement as any arrangement involving any remuneration between a physician (or an immediate family member of such physician) and an entity, we believe it is necessary that the tests address circumstances where the compensation is from the entity to the physician, as well as where the compensation is from the physician to the entity. Therefore, we are proposing two separate special rules for the volume or value standard (proposed § 411.354(d)(5)(i) and (6)(i)) and two special rules for the other business generated standard (proposed § 411.354(d)(5)(ii) and (6)(ii)). Our proposals apply only for purposes of section 1877 of the Act and the physician self-referral regulations.

Under the policy proposed at § 411.354(d)(5)(i)(A), compensation from an entity to a physician (or immediate family member of the physician) takes into account the volume or value of referrals only if the formula used to calculate the physician's (or immediate family member's) compensation includes the physician's referrals to the entity as a variable, resulting in an increase or decrease in the physician's (or immediate family member's) compensation that *positively correlates* with the number or value of the physician's referrals to the entity. For example, if the physician (or immediate family member) *receives additional compensation* as the number or value of the physician's referrals to the entity increase, the physician's (or immediate family member's) compensation would positively correlate with the number or value of the physician's referrals. Unless the special rule at § 411.354(d)(2) for unit-based compensation applies and its conditions are met, the physician's (or immediate family member's) compensation would take into account the volume or value of referrals. To illustrate, assume that a physician practice does not qualify as a group practice under § 411.352 of the physician self-referral regulations. The practice pays its physicians a percentage of collections attributed to the physician, including personally performed services and services furnished by the practice (the physician's ''pool''). If the physician's pool includes amounts collected for designated health services furnished by the practice that he ordered but did not personally perform, under proposed § 411.354(d)(5)(i), the physician's compensation would take into account the volume or value of his referrals to the practice. Assuming the physician is paid 50 percent of the amount in his pool, the mathematical formula that illustrates the physician's compensation would be: Compensation = (.50 × collections from personally performed services) + (.50 × collections from referred designated health services) + (.50 × collections from non-designated health services referrals). The policy proposed at § 411.354(d)(5)(ii)(A) with respect to when compensation from an entity to a physician (or immediate family member of the physician) takes into account other business generated would operate in the same manner.

Analogously, under the policy proposed at § 411.354(d)(6)(i)(A), compensation from a physician (or immediate family member of the physician) to an entity takes into account the volume or value of referrals only if the formula used to calculate the compensation paid by the physician includes the physician's referrals to the entity as a variable, resulting in an increase or decrease in the compensation that negatively correlates with the number or value of the physician's referrals to the entity. For example, if the physician (or immediate family member) *pays less compensation* as the number or value of the physician's referrals to the entity increase, the compensation from the physician to the entity would negatively correlate with the number or value of the physician's referrals. Unless the special rule at § 411.354(d)(2) for unit-based compensation applies and its requirements are met (which seems unlikely), the compensation would take into account the volume or value of referrals. To illustrate, assume a physician leases medical office space from a hospital. Assume also that the rental charges are $5000 per month and the arrangement provides that the monthly rental charges will be reduced by $5 for each diagnostic test ordered by the physician and furnished in one of the hospital's outpatient departments. Under proposed § 411.354(d)(6)(i), the compensation (that is, the rental charges) would take into account the volume or value of the physician's referrals to the hospital. The mathematical formula that illustrates the rental charges paid by the physician

to the hospital would be: Compensation = $5000 − ($5 × the number of designated health services referrals). The policy proposed at § 411.354(d)(6)(ii)(A) with respect to when compensation from a physician (or immediate family member of the physician) to an entity takes into account other business generated would operate in the same manner.

We are also proposing at § 411.354(d)(5)(i)(B) and (ii)(B), and at § 411.354(d)(6)(i)(B) and (ii)(B), additional policies outlining the narrowly-defined circumstances under which we would consider fixed-rate compensation (for example, a fixed annual salary or an unvarying per-unit rate of compensation) to be determined in a manner that takes into account the volume or value of referrals or other business generated by a physician for the entity paying the compensation. Under this approach, compensation would take into account the volume or value of referrals where the parties utilize a predetermined tiered approach to compensation under which the volume or value of a physician's prior referrals is the basis for determining the unvarying rate of compensation from an entity to a physician (or an immediate family member of a physician) or the unvarying rate of compensation that a physician (or an immediate family member of a physician) must pay an entity over the entire duration of the arrangement. The policy would operate analogously with respect to other business previously generated by the physician for the entity. Under this approach, the compensation need not be determined based on a mathematical formula, but there must be a predetermined, direct positive or negative correlation between the volume or value of the physician's prior referrals (or other business previously generated for the entity) and the exact rate of compensation paid to or by the physician (or an immediate family member of the physician) in order for the compensation to violate the volume or value standard or the other business generated standard. Put another way, there must be a predetermined, direct, and meaningful ''if X, then Y'' correlation between the volume or value of the physician's prior referrals (or the other business previously generated by the physician for the entity) and the prospective rate of compensation to be paid over the entire duration of the arrangement for which the compensation is determined. Merely hoping for or even anticipating future referrals or other business is not enough to show that compensation is determined in a manner that takes into account the volume or value of referrals or the other business generated by the physician for the entity.

We note that an ''if X, then Y'' compensation methodology is capable of reproduction in a mathematical formula that positively or negatively correlates with the number or value of the physicians' referrals to the entity. (In Boolean algebra, the formula $p \rightarrow q$ represents this type of compensation methodology.) To illustrate, assume that a hospital-employed physician is paid on the basis of her personally performed professional services (in this example, the physician is paid a predetermined rate per physician work relative value unit (wRVU)). The hospital has a predetermined tiered system for determining physician compensation when entering into renewal employment arrangements under which a physician is paid $30 per wRVU if she ordered 300 or fewer outpatient diagnostic tests per year during the prior term of employment and $35 per wRVU if she ordered more than 300 outpatient diagnostic tests per year during the prior term of employment. Because the physician ordered 250 outpatient diagnostic tests per year during the prior term of her employment, her compensation for the duration of the renewal arrangement is $30 per wRVU. Even though the physician is paid an unvarying rate of $30 per wRVU regardless of whether she makes zero, 10, or 1,000 referrals to the entity during the term of the renewal arrangement, her compensation would nonetheless take into account the volume or value of her referrals and other business generated for the entity. As another example, assume that a physician leases medical office space from a hospital and the rental charges are as follows: $2000 per month if the physician is in the top 25 percent of admitting physicians at the hospital (measured by the gross charges per inpatient admission); $2500 per month if the physician is in the second quartile of admitting physicians on the hospital's medical staff (measured by the gross charges per inpatient admission); and $3500 per month if the physician is in the bottom half of admitting physicians at the hospital (measured by the gross charges per inpatient admission). Under our proposed additional approach to the volume or value standard and other business generated standard, the compensation (that is, the rental charges) would be determined in a manner that takes into account the value of the physician's referrals and other business generated for the hospital. We seek comment on this additional proposal.

We are particularly interested in comments regarding whether this approach would achieve our goal of establishing sufficiently objective tests for determining whether the compensation is determined in any manner that takes into account the volume or value of referrals or takes into account other business generated between the parties.

Although our proposals would establish ''special rules'' on compensation, we would interpret them in the same manner as definitions. That is, the special rules are intended to define the universe of circumstances under which compensation is considered to take into account the volume or value of referrals or other business generated by the physician. If the methodology used to determine the physician's compensation or the payment from the physician does not fall squarely within the defined circumstances, the compensation would not take into account the volume or value of the physician's referrals or the other business generated by the physician, as appropriate, for purposes of applying the exceptions to the physician self-referral law.

We do not believe that it is necessary to include the modifier ''directly or indirectly'' in the proposed special rules interpreting the volume or value standard and the other business generated standard or in the definitions and exceptions where these standards appear. We believe that the modifier ''directly or indirectly'' is implicit in the requirements that compensation is not determined in *any* manner that takes into account the volume or value of referrals or the volume or value of other business generated. For this reason, and in the interest of having uniform language throughout our regulations that describes the volume or value standard and the other business generated standard, we are proposing to remove the modifier from the regulations where it appears in connection with the standards and the related requirements. We also believe that leaving the modifying language in the regulations might create confusion if the proposed special rules interpreting the volume or value standard and other business generated standard are finalized. Where the statute or regulations specifically allow parties to determine compensation in a manner that only indirectly takes into account the volume or value of referrals (for example, in the exception for EHR items and services at § 411.357(w)(6) and the rules for a group practice's distribution

of profit shares and payment of productivity bonuses at section 1877(h)(4)(B) of the Act and § 411.352(i)), our regulations include guidance regarding direct versus indirect manners of determining compensation. We solicit comment on whether additional guidance is necessary in light of our proposed interpretation of the volume or value standard and the other business generated standard included in this proposed rule. We note that the proposed exception for donations of cybersecurity technology and related services discussed in section II.E.2. of this proposed rule would also permit certain remuneration that indirectly takes into account the volume or value of referrals but does not include specific deeming provisions or other guidance regarding direct versus indirect manners of determining remuneration. We seek comment in section II.E.2. regarding the need for additional guidance or regulation text that includes deeming provisions related to the volume or value standard in the proposed exception.

Finally, a large number of the CMS RFI commenters that addressed the volume or value and other business generated standards requested that we confirm, if not codify, related guidance in our Phase II regulation (69 FR 16088 through 16089). In Phase II, a commenter presented a scenario under which a hospital employs a physician at an outpatient clinic and pays the physician for each patient seen at the clinic; the physician reassigns his or her right to payment to the hospital, and the hospital bills for the Part B physician service (with a site-of-service reduction); and the hospital also bills for the hospital outpatient services, which may include some procedures furnished as ''incident to'' services in a hospital setting. The Phase II commenter's concern was that the payment to the physician is inevitably linked to a facility fee, which is a designated health service (that is, a hospital service). Accordingly, the commenter wondered whether the payment to the physician would be considered an improper productivity bonus based on a referral of designated health services (that is, the facility fee). In response, we stated that the fact that corresponding hospital services are billed would not invalidate an employed physician's personally performed work, for which the physician may be paid a productivity bonus (subject to the fair market value requirement). The CMS RFI commenters expressed concern that, following the July 2, 2015 opinion of the United States Court of Appeals for the Fourth Circuit in *United States ex rel. Drakeford* v. *Tuomey Healthcare System, Inc.,* CMS may no longer endorse this policy.

We believe that the proposed objective tests for determining when compensation takes into account the volume or value of referrals or the volume or value of other business generated may address the CMS RFI commenters' concerns. However, for clarity, we reaffirm the position we took in the Phase II regulation. With respect to employed physicians, a productivity bonus will not take into account the volume or value of the physician's referrals solely because corresponding hospital services (that is, designated health services) are billed each time the employed physician personally performs a service. We are also clarifying that our guidance extends to compensation arrangements that do not rely on the exception for *bona fide* employment relationships at § 411.357(c), and under which a physician is paid using a unit-based compensation formula for his or her personally performed services, provided that the compensation meets the conditions in the special rule at § 411.354(d)(2). That is, under a personal service arrangement, an entity may compensate a physician for his or her personally performed services using a unit-based compensation formula—even when the entity bills for designated health services that correspond to such personally performed services—and the compensation will not take into account the volume or value of the physician's referrals if the compensation meets the conditions of the special rule at § 411.354(d)(2) (see 69 FR 16067).

4. Patient Choice and Directed Referrals (§ 411.354(d)(4))

When the conditions of the special rule at existing § 411.354(d)(4) are met, compensation from a *bona fide* employer, under a managed care contract, or under a personal services arrangement is deemed not to take into account the volume or value of referrals, even if the physician's compensation was predicated, either expressly or otherwise, on the physician making referrals to a particular provider, practitioner, or supplier. This special rule was established in Phase I after many commenters objected to our statement in the 1998 proposed rule that fixed payments to a physician could be considered to take into account the volume or value of referrals if a condition or requirement for receiving the payment was that the physician refer designated health services to a given entity, such as an employer or an affiliated entity (63 FR 1700). In Phase I, we acknowledged that the proposed interpretation could have had far-reaching effects, especially for managed care arrangements and group practices. We determined to permit directed referrals without considering the physician's compensation to take into account the volume or value of his or her referrals, but only if the referral requirement does not apply if a patient expresses a preference for a different provider, practitioner, or supplier; the patient's insurer determines the provider, practitioner, or supplier; or the referral is not in the patient's best medical interests in the physician's judgment. In addition, the referral requirement must be set out in writing and signed by the parties, and the compensation to the physician must be: (1) Set in advance for the term of the compensation arrangement; and (2) consistent with fair market value for the services performed. Finally, the compensation arrangement must otherwise comply with an applicable exception in § 411.355 or § 411.357 (66 FR 878).

We continue to believe in the importance of preserving patient choice, protecting the physician's professional medical judgment, and avoiding interference in the operations of a managed care organization. However, given our proposed interpretation of the volume or value standard, we are concerned that current § 411.354(d)(4) may apply in fewer instances, if at all, to serve these important goals. Therefore, to reiterate how critical these protections are, we are proposing to include in the exceptions applicable to the types of contracts or arrangements to which the special rule has historically applied an affirmative requirement that the compensation arrangement meet the conditions of the special rule at § 411.354(d)(4) (as modified in accordance with the proposal set forth in this section of the proposed rule). To that end, we are proposing to include in the exceptions at § 411.355(e) for academic medical centers, § 411.357(c) for *bona fide* employment relationships, § 411.357(d)(1) for personal service arrangements, § 411.357(d)(2) for physician incentive plans, § 411.357(h) for group practice arrangements with a hospital, § 411.357(l) for fair market value compensation, and § 411.357(p) for indirect compensation arrangements, a requirement that, in addition to satisfying the other requirements of the exception, the relevant arrangement must comply with the revised special

rule at § 411.354(d)(4). In making this proposal, we are relying on the authority granted to the Secretary under sections 1877(b)(4), (e)(2)(D), (e)(3)(A)(vii), (e)(3)(B)(i)(II), and (e)(7)(vii) of the Act. We solicit comment as to whether, given the nature of academic medical centers, the proposed requirement at revised § 411.354(d)(4) is necessary.

We are also proposing to revise § 411.354(d)(4) to eliminate certain language regarding: (1) Whether the ''set in advance'' and ''fair market value'' conditions of the special rule apply to the compensation arrangement (as stated in the regulation) or to the compensation itself; and (2) when compensation is considered fair market value. Under proposed § 411.354(d)(4), we are clarifying that the physician's compensation must be set in advance. Any changes to the compensation (or the formula for determining the compensation) must also be set in advance (that is, made prospectively). We are also clarifying that the physician's compensation must be consistent with the fair market value of the services performed. In addition, we are proposing to eliminate the parenthetical language in existing § 411.354(d)(4) as it conflates the concept of fair market value and the volume or value standard. As noted previously, these are separate standards, and compliance with one is not contingent on compliance with the other. We are taking the opportunity to also propose nonsubstantive revisions for clarity. Although, as proposed, revised § 411.354(d)(4) sets forth protections that apply to both the compensation arrangement that includes a directed referral requirement and also specifically to the compensation itself, for continuity in the application of the protections of the regulation, we are proposing to leave the regulation in § 411.354(d) (special rules on compensation) rather than include it in § 411.354(e), which includes special rules for compensation arrangements. We seek comment on this approach.

5. Fair Market Value (§ 411.351)

The term ''fair market value,'' as it is defined at section 1877(h)(3) of the Act, consists of three basic components. Fair market value is defined generally as ''the value in arms length [sic] transactions, consistent with the general market value.'' The statutory definition includes additional qualifications for leases generally, providing that fair market value with respect to rentals or leases also means ''the value of rental property for general commercial purposes (not taking into account its intended use).'' Finally, with respect to the lease of office space, in particular, the statutory definition further stipulates that fair market value also means that that value of the rental property is ''not adjusted to reflect the additional value the prospective lessee or lessor would attribute to the proximity or convenience to the lessor where the lessor is a potential source of patient referrals to the lessee.'' Most of the statutory exceptions at section 1877(e) of the Act relating to compensation arrangements include requirements pertaining to fair market value compensation, including the exceptions for the rental of office space, the rental of equipment, *bona fide* employment relationships, personal service arrangements, isolated transactions, and payments by a physician. Many of the regulatory exceptions created using the Secretary's authority under section 1877(b)(4) of the Act also include requirements pertaining to fair market value compensation, including the exceptions for academic medical centers, fair market value compensation, indirect compensation arrangements, EHR items and services, and assistance to compensate a nonphysician practitioner.

The term ''fair market value'' is defined in our regulations in § 411.351. In the 1992 proposed rule (57 FR 8602) and the 1995 final rule (60 FR 41978), we incorporated the statutory definition of ''fair market value'' into our regulations without modification. In the 1998 proposed rule (63 FR 1686), we proposed to include in our definition of ''fair market value'' a definition of ''general market value,'' to explain what it means for a value to be ''consistent with the general market value.'' In an attempt to ensure consistency across our regulations, we proposed to adopt the definition of ''general market value'' from part 413 of our regulations, which pertains to reasonable cost reimbursement for end stage renal disease services. In the context of determining the cost incurred by a present owner in acquiring an asset, § 413.134(b)(2) defined ''fair market value'' as ''the price that the asset would bring by *bona fide* bargaining between well-informed buyers and sellers at the date of acquisition. Usually the fair market price is the price that *bona fide* sales have been consummated for assets of like type, quality, and quantity in a particular market at the time of acquisition.'' We modified the definition drawn from § 413.134(b)(2) to include analogous provisions for determining the fair market value of any items or services, including personal services, employment relationships, and rental arrangements. As proposed in the 1998 proposed rule, ''general market value'' would mean:

> The price that an asset would bring, as the result of *bona fide* bargaining between well-informed buyers and sellers, or the compensation that would be included in a service agreement, as the result of *bona fide* bargaining between well-informed parties to the agreement, on the date of acquisition of the asset or at the time of the service agreement. Usually the fair market price is the price at which *bona fide* sales have been consummated for assets of like type, quality, and quantity in a particular market at the time of acquisition, or the compensation that has been included in *bona fide* service agreements with comparable terms at the time of the agreement.

The proposed definition of ''fair market value'' in the 1998 proposed rule did not substantively modify the provisions of the fair market value definition pertaining to leases in general and office space leases in particular. In Phase I, we finalized the definition of ''fair market value'' from the 1998 proposed rule with one modification (66 FR 944 through 945). The definition of ''fair market'' value finalized in Phase I clarified that a rental payment ''does not take into account intended use if it takes into account costs incurred by the lessor in developing or upgrading the property or maintaining the property or its improvements.'' In Phase I we also responded to commenters who requested guidance on how to determine fair market value in a variety of circumstances. We stated that we would accept any commercially reasonable method for determining fair market value. However, we noted that, in most exceptions, the fair market value requirement is further modified by language that precludes taking into account the volume or value of referrals, and, in some cases, other business generated by the referring physician. We concluded that, in determining whether compensation is fair market value, requirements pertaining to the volume or value of referrals and other business generated may preclude reliance on comparables that involve entities and physicians in a position to refer or generate business (66 FR 944). Elsewhere in Phase I, we suggested a similar underlying connection between the fair market value requirement and requirements pertaining to the volume or value of a physician's referrals and other business generated (66 FR 877). In a discussion of the requirement that compensation not take into account other business generated, we stated that—

[T]he additional limiting phrase 'not taking into account * * * other business generated between the parties' means simply that the fixed, fair market value payment cannot take into account, or vary with, referrals of Medicare or Medicaid [designated health services] or any other business generated by the referring physician, including other Federal and private pay business. Simply stated, section 1877 of the Act establishes a straightforward test that compensation arrangements should be at fair market value for the work or service performed or the equipment or space leased—not inflated to compensate for the physician's ability to generate other revenues.

Despite our intimation in Phase I that the concepts of fair market value and the volume and value of referrals or other business generated were fundamentally interrelated, the definition of fair market value finalized in Phase I did not include any reference to the volume or value of a physician's referrals.

In Phase II, we made two significant modifications to the definition of ''fair market value.'' First, we proposed certain ''safe harbors'' for determining fair market value for hourly payments made to physicians for physician services (69 FR 16092 and 16107). (These safe harbors were not finalized.) Second, and more importantly, we incorporated into the definition of ''fair market value'' a reference to the volume or value standard found in many exceptions to the physician self-referral law. The Phase II definition of ''fair market value'' provided, in relevant part, that fair market value is usually the price at which *bona fide* sales have been consummated for assets of like type, quality, and quantity in a particular market at the time of acquisition, or the compensation that has been included in *bona fide* service agreements with comparable terms at the time of the agreement, where the price or compensation has not been determined in any manner that takes into account the volume or value of anticipated or actual referrals. We explained our view that the determination of fair market value under the physician self-referral law differs in significant respects from standard valuation techniques and methodologies. In particular, we noted that the methodology must exclude valuations where the parties to the transactions are at arm's length but in a position to refer to one another. We made no substantive changes to the definition of ''fair market value'' in Phase III or in any of our subsequent rulemaking.

In the CMS RFI, we solicited specific comments regarding possible approaches to modifying the definition of ''fair market value'' consistent with the statute and in the context of the exceptions to the physician self-referral law (83 FR 29526). CMS RFI commenters from within and outside the health care provider community, including independent valuators, submitted comments explaining a variety of concerns and challenges with applying the definition of ''fair market value'' in our current regulations at § 411.351. After carefully reviewing the CMS RFI comments and the statements in our prior rules, we undertook a fresh review of the statutory definition of ''fair market value'' and the structure of the exceptions for various types of compensation arrangements at section 1877(e) of the Act and in our regulations in §§ 411.355 and 411.357.

As a preliminary matter and as described previously in section II.B.1. of this proposed rule, a careful reading of the statute shows that the fair market value requirement is separate and distinct from the volume or value standard and the other business generated standard. (See section II.B.3. of this proposed rule for a detailed discussion of the volume or value standard and the other business generated standard.) The volume or value and other business generated standards do not merely serve as ''limiting phrases'' to modify the fair market value requirement. In order to satisfy the requirements of the exceptions in which these concepts appear, compensation must both: (1) Be fair market value for items or services provided; *and* (2) not take into account the volume or value of referrals (or the volume or value of other business generated by the physician, where such standard appears). We believe that the appropriate reading of the statute is that the requirement that compensation does not take into account the volume or value of referrals—which is plainly set out as an independent requirement of the relevant exceptions—is not also part of the definition of ''fair market value.'' We note that the statutory definition of ''fair market value'' at section 1877(h)(3) of the Act includes no reference to the volume or value of referrals (or other business generated between the parties). For these reasons, we are proposing to revise the definition of ''fair market value'' to eliminate the connection to the volume or value standard.

In proposing revisions to the definition of ''fair market value'' at § 411.351, we undertook to establish regulations that give meaning to the statutory language at section 1877(h)(3) of the Act. As described previously, the statute states a general definition of ''fair market value'' and then modifies that definition for application to leases of equipment and office space. One of the modifications applies to leases of both equipment and office space; the other applies only to the lease of office space. To illustrate this more clearly in our regulations, we are proposing to modify the definition of ''fair market value'' to provide for a definition of general application, a definition applicable to the rental of equipment, and a definition applicable to the rental of office space. (We are proposing to use the terms ''rental'' of equipment and ''rental'' of office space as those are the titles of the statutory exceptions at section 1877(e)(1)(A) and (B) of the Act and our regulatory exceptions at § 411.357(a) and (b).) We believe that this approach provides parties with ready access to the definition of ''fair market value,'' with the attendant modifiers, that is applicable to the specific type of compensation arrangement at issue. Therefore, we are proposing that, generally, fair market value means the value in an arm's-length transaction with like parties and under like circumstances, of assets or services, consistent with the general market value of the subject transaction. We are also proposing that, with respect to the rental of equipment, fair market value means the value, in an arm's-length transaction with like parties and under like circumstances, of rental property for general commercial purposes (not taking into account its intended use), consistent with the general market value of the subject transaction. And, with respect to the rental of office space, we are proposing that fair market value means the value in an arm's length transaction, with like parties and under like circumstances, of rental property for general commercial purposes (not taking into account its intended use), without adjustment to reflect the additional value the prospective lessee or lessor would attribute to the proximity or convenience to the lessor where the lessor is a potential source of patient referrals to the lessee, and consistent with the general market value of the subject transaction. We note that the proposed structure of the definition merely reorganizes for clarity, but does not significantly differ from, the statutory language at section 1877(h)(3) of the Act. We seek comment on our approach.

Second, we are proposing changes to the definition of ''general market value,'' currently included within the definition of fair market value at § 411.351. The current definition of ''fair market value'' states the following, some of which relates to fair market value and some of which relates to the included term,

''general market value.'' Numerical references are added here for ease but do not appear in our current regulations:

(1) Fair market value means the value in arm's-length transactions, consistent with the general market value.

(2) General market value means the price that an asset would bring as the result of *bona fide* bargaining between well-informed buyers and sellers who are not otherwise in a position to generate business for the other party, or the compensation that would be included in a service agreement as the result of *bona fide* bargaining between well-informed parties to the agreement who are not otherwise in a position to generate business for the other party, on the date of acquisition of the asset or at the time of the service agreement.

(3) Usually, the fair market price is the price at which *bona fide* sales have been consummated for assets of like type, quality, and quantity in a particular market at the time of acquisition, or the compensation that has been included in *bona fide* service agreements with comparable terms at the time of the agreement, where the price or compensation has not been determined in any manner that takes into account the volume or value of anticipated or actual referrals.

(4) With respect to rentals and leases described in § 411.357(a), (b), and (l) (as to equipment leases only), ''fair market value'' means the value of rental property for general commercial purposes (not taking into account its intended use).

(5) In the case of a lease of space, this value may not be adjusted to reflect the additional value the prospective lessee or lessor would attribute to the proximity or convenience to the lessor when the lessor is a potential source of patient referrals to the lessee.

(6) For purposes of this definition, a rental payment does not take into account intended use if it takes into account costs incurred by the lessor in developing or upgrading the property or maintaining the property or its improvements.

Items one, four, and five essentially restate the language at section 1877(h)(3) of the Act, albeit with the intervening language in items two and three, and item six was added in Phase I in response to a comment for the purpose of interpreting the modifier ''(not taking into account its intended use)'' in item four and at section 1877(h)(3) of the Act. We stated in the 1998 proposed rule that items two and three were our attempt to give meaning to the statutory requirement that the fair market value of compensation must be ''consistent with the general market value.'' In doing so, we relied on a regulation that relates to the circumstances under which an appropriate allowance for depreciation on buildings and equipment used in furnishing patient care can be an allowable cost. We see no benefit at this time to connect the definition of ''general market value'' to principles of reasonable cost reimbursement for end stage renal disease services in order to explain what it means for a value to be consistent with general market value, as required by the statute. Moreover, the definition at § 413.134(b)(2) upon which we relied states that *fair* market value (emphasis added) is defined as the price that the asset would bring by *bona fide* bargaining between well-informed buyers and sellers at the date of acquisition. The regulation goes on to state that, usually the fair market price is the price that *bona fide* sales have been consummated for assets of like type, quality, and quantity in a particular market at the time of acquisition. This definition more closely ties to the widely accepted IRS definition of ''fair market value,'' [2] not general market value. Therefore, we considered whether current § 411.351 includes an appropriate definition for ''general market value.''

We see no indication in the legislative history or the statutory language itself that the Congress intended that the definition of ''general market value'' for purposes of the physician self-referral law should deviate from general concepts and principles in the valuation community. Yet, our current definition of ''general market value'' is unconnected to the recognized valuation principle of ''market value'' and itself may be the driver of valuation industry policy and procedure. After revisiting the legislative history of section 1877 of the Act and our prior preamble language related to the term ''general market value,'' we believe that the Congress used the term ''general market value'' to ensure that the fair market value of the remuneration (that is, as described below, the hypothetical value) is generally consistent with the valuation that would result using accepted market valuation principles. Therefore, we equate ''general market value'' as that term appears in the statute and our regulations with ''market value,'' the term uniformly used in the valuation industry. Our own research indicates that, in the valuation industry, the term ''market value'' refers to the valuation of a planned transaction between two identified parties for identified assets or services, and intended to be consummated within a specified timeframe. Market value is based solely on consideration of the economics of the subject transaction and should not include any consideration of other business the parties may have with one another. Thus, when parties to a potential personal service arrangement determine the (general) market value of the physician's compensation, they must not consider that the physician could also refer patients to the entity when not acting as its medical director.

We are aware that our regulatory definition is likely at odds with general valuation principles, which do not use the term ''general market value.'' For this reason, we are proposing to establish a definition of ''general market value'' that is consistent with the recognized principle of ''market'' valuation to address this discrepancy and ease the burden on parties attempting to ensure compliance with the fair market value requirement in many of the compensation exceptions to the physician self-referral law. We are proposing to define ''general market value'' at § 411.351 to mean the price that assets or services would bring as the result of *bona fide* bargaining between the buyer and seller in the subject transaction on the date of acquisition of the assets or at the time the parties enter into the service arrangement; or, in the case of the rental of equipment or office space, the price that rental property would bring as the result of *bona fide* bargaining between the lessor and the lessee in the subject transaction at the time the parties enter into the rental arrangement. We note that many CMS RFI commenters requested that we simply return to the statutory language. We disagree that would be the best approach. Generally, *in the absence of agency guidance,* a reasonable interpretation of a statutory or regulatory requirement of the physician self-referral law is satisfactory when asserting compliance with the requirement. We believe it is important to provide guidance with respect to the requirement that compensation is fair market value in order not to stymy our enforcement efforts (or those of our law enforcement partners). This guidance is also crucial to support the compliance efforts of the regulated industry.

It is our view that the concept of *fair* market value relates to the value of an asset or service to hypothetical parties in a hypothetical transaction (that is,

[2] Fair Market Value is defined as ''the price at which the property would change hands between a willing buyer and a willing seller when the former is not under any compulsion to buy and the latter is not under any compulsion to sell, both parties having reasonable knowledge of relevant facts.'' (IRS Rev. Ruling 59–60).

typical transactions for like assets or services, with like buyers and sellers, and under like circumstances), while *general* market value (or market value) relates to the value of an asset or service to the actual parties to a transaction that is set to occur within a specified timeframe. Some of the CMS RFI comments included similar information regarding the definition of general market value. Thus, under the statute, the hypothetical value of a transaction must be consistent with the value of the actual transaction transpiring between the particular buyer and seller. We are cognizant that the hypothetical value of a transaction may not always be identical to the market value of the actual transaction being considered. Extenuating circumstances may dictate that parties to an arm's length transaction veer from values identified in salary surveys and other hypothetical valuation data that is not specific to the actual parties to the subject the transaction. By way of example, assume a hospital is engaged in negotiations to employ an orthopedic surgeon. Independent salary surveys indicate that compensation of $450,000 per year would be appropriate for an orthopedic surgeon in the geographic location of the hospital. However, the orthopedic surgeon with whom the hospital is negotiating is one of the top orthopedic surgeons in the entire country and is highly sought after by professional athletes with knee injuries due to his specialized techniques and success rate. Thus, although the employee compensation of a hypothetical orthopedic surgeon may be $450,000 per year, this particular physician commands a significantly higher salary and the general market value (or market value) of the transaction may, therefore, be well above $450,000. The statute requires that the compensation is the value in an arm's length transaction, but that value must also be consistent with the general market value (or market value) of the subject transaction. In this example, compensation substantially above $450,000 per year may be fair market value.

Some CMS RFI commenters pointed out that failure to consider the general market value (or market value) of a transaction, as we have proposed to define it here, results in hospitals and other entities paying more than they believe appropriate for physician services. By way of example, assume a hospital is engaged in negotiations to employ a family physician. Independent salary surveys indicate that compensation of $250,000 per year would be appropriate for a family physician nationally; no local salary surveys are available. However, the cost of living in the geographic location of the hospital is very low despite its proximity to good schools and desirable recreation opportunities. Yet, due to declining reimbursement rates and a somewhat poor payor mix, the hospital's economic position is tenuous. According to a CMS RFI commenter, the physician may request the $250,000 that the hypothetical physician would earn, and the hospital may believe that it is compelled to pay the physician this amount, because our current definition of ''fair market value'' does not recognize the appropriate definition for the ''general market value'' (or market value) with which the physician's compensation must be consistent under the statute. In this example, the fair market value of the physician's compensation may be less than $250,000 per year.

Finally, we are proposing to remove from the regulation text at § 411.351 in the definition of ''fair market value'' the existing statement that, for purposes of the definition of ''fair market value,'' a rental payment does not take into account intended use if it takes into account costs incurred by the lessor in developing or upgrading the property or maintaining the property or its improvements. This language was added to the regulation text as a result of our response in Phase I to a commenter to the 1998 proposed rule, where we stated that a rental payment does not violate the requirement that the fair market value of rental property is the value of the property for general commercial purposes, not taking into account its intended use, merely because it reflects any costs that were incurred by the lessor in developing or upgrading the property, or maintaining the property or its improvements, regardless of why the improvements were added (66 FR 945). That is, the rental payment may reflect the value of any similar commercial property with improvements or amenities of a similar value, regardless of why the property was improved. We do not believe it is necessary to include this policy in regulation text. Moreover, based on some of the comments to the CMS RFI, this regulation text appears to have caused confusion among stakeholders. For this reason, we are proposing to remove the language from the definition of ''fair market value'' at § 411.351.

C. Group Practices (§ 411.352)

In the CMS RFI, we sought specific comments regarding whether and, if so, what barriers exist to qualifying as a ''group practice'' under the regulations at 42 CFR 411.352 (83 FR 29526). In response, commenters identified several areas where policy clarification could enhance certainty of compliance with the rules for qualifying as a group practice, such as the definition of ''single legal entity'' at § 411.352(a), the ''full range of care'' and ''substantially all'' tests at § 411.352(c) and (d), respectively, and the special rules regarding the distribution of profits shares and productivity bonuses at § 411.352(i). Many commenters expressed frustration that certain methodologies that they viewed as equitable for distributing revenues earned through the participation of practice physicians in alternative payment models could prohibit a physician practice from qualifying as a group practice. Although we acknowledge the commenter's views that clarification of many parts of the group practice rules would be useful, we are limiting our proposals to those that relate to the main purposes of this proposed rule: (1) The proposed definitions and special rules for ''commercially reasonable'' compensation arrangements, ''fair market value'' compensation, and the volume or value standard applicable throughout the physician self-referral law and regulations; or (2) the transition from a volume-based to a value-based health care system. We may consider additional clarifications or revisions in a future rulemaking.

1. The ''Volume or Value Standard'' (§ 411.352(g))

In section II.B. of this proposed rule, we are proposing new special rules for compensation that would codify in regulation our interpretation regarding when compensation will be considered to take into account the volume or value of referrals or other business generated (the ''volume or value standard''). In connection with those proposals, we reviewed the physician self-referral regulations to ensure that the volume or value standard is expressed using standardized terminology and identified several occurrences of inconsistent expression of the volume or value standard. Although section 1877 of the Act uses more than one phrase to describe the volume or value standard, which may be one reason for variations in the regulation text, we believe that the references are all to the same underlying prohibition on compensation that fluctuates with the volume or value of referrals or other business generated. Therefore, as noted previously, we are proposing to make certain conforming changes throughout our regulations to delineate the volume

or value standard as a prohibition on compensation that ''*takes into account* the volume or value'' of referrals or other business generated. Because the language in § 411.352(g) and (i) mirrors the statutory language at section 1877(h)(4)(iv) of the Act, we are not proposing changes to the ''volume or value'' regulation text in either of those paragraphs. The terms ''based on'' and ''related to'' would remain in the regulation text at § 411.352(g) and (i). However, we are taking the opportunity to remind readers that we interpret the requirements of § 411.352(g) and (i) to incorporate the volume or value standard; that is, compensation to a physician who is a member of a group practice may not take into account the volume or value of the physician's referrals (except as provided in § 411.352(i)), and profit shares and productivity bonuses paid to a physician in the group may not be determined in any manner that takes into account the volume or value of the physician's referrals (except that a productivity bonus may directly take into account the volume or value of the physician's referrals if the referrals are for services ''incident to'' the physician's personally performed services).

Our current regulation at § 411.352(i) states that a physician in a group practice may be paid a share of overall profits of the group practice, provided that the share is not determined in any manner that *is directly related to* the volume or value of referrals by the physician. We have long interpreted ''is directly related to'' the volume or value of referrals to mean ''takes into account'' the volume or value of referrals. In Phase I, we discussed this provision and stated that the Congress expressly limited profit shares for group practice members to methodologies that do not directly *take into account* the member's [designated health services] referrals, and that, under the statutory scheme, revenues generated by designated health services may be distributed to group practice members and physicians in the group in accordance with methods that indirectly *take into account* referrals (emphasis added) (66 FR 862 and 908).

Our current regulation at § 411.352(g) states that ''[n]o physician who is a member of the group practice directly or indirectly receives compensation *based on* the volume or value of his or her referrals, except as provided in § 411.352(i)'' (emphasis added). We interpret this to mean that, in order to satisfy this requirement for qualification as a ''group practice,'' no physician who is a member of the group practice receives compensation that directly or indirectly *takes into account* the volume or value of his or her referrals (unless permitted under § 411.352(i)). Our interpretation is consistent with the interpretation of ''related to'' set forth in Phase I. For the most part, we used the terms ''based on,'' ''related to,'' and ''takes into account'' interchangeably when describing the final Phase I group practice regulations (66 FR 908 through 910).

2. Special Rules for Profit Shares and Productivity Bonuses (§ 411.352(i))

a. Distribution of Revenue Related to Participation in a Value-Based Enterprise

We are proposing new § 411.352(i)(3) to address downstream compensation that derives from payments made to a group practice, rather than directly to a physician in the group, that relate to the physician's participation in a value-based arrangement. Certain downstream distribution arrangements are currently protected under waivers in the Shared Savings Program and certain Innovation Center models. However, outside of the Shared Savings Program or an Innovation Center model, as the commenters correctly point out, profit shares or productivity bonuses paid to a physician in a group practice that directly take into account the volume or value of his or her referrals to the group practice are strictly prohibited by the physician self-referral statute and regulations.

Our current special rules for the profit shares and productivity bonuses paid to physicians in a group practice prohibit calculation methodologies that *directly* take into account the volume or value of the recipient physician's referrals to the group practice. Thus, by way of example, in a 100-physician group practice where only two of the physicians participate with a hospital in a commercial payor-sponsored alternative payment model, the profits from the designated health services ordered by the physicians and furnished by the group practice to beneficiaries assigned to the model participants may not be allocated directly to the two physicians. Commenters interpreted this to mean that the special rules at § 411.352(i) would restrict the group practice to allocating alternative payment model-derived income that includes revenues from designated health services among all physicians in the group (or a component of at least five physicians in the group) in order to ensure that such income is allocated in a manner that only *indirectly* takes into account the volume or value of the two physicians' referrals. The commenters suggested that this restriction discourages physician participation in alternative payment or other value-based care models because physicians cannot be suitably rewarded for their accomplishments in advancing the goals of the model, which is at odds with the Secretary's vision for achieving value-based transformation by pioneering bold new payment models. Another commenter asserted that, because physician decisions drive the overwhelming majority of all health care spending and patient outcomes, it is not possible to transform health care without the participation of physicians in value-based health care delivery and payment models with other health care providers. We share the commenters' concerns regarding physician participation in value-based health care delivery and payment models and are also concerned that our current regulations could undermine the success of the Regulatory Sprint or the larger transition to a value-based health care system. Therefore, we are proposing changes to § 411.352(i) with respect to the payment of profit shares.

For the reasons described elsewhere in this proposed rule, in the exceptions for value-based arrangements at proposed new § 411.357(aa), we are not proposing to prohibit remuneration that takes into account the volume or value of a physician's referrals. The proposed changes to § 411.352(i) are an extension of this policy.

Specifically, we are proposing to add regulation text at § 411.352(i)(3) (see discussion in section II.A.2.b of this proposed rule) a deeming provision related to the distribution of profits from designated health services that are directly attributable to a physician's participation in a value-based enterprise. Under our proposal, when such profits are distributed to the participating physician, they would be deemed not to directly take into account the volume or value of the physician's referrals. In other words, a group practice could distribute directly to a physician in the group the profits from designated health services furnished by the group that are derived from the physician's participation in a value-based enterprise, including profits from designated health services referred by the physician, and such remuneration would be deemed not to directly take into account the volume or value of the physician's referrals. Revised § 411.352(i) would permit the 100-physician group practice in the previous example to distribute the profits from designated health services derived from the two physicians' participation in the alternative payment model directly to

those physicians. Physician #1 could receive a profit distribution that considers his or her referrals to the group that are directly attributable to his or her participation in the model, and Physician #2 could receive a profit distribution that considers his or her referrals to the group that are directly attributable to his or her participation in the model. Neither distribution would jeopardize the group's ability to qualify as a ''group practice'' under § 411.352. We seek comment regarding whether we should permit the distribution of ''revenue'' from designated health services or ''profits'' from designated health services (as proposed) in order to effectuate the goals described elsewhere in this proposed rule.

b. Clarifying Revisions

We are proposing to restructure and renumber § 411.352(i) as well as clarify several provisions of the regulation. We believe that these revisions would enable groups to determine with more certainty whether compensation paid to a physician in the group as profit shares or productivity bonuses takes into account the volume or value of referrals and, if it does, whether there is a direct or indirect connection to the volume or value of the physician's referrals. Our purpose in restructuring the regulation is to more closely adhere to the structure of section 1877(h)(4)(B) of the Act and to express in affirmative language which profit shares and productivity bonuses are permissible; that is, permitting the payment of a profit share or productivity bonus that indirectly takes into account the volume or value of referrals is the affirmative and more simple way of saying, as our current regulations do, that the profit share or productivity bonus is permissible but only if it does not directly take into account the volume or value of referrals. In addition, as proposed, the special rules for profit shares and productivity bonuses would follow the format of our special rules on compensation at § 411.354(d) and our special rules for compensation arrangements at § 411.354(e). We do not intend that our proposed addition of introductory language at § 411.352(i) and proposed revised language at § 411.352(i)(1) and 411.352(i)(2) would be a substantive change to the noted provisions, but seek comment regarding the impact of these restructuring and rewording proposals.

We are also proposing revisions to clarify our interpretation of the overall profits of a group that can be distributed to physicians in the group. In current § 411.352(i)(2), the term ''overall profits'' is defined to mean two different things: (1) The group's entire profits derived from designated health services; and (2) the profits derived from designated health services of any component of the group practice that consists of at least five physicians. Although we believe our intent when establishing this definition was clear, stakeholders have informed us that they are confused about the definition. For example, stakeholders have informally inquired whether the profits of a group practice that has only two, three or four physicians may be distributed at all. In response to these types of inquiries, we are proposing to revise the definition of ''overall profits'' to state that this term means the profits derived from all the designated health services of any component of the group that consists of at least five physicians, which may include all physicians in the group. To further clarify this definition, we are proposing regulation text at revised § 411.352(i)(1)(ii) stating that, if there are fewer than five physicians in the group, ''overall profits'' means the profits derived from all the designated health services of the group. We believe that this more precisely states the policy articulated in Phase I (66 FR 909 through 910).

The proposed revision at § 411.352(i)(1)(ii) includes the words ''all the'' before ''designated health services'' to codify in regulation our intent when finalizing the group practice rules in Phase I. Stakeholders' informal inquiries regarding the permissible methods of distributing profits from designated health services have highlighted that the current regulation text may not precisely evidence our intent. Stakeholders have inquired whether it is permissible to distribute profit shares of only some types of designated health services provided by a group practice, without distributing the profits from the other types of designated health services provided by the group practice. Stakeholders also inquired whether a group practice may share the profits from each of the types of designated health services independently; that is, whether it is permissible under our current regulations to share profits from one type of designated health service with a subset of physicians in a group practice and the profits from another type of designated health service with a different (possibly overlapping) subset of physicians in the group practice.

In response to these inquiries and to provide a clear expression of our policy, we are proposing that ''the profits derived from all the designated health services'' in proposed § 411.352(i)(1)(ii) would mean that the profits from all the designated health services of the practice (or a component of at least five physicians in the practice) must be aggregated and distributed, with profit shares not determined in any manner that directly takes into account (that is, in any manner that is directly related to) the volume or value of a physician's referrals. Under our proposal, a physician practice that wishes to qualify as a group practice could not distribute profits from designated health services on a service-by-service basis. To illustrate, suppose a physician practice provides both clinical laboratory services and diagnostic imaging services—both designated health services—to its patients in a location that qualifies as a ''same building'' under § 411.351 and meets the requirements at § 411.355(b)(2)(i). If the practice wishes to qualify as a group practice, it may not distribute the profits from clinical laboratory services to one subset of its physicians or using a particular methodology and distribute the profits from diagnostic imaging to a different subset of its physicians (or the same subset of its physicians but using a different methodology). We seek comment on our proposal to modify the renumbered regulation text at § 411.352(i)(1)(ii) to clarify the guidelines for the distribution of ''overall profits'' from designated health services.

We are also proposing to remove the reference to Medicaid from the definition of overall profits. We believe the inclusion of this reference unnecessarily complicates the regulation. It is possible that the reference to designated health services payable by Medicaid is related to the proposed definition of ''referral'' in the 1998 proposed rule (63 FR 1692). There, with respect to the definition of group practice, we stated that, because of our interpretation of what constitutes a ''referral,'' an entity wishing to be considered a group practice in order to use the in-office ancillary services exception cannot compensate its members based on the volume or value of referrals for designated health services for Medicare or Medicaid patients but could do so in the case of other patients (63 FR 1690). However, when finalized, the definition of ''referral'' omitted all references to Medicaid. Nonetheless, the reference to Medicaid in final § 411.352(i)(2), which was also proposed in the 1998 proposed rule (as a definition in § 411.351), was not likewise omitted when finalized. Moreover, under our current definition of ''designated health services'' at § 411.351, ''designated health services

payable by . . . Medicaid'' would not include any services. This is because the definition of ''designated health services'' includes only those services payable in whole or in part by Medicare. Although the qualifying language in this definition potentially allows for a different definition ''as otherwise noted in this subpart,'' the regulations at § 411.352(i)(2) do not expressly articulate an alternative definition for ''designated health services.'' Rather, they simply state that the overall profits of a group include designated health services payable by Medicaid. For consistency with the final definitions and regulations, we are updating the group practice rules at § 411.352 by eliminating the references to Medicaid in the definition of overall profits.

Proposed § 411.352(i)(1)(iii) articulates the general rule that overall profits should be divided in a reasonable and verifiable manner that is not directly related to the volume or value of the physician's referrals of designated health services. The prefatory language of this subparagraph is simply moved from existing § 411.352(i)(2) without substantive change. Proposed § 411.352(i)(1)(iii) also makes revisions to the language introducing the methods for distributing profit shares that are deemed permissible under the physician self-referral law (the deeming provisions) by substituting ''and would not be considered designated health services if they were payable by Medicare'' for ''are not [designated health services] payable by any Federal health care program or private [payor].'' Current § 411.352(i)(2)(ii) provides that a share of overall profits will be deemed not to directly take into account the volume or value of referrals if revenues derived from designated health services are distributed based on the distribution of the group practice's revenues attributed to services that are not designated health services payable by ''any Federal health care program or private payer.'' As we noted, the definition of designated health services includes only those specified services that are payable by Medicare. Thus, we believe it better reflects our policy that overall profits may be distributed based on the distribution of the group practice's revenues from services other than those in the categories of services that are ''designated health services'' to deem the payment of a profit share not to directly take into account the volume or value of a physician's referrals if the revenues derived from designated health services are distributed based on the distribution of the group's revenues attributed to services that are not designated health services and would not be considered designated health services if they were payable by Medicare. We are proposing to revise the regulation in this manner and renumber current § 411.352(i)(2)(ii) to § 411.352(i)(1)(iii)(B). We note that the regulation that deems a productivity bonus not to directly take into account the volume or value of a physician's referrals under certain circumstances includes a provision similar to § 411.352(i)(1)(iii)(B) for overall profits. Therefore, we are proposing corresponding revisions at proposed § 411.352(i)(2)(ii)(B) (renumbered from current § 411.352(i)(3)(ii)) that would deem the payment of a productivity bonus not to directly take into account the volume or value of a physician's referrals if the services on which the productivity bonus is based are not revenues derived from designated health services and would not be considered designated health services if they were payable by Medicare. Finally, we are proposing to replace the term ''allocated'' with ''distributed'' at proposed (redesignated) § 411.352(i)(1)(iii)(C) as the latter term reflects the actual payment of the profit share.

We are also proposing to renumber the regulation that lists the deeming provisions related to the payment of productivity bonuses from § 411.352(i)(3) to § 411.352(i)(2) and are proposing minor changes to the deeming provisions themselves. In addition to the proposal removing the language referencing Federal health care programs and private payers, we are proposing to update the language of existing § 411.352(i)(1) (relocated to proposed § 411.352(i)(2)(i)) to remove ''or both'' as unnecessary because the word ''or'' is interpreted to mean the conjunctive ''and'' as well as the disjunctive ''or.'' Groups may continue to pay a productivity bonus based on services that the physician has personally performed, or services ''incident to'' such personally performed services, or both, provided that the bonus only indirectly takes into account the volume or value of the physician's referrals (except that the bonus may directly take into account the volume or value of referrals by the physician if the referrals are for services ''incident to'' the physician's personally performed services).

For consistency with the regulations related to the payment of a share of overall profits, we are proposing to revise the introductory language in the deeming provisions for productivity bonuses at renumbered § 411.352(i)(2)(ii) to state that a productivity bonus must be calculated in a reasonable and verifiable manner. To correct a misstatement about the nature of § 414.22 of this chapter included in existing § 411.352(i)(3)(i), we are proposing to revise the deeming provision related to the physician's total patient encounters or relative value units to state that a productivity bonus will be deemed not to take into account the volume or value of a physician's referrals if it is based on the physician's total patient encounters or the relative value units (as described in § 414.22 of this chapter) personally performed by the physician. We seek comment regarding whether this provision should limit the methodology to physician work relative value units as defined at § 414.22(a) or whether any personally-performed relative value units should be an acceptable basis for calculating a productivity bonus that is deemed not to relate directly to (that is, directly take into account) the volume or value of referrals. Finally, we are proposing to replace the term ''allocated'' with ''distributed'' at proposed (redesignated) § 411.352(i)(2)(ii)(C) as the latter term reflects the actual payment of the productivity bonus.

D. Recalibrating the Scope and Application of the Regulations

As we stated previously and in our Phase I rulemaking, our intent in implementing section 1877 of the Act was ''to interpret the [referral and billing] prohibitions narrowly and the exceptions broadly, to the extent consistent with statutory language and intent'' (66 FR 860). One purpose of this proposed rule is to reexamine our current regulations to assess whether we have held true to that intention. In doing so, we have considered our own experience in administering the SRDP, stakeholder interactions and comments to the CMS RFI, and our experience working with our law enforcement partners. In this proposed rule, we are proposing revisions to, including deletions of, certain requirements in our regulatory exceptions that may be unnecessary at this time. We describe our specific proposals in this section of the proposed rule.

1. Decoupling the Physician Self-Referral Law From the Federal Anti-Kickback Statute and Federal and State Laws or Regulations Governing Billing or Claims Submission

Section 1877 of the Act established numerous exceptions to the statute's referral and billing prohibitions and granted the Secretary authority to create regulatory exceptions for other financial

relationships that do not pose a risk of program or patient abuse. The vast majority of the exceptions issued using the Secretary's authority at section 1877(b)(4) of the Act to establish exceptions for financial relationships that do not pose a risk of program or patient abuse (which we often call the regulatory exceptions) require that the arrangement does not violate the anti-kickback statute. Most of these exceptions also require that the arrangement does not violate any Federal or State law or regulation governing billing or claims submission.

In Phase I, we stated that the requirements pertaining to the anti-kickback statute and billing or claims submission are necessary in regulatory exceptions issued under the Secretary's authority at section 1877(b)(4) of the Act to ensure that the excepted financial relationships do not pose a risk of program or patient abuse (66 FR 863). Even though we acknowledged that the physician self-referral law and the anti-kickback statute are different statutes, we were concerned that, if the regulatory exceptions did not require compliance with the anti-kickback statute, unscrupulous physicians and entities could potentially protect intentional unlawful and abusive conduct by complying with the minimal requirements of a regulatory exception created under section 1877(b)(4) of the Act. In Phase II, we stated our interpretation that the statutory ''no risk'' standard is not limited to risks as determined under the physician self-referral law (69 FR 16108). We added that many arrangements that might otherwise warrant an exception under section 1877 of the Act—a strict liability statute—pose some degree of risk under the anti-kickback statute; these arrangements cannot, therefore, be said to pose *no* risk. Similarly, we stated that some arrangements that may be permissible under the physician self-referral law could pose a risk of violating certain laws pertaining to billing or claims submission. Therefore, we concluded that the regulatory exceptions created under the Secretary's authority at section 1877(b)(4) of the Act must require that the excepted financial relationship not violate the anti-kickback statute or any Federal or State law or regulation governing billing or claims submission.

A substantial number of CMS RFI commenters expressed opposition to the continued coupling of the physician self-referral law with the anti-kickback statute and other billing and claims submission laws, explaining the significant burden associated with the inclusion of these requirements in regulatory exceptions to the physician self-referral law. Commenters noted that the physician self-referral law is a strict liability statute and compliance with each element of an exception is mandatory if the entity wishes to submit a claim for designated health services referred by a physician with which it has a financial relationship, while the anti-kickback statute is an intent-based criminal statute and compliance with a safe harbor is not required. The commenters asserted that the inclusion of a requirement for compliance with the anti-kickback statute is misplaced in an exception to the physician self-referral law because it introduces an intent-based requirement into a strict liability statute. Commenters further noted that this requirement can make it unreasonably difficult for entities to meet their burden of proof under § 411.353(c)(2) that a referral for designated health services does not violate the physician self-referral law. Commenters also noted that the requirement for compliance with the anti-kickback statute and the requirement pertaining to Federal or State laws or regulations governing billing or claims submission are not necessary, because parties remain subject to these laws or regulations, regardless of whether their financial relationships otherwise comply with the physician self-referral law.

Based on our experience working with our law enforcement partners in reviewing conduct that implicates the physician self-referral law and other Federal fraud and abuse laws, it is our belief that, when a compensation arrangement violates the intent-based criminal anti-kickback statute, it will likely also fail to meet one or more of the more key requirements of an exception to the physician self-referral law. That is, the compensation in such cases likely is not fair market value or is determined in a manner that takes into account the volume or value of the physician's referrals or other business generated for the entity. Since the Phase I regulation was issued, we are unaware of any instances of noncompliance with the physician self-referral law turned solely on an underlying violation of the anti-kickback statute (or any other Federal or State law governing billing or claims submission).

We have reconsidered our position and, based on our experience working with our law enforcement partners since our regulations were finalized, as well as comments received in response to the CMS RFI, we no longer believe that it is necessary or appropriate to include requirements pertaining to compliance with the anti-kickback statute and Federal and State laws or regulations governing billing or claims submission as requirements of the exceptions to the physician self-referral law. We note further that the Congress did not require compliance with the anti-kickback statute or any other law in existence at the time of enactment of the statute or its subsequent revision in order to avoid the law's referral and billing prohibitions. Therefore, we are proposing to remove from the exceptions in 42 CFR part 411, subpart J the requirement that the arrangement does not violate the anti-kickback statute or any Federal or State law governing billing or claims submission wherever such requirements appear. Specifically, we are proposing to remove the following sections from our regulations: § 411.353(f)(1)(iii); § 411.355(b)(4)(v), (e)(1)(iv), (f)(3), (f)(4), (g)(2), (g)(3), (h)(2), (h)(3), (i)(2), (i)(3), (j)(1)(iv); § 411.357(e)(4)(vii), (j)(3), (k)(1)(iii), (l)(5), (m)(7), (p)(3), (r)(2)(x), (s)(5), (t)(3)(iv), (u)(3), (w)(12), (x)(1)(viii), and (y)(8). We also propose to delete the following clause from § 411.357(e)(6)(i) and (n): '', Provided that the arrangement does not violate the anti-kickback statute (section 1128B(b) of the Act), or any Federal or State law or regulation governing billing or claims submission.'' Finally, we are proposing to remove the definition of ''does not violate the anti-kickback statute'' in § 411.351. We note that the exceptions for referral services at § 411.357(q) and obstetrical malpractice subsidies at § 411.357(r)(1) provide that arrangements satisfy the requirements of the exception if the arrangements comply with the requirements of certain specified anti-kickback statute safe harbors. Our proposal would not apply to or affect these provisions.

We emphasize that this proposal in no way affects parties' liability under the anti-kickback statute. Indeed, the Congress clarified when enacting section 1877 of the Act that ''any prohibition, exemption, or exception authorized under this provision in no way alters (or reflects on) the scope and application of the anti-kickback provisions in section 1128B of the Social Security Act'' (H. Report 101–386, 856 (1989).) Most importantly, the fact that a financial relationship complies with an exception to the physician self-referral law does *not* entail that the financial relationship does not violate the anti-kickback statute. (See 66 FR 879.) Similarly, compliance with the anti-kickback statute does not entail compliance with the physician self-referral law. To the extent that the financial relationship is

governed by other laws or regulations, our proposed action does not affect the parties' compliance obligations under those other laws or regulations. Specifically, claims submitted to the Medicare program must comply with all laws, regulations, and other requirements governing billing and claims submission.

Although we no longer believe that the Secretary must include a requirement that the financial relationship does not violate the anti-kickback statute in exceptions to the physician self-referral law, we continue to believe that the Secretary has the authority under the statute to impose a requirement that the financial relationship not violate the anti-kickback or any other requirement if the Secretary determines it necessary and appropriate to ensure that an excepted financial relationship does not pose a risk of program or patient abuse. We intend to monitor excepted financial relationships, and we may propose in a future rulemaking to include the requirements proposed here for deletion in some or all of the exceptions issued pursuant to the Secretary's statutory authority if we determine such requirements are necessary or appropriate to protect against program or patient abuse.

2. Definitions (§ 411.351)

a. Designated Health Services

Section 1877(1)(A) of the Act provides that, if a physician (or an immediate family member of a physician) has a financial relationship with an entity, the physician may not make a referral to the entity for the furnishing of a designated health service for which payment may otherwise be made under Title XVIII of the Act, unless an exception applies. The referral prohibition is codified in our regulations at § 411.353(a). In the 1998 proposed rule (63 FR 1694), we interpreted the phrase ''designated health service for which payment otherwise may be made'' broadly to mean ''any designated health service that ordinarily 'may be' covered under Medicare (that is, that could be a covered service under Medicare in the community in which the service has been provided) for a Medicare-eligible individual, regardless of whether Medicare would actually pay for this particular service, at the time, for that particular individual. . . .'' Our proposed definition of the term ''designated health services'' in the 1998 proposed rule was consistent with this broad interpretation of the referral prohibition. Section 1877(h)(6) of the Act defines ''designated health services'' by listing various categories of services that qualify as designated health services (for example, clinical laboratory services). In the 1998 proposed rule, we stated that a designated health service remains such ''even if it is billed as something else or is subsumed within another service category by being bundled with other services for billing purposes'' (63 FR 1673). By way of example, we stated that clinical laboratory services that are provided by a skilled nursing facility (SNF) and reimbursed as part of the SNF composite rate would remain designated health services for purposes of section 1877 of the Act, even though SNF services are not listed as designated health services at section 1877(h)(6) of the Act and Medicare would not separately pay for the clinical laboratory service furnished by the SNF.

The now-deleted exception at § 411.355(d), which was first finalized in the 1995 final rule (60 FR 41975), served as a counterbalance to the broad interpretation of designated health services that was proposed in the 1998 proposed rule. As finalized in the 1995 final rule (60 FR 41980), § 411.355(d) provided that the referral prohibition in § 411.353 did not apply to services furnished in an ambulatory surgical center (ASC) or end-stage renal disease (ESRD) facility, or by a hospice, if payment for those services was included in the ASC rate, the ESRD composite rate, or as part of the per diem hospice charge. We explained that the application of the composite rate ''constitutes a barrier to either Medicare program or patient abuse because the Medicare program will pay only a set amount to the facilities irrespective of the number and frequency of laboratory tests that are ordered'' (60 FR 41940). In the 1998 proposed rule, we proposed an amendment to § 411.355(d) that would have allowed the Secretary to except services furnished under other payment rates that did not pose a risk of program or patient abuse (63 FR 1666). However, in Phase I, instead of expanding the exception at § 411.354(d) to include services furnished under other payment rates, we narrowed the definition of designated health services (as explained in this section of the proposed rule) to exclude certain services that are paid as part of a composite rate, and we solicited comments on whether the exception at § 411.355(d) was still necessary in light of the narrowed definition of designated health services in Phase I (66 FR 923 through 924). We ultimately determined in Phase II that § 411.355(d) was no longer necessary, given the change to the definition of designated health services finalized in Phase I, and we removed the exception from our regulations (69 FR 16111).

As finalized in Phase I, the definition of ''designated health services'' includes only designated health services payable, in whole or in part, by Medicare, and does not include services that would otherwise constitute designated health services, but that are reimbursed by Medicare as part of a composite rate, except to the extent that the services are specifically identified in § 411.351 and are themselves payable through a composite rate. SNF services paid for under the Part A composite rate (that is, the Skilled Nursing Facility Prospective Payment System), for example, are not designated health services, even if the bundle of services includes services that would otherwise be designated health services, such as clinical laboratory services.[3] On the other hand, although home health and inpatient and outpatient hospital services are reimbursed on a composite rate, they remain designated health services under the definition finalized in Phase I because section 1877(h)(6) of the Act explicitly lists these services as designated health services. We explained in Phase I that our ultimate definition of ''designated health services'' was based on issues of statutory construction (66 FR 923). In particular, commenters on the 1998 Proposed Rule asserted that the proposed definition of designated health services would have expanded the list of services that are considered to be designated health services beyond the services explicitly listed at section 1877(h)(1) of the Act. For example, clinical laboratory services furnished by a SNF and reimbursed under the Skilled Nursing Facility Prospective Payment System would have been considered designated health services under the proposed definition, even though SNF services are not included in the statutory list of designated health services. The commenters maintained that, where the Congress intended the physician self-referral law to cover specific services, including services that are paid on a composite rate such as home health services, it did so by explicitly listing the services at section

[3] ESRD services are also reimbursed on a composite rate, and thus are not considered to be designated health services. In this context, we would like to refer readers to the comment and response section of the CY 2018 ERSD PPS Final Rule, where we explained that, for purposes of the physician self-referral law, the ''composite rate'' for ESRD services is interpreted as the per-treatment payment amount (82 FR 50751). To the extent that outpatient prescription drugs are included in the ESRD per-treatment payment amount, they do not qualify as designated health services.

1877(h)(6) of the Act. We ultimately agreed with this statutory construction and finalized the definition of ''designated health services'' to include only those services paid under a composite rate that are explicitly listed at section 1877(h)(1) of the Act; that is, home health services and inpatient and outpatient hospital services.

In light of our experience with the SRDP and our review of the comments to our CMS RFI, we reviewed the regulatory history of our definition of ''designated health services'' at § 411.351 to identify whether further clarification regarding what constitutes a designated health service is necessary. We are proposing here to revise the definition of ''designated health services'' to clarify that a service provided by a hospital to an inpatient does not constitute a designated health service payable, in whole or in part, by Medicare, if the furnishing of the service does not affect the amount of Medicare's payment to the hospital under the Acute Care Hospital Inpatient Prospective Payment System (IPPS).

To illustrate, suppose that, after an inpatient has been admitted to a hospital under an established diagnosis-related group (DRG), the patient's attending physician requests a consultation with a specialist who was not responsible for the patient's admission, and the specialist orders an X-ray. By the time the specialist orders the X-ray, the rate of Medicare reimbursement under the IPPS has already been established by the DRG (diagnostic imaging is bundled into the payment for the inpatient admission), and, unless the X-ray results in an outlier payment, the hospital will not receive any additional payment for the service over and above the payment rate established by the DRG.

Moreover, insofar as the provision of the X-ray does not affect the rate of payment, the physician has no financial incentive to over-prescribe the service. As illustrated here, we do not believe that the X-ray is a designated health service that is payable, in whole or part, by Medicare, and our proposed definition of designated health services at § 411.351 would exclude this service from the definition of designated health services, even though it falls within a category of services that, when billed separately, would be ''designated health services.'' Thus, assuming the specialist had a financial relationship with the hospital that failed to satisfy the requirements of an exception to the physician self-referral law at the time the X-ray was ordered, the inpatient hospital services would not be tainted by the unexcepted financial relationship, and the hospital would not be prohibited from billing Medicare for the admission. On the other hand, if the physician who ordered the inpatient hospital admission had a financial relationship with the hospital that failed to satisfy the requirements of an applicable exception, § 411.353(b) would prohibit the hospital for billing for the inpatient hospital services.

We received several comments to our CMS RFI suggesting modifications similar to the change we are proposing. One commenter requested that we clarify that a service is not a designated health service ''for which payment otherwise may be made'' if the physician making a referral for the service ''has not caused the beneficiary to be admitted, the patient has already been admitted, and the service ordered by the physician is subsumed within the DRG already established for the beneficiary.'' Numerous other commenters requested that we modify the definition of ''referral'' to clarify that a referral, for purposes of the physician self-referral law, must result in additional payments or an increase in payment. Although the change to the definition of ''referral'' suggested by the latter commenters would apply to referrals for any category of designated health services, the commenters provided examples drawn exclusively from the context of inpatient services. We do not believe it is necessary to modify the definition of ''referral'' to achieve the policy goals identified by the commenters. We believe that the situation identified by the commenters, where a service furnished pursuant to a physician's referral does not increase the reimbursement received by the entity, occurs primarily or exclusively in the context of inpatient hospital services, where the DRG is established at the time of admission and physicians other than the attending or admitting physician may refer a patient for services that will not result in additional payment to the hospital. For this reason, our proposed clarification of the definition of ''designated health services'' would apply only to inpatient services that do not affect the Medicare reimbursement rate under the IPPS. Although outpatient services are also paid on a composite rate, we believe that there is typically only one ordering physician for outpatient services, and it rarely happens that physicians other than the ordering physician refer outpatients for additional outpatient services that would not be compensated separately under the OPPS. For this reason, our proposed modification of the definition of ''designated health services'' at § 411.351 does not apply to outpatient hospital services.

Lastly, we are aware that not all hospitals are paid under the IPPS. We are soliciting comments as to whether our proposal regarding certain hospital services that are not ''designated health services payable, in whole or in part, by Medicare'' should be extended to analogous services provided by hospitals that are not paid under the IPPS, and, if so, how we should effectuate this change in our regulation text. In addition, we are soliciting comment regarding whether we should extend our proposal to outpatient hospital services or other categories of designated health services and, if so, how we should effectuate this change in our regulation text.

b. Physician

In the 1992 proposed rule, we stated that, for purposes of the physician self-referral law, physicians are certain professionals who are ''legally authorized to practice by the State in which they perform their professional functions or actions and when they are acting within the scope of their licenses.'' (57 FR 8593). We included in the definition a doctor of medicine or osteopathy, a doctor of dental surgery or dental medicine, a doctor of optometry, and a chiropractor who meets certain qualifications. In Phase I, we finalized our definition of ''physician'' at § 411.351, defining the term as ''a doctor of medicine or osteopathy, a doctor of dental surgery or dental medicine, a doctor of podiatric medicine, a doctor of optometry, or a chiropractor, as defined at section 1861(r) of the Act.'' (66 FR 955). Since Phase I, our definition of ''physician'' at § 411.351 has consistently referred to the definition of ''physician'' at section 1861(r) of the Act. However, while the definition of ''physician'' found at § 411.351 cross-references section 1861(r) of the Act, the two definitions are not entirely consistent. In particular, the definition of ''physician'' at § 411.351 does not include all the limitations imposed by the definition of ''physician'' at section 1861(r) of the Act. In order to correct this discrepancy and provide uniformity with regard to the definition of a ''physician,'' we are proposing to amend the definition of ''physician'' at § 411.351. Under the proposed definition, the types of practitioners who qualify as ''physicians'' for purposes of the physician self-referral law will be defined by cross-reference to section 1861(r) of the Act. This amendment will incorporate into our definition of ''physician'' at § 411.351 the statutory limitations imposed on the

definition of ''physician'' by section 1861(r) of the Act. The definition at § 411.351 would continue to provide that a physician is considered the same as his or her professional corporation for purposes of the physician self-referral law.

c. Referral

In Phase II, we stated that the exception for fair market value compensation is not available to protect recruitment arrangements (69 FR 16096). We noted that a hospital is not permitted to pay a physician for the benefit of receiving the physician's referrals, and that such payments are antithetical to the premise of the statute. We are taking this opportunity to reiterate that a physician's referrals are not items or services for which payment may be made under the physician self-referral law, and that neither the existing exceptions to the physician self-referral law nor the proposed exceptions in this proposed rule would protect such payments. We are proposing to revise the definition of ''referral'' at § 411.351 to explicitly state our longstanding policy that a referral is not an item or service for purposes of section 1877 of the Act and the physician self-referral regulations.

d. Remuneration

A compensation arrangement between a physician (or an immediate family member of such physician) and an entity furnishing designated health services implicates the referral and billing prohibitions of the physician self-referral law. Section 1877(h)(1)(A) of the Act defines the term ''compensation arrangement'' as any arrangement involving any ''remuneration'' between a physician (or an immediate family member of such physician) and an entity. However, section 1877(h)(1)(C) of the Act identifies certain types of remuneration which, if provided, would not create a compensation arrangement subject to the referral and billing prohibitions of the physician self-referral law. Under section 1877(h)(1)(C)(ii) of the Act, the provision of the following does not create a compensation arrangement between the parties: Items, devices, or supplies that are used solely to collect, transport, process, or store specimens for the entity providing the items, devices, or supplies, or to order or communicate the results of tests or procedures for such entity. Furthermore, under our definition of ''remuneration'' at § 411.351, the provision of such items, devices, or supplies is not considered to be remuneration.

In the 1998 proposed rule we explained our interpretation of the phrase ''used solely'' at section 1877(h)(1)(C)(ii) of the Act (66 FR 1693 through 1694). We observed that some pathology laboratories had been furnishing physicians with materials ranging from basic collection and storage items to more specialized or sophisticated items, devices, or equipment. We clarified that, in order for these items and devices to meet the statutory requirement, they must be used *solely* to collect, transport, process, or store specimens for the entity that provided the items and devices, or to order or communicate the results of tests or procedures for such entity. We provided examples of items that could meet the ''used solely'' test, including cups used for urine collection or vials used to hold and transport blood to the entity that supplied the items or devices. We emphasized that an item or device would not meet the ''used solely'' requirement if it is used for any purpose besides the purposes listed in the statute. In particular, we noted that certain surgical tools which can be used to collect or store samples, but are also routinely used as part of a surgical or medical procedure, would not satisfy the ''used solely'' requirement.

As finalized in Phase I, the definition of ''remuneration'' included a parenthetical stipulating that the provision of surgical items, devices, and supplies would not qualify for the carve-out to the definition of ''remuneration'' for items, devices, or supplies that are used solely for the purposes listed at section 1877(h)(1)(C)(ii) of the Act (66 FR 947).

We explained that we did not believe that the Congress intended section 1877(h)(1)(C)(ii) of the Act to allow entities to supply physicians with surgical items for free, noting that such items may have independent economic value to physicians apart from the six statutorily permitted uses. We stated our belief that the Congress intended to include at section 1877(h)(1)(C)(ii) of the Act single-use items, devices, and supplies of low value that are primarily provided by laboratories to ensure proper collection of specimens. In this context, we explained that reusable items may have value to physicians unrelated to the collection of specimens, and therefore could not meet the ''used solely'' requirement. Lastly, we stated that the provision of an excessive number of collection supplies creates an inference that the supplies are not provided ''solely'' to collect, transport, process, or store specimens for the entity that furnished them.

We made no changes to the definition of ''remuneration'' in Phase II and Phase III. In the CY 2016 PFS final rule, we clarified that the provision of an item, device, or supply that is used for *one or more* of the six purposes listed in the statute, and no other purpose, does not constitute remuneration (80 FR 41918). In two advisory opinions issued in 2013 we applied the definition of ''remuneration'' at § 411.351 to two proposed arrangements to provide certain devices to physicians free of charge. In CMS–AO–2013–01, we concluded that, based on the specific facts certified by the requestor of the opinion, the provision of liquid-based Pap smear specimen collection kits did not constitute remuneration, because the collection kits are not surgical devices, and because the devices are used solely in the collection of specimens. Among other things, our ''used solely'' analysis highlighted the following facts, as certified by the requestor: (1) The Pap smear collection kits contain only disposable items that cannot be reused after a specimen is collected; and (2) the entity furnishing the Pap smear collection kits has a system in place to ensure that physicians receive only the quantity of devices necessary for their practice needs, and to address potential instances of separation of the devices into their component parts for use other than to collect specimens. In contrast, in CMS–AO–2013–02, we concluded that, based on the specific facts certified by the requestor of the opinion, the furnishing of certain disposable biopsy brushes for use in obtaining a biopsy of visible exocervical lesions constituted remuneration under the definition at § 411.351.

We noted that, as certified by the requestor, the biopsy brush is a disposable, single-use, cervical biopsy device that is used to collect a specimen to be sent to a laboratory. After reviewing FDA rules and regulations and American Medical Association guidelines, and consulting with CMS medical officers, we concluded that the device is a ''surgical item, device, or supply'' for purposes of the physician self-referral law and, therefore, that the provision of the device constitutes remuneration under § 411.351.

We have further considered our interpretation of section 1877(h)(1)((C)(ii) of the Act and the analysis set forth in the 2013 advisory opinions, and are proposing certain modifications to the definition of ''remuneration'' at § 411.351. Specifically, we are proposing to remove the parenthetical in the current definition of ''remuneration,'' which

stipulates that the carve-out to the definition of ''remuneration'' does not apply to surgical items, devices, or supplies. We are no longer convinced that the mere fact that an item, device, or supply is routinely used as part of a surgical procedure means that the item, device, or supply is not used solely for one of the six purposes listed at section 1877(h)(1)(C)(ii) of the Act. Rather, we believe that the relevant inquiry for purposes of the physician self-referral law is whether the item, device, or supply is used solely for one or more of the statutory purposes, regardless of whether the device is also classified as a surgical device. To be clear, we continue to believe that the Congress intended the carve-out at section 1877(h)(1)(C)(ii) of the Act to cover single-use items, devices, or supplies of low value [4] that are primarily provided by laboratories to ensure proper collection of specimens, but we are no longer convinced that the mere fact that an item, supply, or device is classified as a ''surgical device'' means that it does not fall within the carve-out.

We are also taking this opportunity to clarify the ''used solely'' requirement at § 411.351. While the furnished item, device, or supply cannot be used for any purpose other than one or more of the six purposes listed in the statute, we recognize that in many instances the item, device, or supply could theoretically be used for numerous purposes. For example, a specimen lockbox could potentially be used for several purposes; it could be used to store unused specimen collection supplies or as a doorstop. However, if, during the course of the arrangement, the specimen box provided to the physician is not used for any of these purposes and is, in fact, used only for one or more of the six purposes outlined in the statute and our regulations, the furnishing of the specimen box would not be considered remuneration between parties. In other words, the mere fact that an item, device, or supply *could* be used for a purpose other than one or more of the permitted purposes does not automatically mean that the furnishing of the item, device, or supply at no cost constitutes remuneration. We are proposing to add the phrase ''in fact'' to the ''used solely'' requirement to clarify that an item, device, or supply can have several uses, including uses that are not among the six purposes listed in the statute; however, the furnishing of such items, supplies, or devices would not be considered remuneration if the item, device, or supply in question is, in fact, only used for one or more of the six purposes outlined in the statute. We refer readers to the guidance provided in the 1998 proposed rule and in Phase I on steps that a party can take to ensure that the furnished items, supplies, or devices are used appropriately (63 FR 1694 and 66 FR 947 through 948, respectively).

Although we are proposing certain modifications to the definition of ''remuneration,'' our proposal would not exclude from the definition those items, devices, or supplies whose main function is to prevent contamination or infection, even if the item, device, or supply could potentially be used for one or more of the six statutory purposes at section 1877(h)(1)(C)(ii) of the Act. In Phase I, we made clear that, although sterile gloves are essential to the proper collection of specimens, we believe they are not items, devices, or supplies that are used *solely* to collect, transport, process, or store specimens (66 FR 947). Sterile gloves are essential to the specimen collection process, but their primary purpose is to prevent infection or contamination. In addition, sterile gloves are fungible, general purpose items, and we continue to believe it would be impractical for parties to monitor the use of the gloves to ensure that they are used solely for one or more of the purposes listed at section 1877(h)(1)(C)(ii) of the Act. Likewise, although there may be certain specialized equipment (including surgical tools) that may be used for one or more of the purposes described in the statute, in order not to be considered remuneration, the item, device, or supply must not have a primary function of preventing infection or contamination, or some other purpose besides one of the six purposes listed in the statute.

e. Transaction

Section 1877(e)(6) of the Act provides that an isolated financial transaction, such as a one-time sale of property or practice, is not a compensation arrangement for purposes of the physician self-referral law if: (1) The amount of remuneration under the transaction is consistent with fair market value of the transaction and is not determined in a manner that takes into account (directly or indirectly) the volume or value of referrals by the referring physician; (2) the remuneration is pursuant to an arrangement that would be commercially reasonable even if no referrals were made to the entity; and (3) the transaction meets any other requirements that the Secretary imposes by regulation as needed to protect against program or patient abuse. As enacted by OBRA 1989, the statutory exception identified a one-time sale of property as an example of an isolated financial transaction. In OBRA 1993, the Congress further clarified the statutory exception by providing an additional example of an isolated transaction, namely, a one-time sale of a practice. (*See* House Conference Report at H.R. Rep. No. 213, 103d Cong., 1st Sess. 813–815 (1993).)

In our 1992 proposed rule, we proposed an exception at § 411.357(f) to mirror the statutory exception at section 1877(e)(6) of the Act for certain isolated financial transactions (both titled and together referred to as the exception for isolated transactions) (57 FR 8588). In our proposal, we included a requirement—in addition to the statutory requirements—that there be no other transactions (that is, financial relationships) between the parties for 1 year before and 1 year after the financial transaction to ensure that financial transactions excepted under section 1877(e)(6) of the Act and § 411.357(f) are truly *isolated* in nature (57 FR 8599). In the 1995 final rule, we finalized an exception for isolated financial transactions at § 411.357(f), and we modified the proposed 1-year requirement in response to commenters who asserted that the requirement would create substantial and unnecessary problems (60 FR 41960). We stated that a transaction would be considered an isolated transaction for purposes of § 411.357(f) if there were no other transactions between the parties for 6 months after the transaction, except those transactions that are specifically excepted by another provision in §§ 411.355 through 411.357. We further stated that individual payments between parties generally characterize a compensation arrangement; however, debt, as described in the definition of ''ownership or investment interest'' at section 1877(a)(2) of the Act, can constitute an ownership interest that continues to exist until the debt is paid off (60 FR 41960). The 1995 final rule also established definitions of ''transaction'' and ''isolated transaction'' at § 411.351. We defined a ''transaction'' as an instance or process of two or more persons doing business and an ''isolated transaction'' as a transaction involving a single payment between two or more persons. The regulation at § 411.351 specified that a transaction involving long-term or installment payments is not considered an isolated transaction.

[4] See, for example, the OBRA 1993 Conference Report, H.R. 103–213 pp. 818 through 819, which characterized section 1877(h)(1)(C)(ii) of the Act as an ''exception'' for ''certain minor remuneration.''

In the 1998 proposed rule, we proposed to revise the definition of ''transaction'' at § 411.351 to clarify that a transaction can involve persons *or* entities, but we did not propose any substantive changes to the exception at § 411.357(f) (63 FR 1669). This definition was finalized in Phase II, with modification to permit installment payments (and post-closing adjustments) under certain circumstances (69 FR 16098). In Phase II, we also responded to commenters who objected to the prohibition on other transactions within 6 months of the excepted transaction. We declined to modify the 6-month prohibition on other transactions, and we explained that the concept of an *isolated* transaction is incompatible with the parties routinely engaging in multiple transactions in a year or during a short period of time. In Phase III, we made no changes to the exception at § 411.357(f), but updated the term ''isolated transaction'' at § 411.351 to refer to an ''isolated financial transaction,'' as that specific term is used in the statutory and regulatory exceptions (72 FR 51084).

Through our administration of the SRDP, work with our law enforcement partners, and interactions with stakeholders, it has come to our attention that certain parties may believe that CMS' policy is that the exceptions in section 1877(e)(6) of the Act and § 411.357(f) for isolated transactions are available to protect service arrangements where a party makes a *single* payment for *multiple* services provided over an extended period of time. To illustrate, assume that a hospital makes a single payment to a physician for working multiple call coverage shifts over the course of a month (or several months) and seeks to utilize the exception at § 411.357(f) to avoid qualification of the payment as a financial relationship subject to the physician self-referral law's referral and billing prohibitions. That is, the parties wish to consider the single payment for multiple services an ''isolated financial transaction.'' We have observed that parties turn to the exception for isolated transactions to protect single payments for multiple services when they discover, typically after the services have been provided, that they failed to set forth the service arrangement in writing, and thus cannot rely on the exceptions for personal service arrangements or fair market value compensation. In fact, it is our policy that the exception for isolated transactions is *not* available to except payments for multiple services provided over an extended period of time, even if there is only a single payment for all the services. Elsewhere in this proposed rule, we are proposing regulations that will facilitate compliance with the physician self-referral law in general and the writing and signature requirements in particular, including a 90-day period to reduce arrangements to a signed writing and an exception for limited remuneration to a physician. We believe that these provisions, if finalized, would afford parties with sufficient flexibility to ensure that personal service arrangements comply with the physician self-referral law, and see no reason to unduly stretch the meaning and applicability of the exception for isolated transactions beyond what was intended by the Congress.

To illustrate the kind of transactions that section 1877(e)(6) of the Act is meant to exempt, the Congress provided as examples a one-time sale of property and a one-time sale of a practice. In our view, a one-time sale of property or a practice is a unique, singular transaction. It is not possible for one party to repeatedly offer and sell the same property or medical practice to another party. In contrast, services can be provided and purchased on a repeated basis. Moreover, in a one-time sale of property or a practice, the consideration for the transaction (that is, the transfer of ownership of the property or practice) is exchanged at the time payment is made in a single transaction (although § 411.357(f) permits installment payments under certain circumstances). In contrast, if a physician provides multiple services to an entity over an extended period of time, remuneration in the form of an in-kind benefit has passed repeatedly from the physician to the entity receiving the service prior to the payment date. The provision of remuneration in the form of services commences a compensation arrangement at the time the services are provided, and the compensation arrangement must satisfy the requirements of an applicable exception *at that time* if the physician makes referrals for designated health services and the entity wishes to bill Medicare for such services. The exception for isolated transactions is not available to retroactively cure noncompliance with the physician self-referral law. Finally, we note that the Congress created an exception for personal service arrangements at section 1877(e)(3) of the Act and required, among other things, that the arrangement is set out in writing and signed by the parties, that the term of the arrangement is at least 1 year, and that the compensation is set in advance. We do not believe that the Congress would impose such requirements for service arrangements under this exception, and then permit parties to avoid these requirements as long as the parties made one retrospective payment for multiple services provided over an extended period of time relying on the exception for isolated transactions.

To provide a clear expression of our policy described in this section II.D.2.d. of this proposed rule, we are proposing to establish an independent definition of ''isolated financial transaction'' at § 411.351 and clarify that an ''isolated financial transaction'' does not include payment for multiple services provided over an extended period, even if there is only one payment for such services. We are not proposing further changes to the definition of ''transaction'' at § 411.351. Under our proposals, the term ''transaction'' would mean an instance or process of two or more persons doing business. We are proposing corresponding revisions to the exception for isolated transactions at § 411.357(f) to reference isolated *financial* transactions in order to align the regulation text with the statutory provisions at section 1877(e)(6). Even though the exception at § 411.357(f) applies to isolated *financial* transactions, we are not proposing to change the title of the exception from ''isolated transactions'' to ''isolated financial transactions,'' as the title of the statutory exception is ''isolated transactions.''

3. Denial of Payment for Services Furnished Under a Prohibited Referral—Period of Disallowance (§ 411.353(c)(1))

In the CY 2008 PFS proposed rule, we solicited comments on how to determine the period of time during which a physician may not make referrals for designated health services to an entity and the entity may not bill Medicare for the referred designated health services when a financial relationship between the parties failed to satisfy the requirements of any applicable exception (72 FR 38183). We referred to this time period as the ''period of disallowance.'' We stated that, as a general matter, the period of disallowance under the physician self-referral law should begin on the date when a financial relationship fails to satisfy the requirements of any applicable exception and end on the date that the financial relationship ends or is brought back into compliance (that is, satisfies all requirements of an applicable exception). We noted, however, that it is not always clear

when a financial relationship has ended. By way of example, we stated that, if a physician paid less than fair market value for the rental of office space, the below market rental payments may have been in exchange for future or anticipated referrals, so it is not clear if the financial relationship ended on the date that the lease expires. We sought comments on whether we should employ a case-by-case method for determining when a financial relationship ends or if we should, to the extent practicable, create a provision that would deem certain kinds of financial relationships to last a prescribed period of time for purposes of determining the period of disallowance. Assuming we were to prescribe a determinate amount of time for the period of disallowance in certain circumstances, we sought comments on whether the period of disallowance could be terminated if parties returned or repaid the value of any problematic compensation under an arrangement.

In the FY 2009 IPPS proposed rule, we proposed provisions pertaining to the period of disallowance at § 411.353(c)(1) (73 FR 23690 through 23692). Under that proposal, the period of disallowance would begin when the financial relationship failed to satisfy the requirements of any applicable exception. Where the noncompliance is unrelated to the payment of compensation, the period of disallowance would be deemed to end no later than the date that the financial relationship satisfies all requirements of an applicable exception. On the other hand, where the noncompliance is related to the payment of excess or insufficient compensation, the proposed rule provided that the period of disallowance would be deemed to end no later than the date on which the excess compensation was repaid or the additional required compensation was paid, and the arrangement satisfied all the elements of an applicable exception. We emphasized that the proposal only prescribed an outside limit on the period of disallowance. We acknowledged that, in certain cases, a financial relationship may end before the excess compensation has been returned or the insufficient compensation paid in full, and that the period of disallowance in such cases would end when the financial relationship ended. However, we did not issue any rules or guidance on determining when a financial relationship has ended in such cases, and we stated that the period of disallowance would have to be determined in such instances on a case-by-case basis. Lastly, we recognized that noncompliance may also arise for other reasons related to compensation, such as payments that take into account the volume or value of a physician's referrals, but we did not propose any rules on how to determine the period of disallowance in such cases. In the FY 2009 IPPS final rule, we finalized § 411.353(c)(1) as proposed, without substantive modifications (73 FR 48700 through 48705). We emphasized once again that the rule only prescribed an outside date for the period of disallowance, and that the rule did not prevent parties from arguing that the period of disallowance ended earlier than the outside date prescribed by the rule, on the theory that the financial relationship ended prior to this date. We made it clear in response to commenters that the period of disallowance as prescribed by § 411.353(c)(1) was not intended to extend the period of disallowance beyond the end of a financial relationship. Rather, the rule was merely intended to give parties clear guidance on steps that could be taken to ensure that the period of disallowance had ended. In addition, we explained the application of the rules regarding excess and insufficient compensation at § 411.353(c)(1)(ii) and (iii).

In light of our experience administering the SRDP and stakeholder feedback we have received over the years, we are proposing to delete the rules on the period of disallowance at § 411.353(c)(1) in their entirety because we believe that, although the rules were initially intended merely to establish an outside, bright-line limit for the period of disallowance, the rules, in application, appear to be overly prescriptive and impractical. We emphasize that our current rulemaking is in no way meant to undermine parties who have relied on § 411.353(c)(1)(ii) or (iii) in the past to establish that the period of disallowance has ended.

Throughout our rulemaking on the period of disallowance, we acknowledged that there are no definite rules for establishing in each and every case when a financial relationship has ended, and that the analysis typically must proceed on a case-by-case basis, taking into account the unique facts and circumstances of each financial relationship. The period of disallowance rules were meant to provide certainty in the face of this complexity, and to prescribe definite, practical steps that a party could take to establish that the period of disallowance had ended. However, we are concerned that parties may believe that the *only* way to establish that the period of disallowance has ended is to follow the steps outlined in § 411.353(c)(1). Moreover, it has become clear that the steps outlined at § 411.353(c)(1)(ii) and (iii) are not always as practical or clear cut as we originally envisioned. Often when there is an allegation of excess or insufficient compensation paid under an arrangement, there is a dispute between the parties as to what the proper amount of compensation should have been under the arrangement. To settle the dispute, the parties may need to litigate the matter. It is not clear under § 411.353(c)(1)(ii) and (iii) at what point in the litigation, if any, the period of disallowance should end. In addition, in some cases, the cost of litigating the matter may far outweigh the amount in dispute, making litigation highly impractical. Thus, in practice, the provisions at § 411.353(c)(1)(ii) and (iii) often do not provide the clear, bright-line method for determining the end of the period of disallowance that we originally intended, and parties must continue to rely on a case-by-case analysis to determine when the period of disallowance has ended. For these reasons, we are deleting the period of disallowance rules at § 411.353(c)(1) in their entirety.

We continue to agree with the general principle stated in the CY 2008 PFS proposed rule that the period of disallowance under the physician self-referral law should begin on the date when a financial relationship fails to satisfy all requirements of any applicable exception and end on the date that the financial relationship ends or satisfies all requirements of an applicable exception. We are aware that the payment of excess or insufficient compensation can complicate the question of when a financial relationship has ended or been brought back into compliance for purposes of the physician self-referral law. As a general matter, we agree with the FY 2009 IPPS final rule that *one* way to establish that the period of disallowance has ended in such circumstances is to follow the steps prescribed in § 411.353(c)(1)(ii) or (iii); for example, recover any excess compensation and bring the financial relationship back into compliance with an applicable exception. However, we note that, since the publication of the FY 2009 IPPS final rule, stakeholders have questioned whether our preamble guidance was intended to state that administrative or other operational failures during the course of an arrangement, such as the erroneous payment of ''excess'' compensation or the erroneous failure to pay the full amount of compensation

due during the timeframes established under the terms of an arrangement, would necessarily result in noncompliance with the physician self-referral law. Through submissions to the SRDP and other interactions with stakeholders, we are aware of questions regarding whether administrative errors, such as invoicing for the wrong amount of rental charges (that is, an amount other than the amount specified in the written lease arrangement) or the payment of compensation above what is called for under a personal service arrangement due to a typographical error entered into an accounting system, create the type of ''excess compensation'' or ''insufficient compensation'' described in our preamble guidance and the period of disallowance rules. This was never our intent. However, the failure to remedy such operational inconsistencies could result in a distinct basis for noncompliance with the physician self-referral law.

The effect of deleting the period of disallowance rules would not be to permit parties to a financial relationship to make referrals for designated health services and to bill Medicare for the services when that financial relationship does not satisfy all requirements of an applicable exception. It is a fundamental principle of the physician self-referral law that a physician may not make a referral for designated health services to an entity with which he or she has a financial relationship, and the entity may not bill Medicare for the services, if the financial relationship between the parties does not satisfy all the requirements of an applicable exception. Nothing in this proposed rule affects the billing and referral prohibitions at § 411.353(a) and (b). Our intent in deleting § 411.353(c)(1) is merely to no longer prescribe the particular steps or manner for bringing the period of noncompliance to a close. At the same time, we are taking this opportunity to provide general guidance on how to remedy compensation problems that occur during the course of an arrangement and, when a remedy is not available, how to determine when the period of disallowance ends. Consistent with our intent in deleting the period of disallowance rules at § 411.353(c)(1), we emphasize that the analysis to determine when a financial relationship has ended is dependent in each case on the unique facts and circumstances of the financial relationship, including the operation of the financial relationship as negotiated between the parties, and it is not possible for us to provide definitive rules that would be valid in all cases.

For purposes of this analysis, assume there is a 1-year arrangement beginning January 1 for personal services between an entity and a physician; the arrangement is memorialized at the outset in a written agreement between the parties; the amount of compensation provided for in the writing does not exceed fair market value; and the arrangement otherwise fully complies with the requirements of an applicable exception. Assume further that the entity provides compensation to the physician in months 1 through 6 in an amount other than what is stipulated in the written agreement, and the parties discover the payment discrepancy in early July. For purposes of this illustration, assume that a hospital pays a physician $150 per hour for medical director services when the written agreement between the parties identifies $140 per hour as the physician's rate of pay. If the $150 per hour payment is due to an administrative or other operational error—that is, the discrepancy was unintended—the parties may, while the arrangement is ongoing during the term initially anticipated (in this example, during the year of the arrangement), correct the error by collecting the overage (or making up the underpayment, if that is the case). We expect entities and the physicians who refer designated health services to them to operate effective compliance programs that identify these types of errors and rectify them promptly. However, if the parties fail to identify the error during the term of the arrangement as anticipated (that is, the ''live'' or ongoing arrangement), they cannot simply ''unring the bell'' by correcting it at some date after the termination of the arrangement. Rather, the failure to timely identify and rectify the error through an effective compliance program would expose the parties to the referral and billing prohibitions of the physician self-referral law during the entirety of the arrangement.

In analyzing the compensation arrangement in this example—assuming that the operational error was not timely discovered and rectified—as we would with any financial relationship under the physician self-referral law, we consider the actual arrangement between the parties, which does not always coincide with the terms described in the written documentation. Thus, to properly characterize the potential noncompliance, it is important to determine whether the *actual* amount of compensation paid under the arrangement—that is, the amount the physician actually received, as opposed to the amount stipulated in the written agreement—exceeded fair market value for the services actually provided. Assuming that the *actual* amount paid did not exceed fair market value and was not determined in a manner that took into account the volume or value of the physician's referrals or other business generated, then the potential noncompliance may relate primarily to the failure to properly document the *actual* arrangement in writing (assuming the arrangement otherwise satisfied the requirements of an applicable exception). Various provisions in this proposed rule and in our current regulations may offer parties a means of limiting the scope of potential noncompliance in such circumstances. For example, the parties could rely on the proposed special rule for writing and signature requirements at § 411.354(e)(3), coupled with the clarification of the writing requirement at § 411.354(e)(2), to establish that the actual amount of compensation provided under the arrangement was set forth in writing within 90 days of the commencement of the arrangement via a collection of documents, including documents evidencing the course of conduct between the parties. In addition, the proposed exception for limited remuneration to a physician may also be available to protect some or all of the payments made during months 1 through 6. In this manner, depending on the facts and circumstances, the parties may be able to establish that the arrangement complied with the physician self-referral law for some or all of months 1 through 6 of the arrangement.

In certain instances, the failure to collect money that is legally owed under an arrangement may potentially give rise to a secondary financial relationship between the parties. In such circumstances, the parties may conclude that the only means to remedy the noncompliance with the physician self-referral law is to recoup the amount owed under the arrangement. This issue is especially acute if the *actual* amount of compensation paid under the arrangement for months 1 through 6 was not consistent with fair market value or took into account the volume or value of referrals. In such circumstances, parties cannot establish compliance by showing that the actual amount of compensation was documented in various writings, because the compensation itself is the reason for the potential noncompliance. Nevertheless, depending on the facts and circumstances, the parties may be able

to remedy the noncompliance. Returning to the previous example, if the entity discovers the payment errors during the course of the arrangement, corrects the errors going forward, and collects any amount to which it is legally entitled as a result of the erroneous payments during months 1 through 6, then the arrangement may comply with the physician self-referral law for its duration, including months 1 through 6. The relevant inquiry is whether the payment errors during months 1 through 6 gave rise to a secondary financial relationship (for example, an interest free loan) which must satisfy the requirements of an applicable exception, or, on the other hand, whether the payment errors arose from operational or administrative problems that were detected and corrected during the course of the arrangement as part of a normal business practice. In this context, we are taking this opportunity to clarify statements in the FY 2009 IPPS final rule regarding whether parties can ''turn back the clock'' or retroactively ''cure'' noncompliance. We believe that parties who detect and correct administrative or operational errors or discrepancies *during* the course of the arrangement are not necessarily ''turning back the clock'' to address past noncompliance. Rather, it is a normal business practice, and a key element of an effective compliance program, to actively monitor active ongoing, live financial relationships, and to correct problems that such monitoring uncovers. An entity that detects a problem in an active financial relationship and corrects the problem while the financial relationship is still active is addressing a current problem and is not ''turning back the clock'' to fix past noncompliance. On the other hand, once a financial relationship has ended, we believe that parties cannot retroactively ''cure'' previous noncompliance by recovering or repaying problematic compensation. Of course, to the extent that the financial relationship has ended, the period of disallowance has ended as well. We believe this policy encourages active, ongoing review of arrangements for compliance with the physician self-referral law.

4. Ownership or Investment Interests (§ 411.354(b))

a. Titular Ownership or Investment Interest (§ 411.354(b)(3)(vi))

In the FY 2009 IPPS final rule, we introduced the concept of titular ownership or investment interests in the context of our rulemaking pertaining the physician ''stand in the shoes'' provisions at § 411.354(c) (73 FR 48693 through 48699). Under the rules finalized in the FY 2009 IPPS final rule, for purposes of determining whether a compensation arrangement between an entity and a physician organization is deemed to be a compensation arrangement between the entity and the physicians associated with the organization, a physician whose ownership or investment interest in the physician organization is merely titular in nature is not required to stand in the shoes of the physician organization (73 FR 48694). We explained that an ownership or investment interest is considered to be ''titular'' if the physician is not able or entitled to receive any of the financial benefits of ownership or investment, including, but not limited to, the distribution of profits, dividends, proceeds of sale, or similar returns on investment (73 FR 48694). The concept of titular ownership or investment interests set forth in the FY 2009 IPPS final rule applied only to the stand in the shoes rules at § 411.354(c) pertaining to compensation arrangements. Because we were responding to a comment to the 1998 proposed rule (and the Phase I comments thereafter) regarding the application of the exceptions for compensation arrangements, we did not propose to extend the concept of titular ownership or investment interests to the provisions at § 411.354(b) pertaining to ownership or investment interests, although we had previously concluded in a 2005 Advisory Opinion (CMS–AO–2005–08–01) that, for purposes of section 1877(a) of the Act, physician-shareholders of a group practice who did not receive any of the purchase and ownership rights or financial risks and benefits typically associated with stock ownership would not be considered to have an ownership or investment interest in the group practice.

We are now proposing to extend the concept of titular ownership or investment interests to our rules governing ownership or investment interests at § 411.354(b). In particular, under proposed § 411.354(b)(3)(vi), ownership and investment interests would not include titular ownership or investment interests. Consistent with the FY 2009 IPPS final rule, a ''titular ownership or investment interest'' would be an interest that excludes the ability or right to receive the financial benefits of ownership or investment, including, but not limited to, the distribution of profits, dividends, proceeds of sale, or similar returns on investment. As noted in the FY 2009 IPPS final rule, whether an ownership or investment interest is titular is determined by whether the physician has any right to the financial benefits through ownership or investment (73 FR 48694). We believe that proposed § 411.354(b)(3)(vi) would afford providers and suppliers with greater flexibility and certainty under our regulations, especially in states where the corporate practice of medicine is prohibited. For the reasons similar to those stated in CMS–AO–2005–08–01, namely that a physician with a titular ownership in an entity does not have a right to the distribution of profits or the proceeds of sale and, therefore, does not have a financial incentive to make referrals to the entity in which the titular ownership or investment interest exists, we believe that our proposed interpretation and revised definition of ''ownership or investment interest'' does not pose a risk of program or patient abuse.

b. Employee Stock Ownership Program

We stated in the preamble of the 1998 proposed rule that an interest in an entity arising through a retirement fund constitutes an ownership or investment interest in the entity for purposes of section 1877 of the Act (63 FR 1708). Our interpretation was based on the premise that a retirement interest in an entity creates a financial incentive to make referrals to the entity. In Phase I, we reconsidered the issue and withdrew the statement regarding retirement interests made in the 1998 proposed rule (66 FR 870). As finalized in Phase I, § 411.354(b)(3)(i) excluded an interest in a retirement plan from the definition of ''ownership or investment interest.'' We stated that retirement contributions, including contributions from an employer, would instead be considered to be part of an employee's overall compensation.

We made no changes to § 411.354(b)(3)(i) in Phase II. However, after publishing Phase II, we received a comment stating that, contrary to our intent, some physicians were using their retirement plans to purchase or invest in other entities (that is, entities other than the entity that sponsored the retirement plan) to which the physicians were making referrals for designated health services. We made no changes to § 411.354(b)(3)(i) in Phase III, but proposed in the CY 2008 PFS proposed rule to address the potential abuse described by the commenter to Phase II (72 FR 38183). After reviewing the comments received in response to that proposal, in the FY 2009 IPPS final rule, we finalized changes to § 411.354(b)(3)(i) that restricted the retirement interest carve-out to an

interest in an entity that arises from a retirement plan offered by the entity to the physician (or an immediate family member) through the physician's (or immediate family member's) employment with that entity (73 FR 48737 through 48738). Under the current regulation at § 411.354(b)(3)(i), if, through his or her employment by Entity A, a physician has an interest in a retirement plan offered by Entity A, any interest the physician may have in Entity A by virtue of his or her interest in the retirement plan would not be considered to be an ownership or investment interest for purposes of section 1877 of the Act. On the other hand, if the retirement plan sponsored by Entity A purchased or invested in Entity B, the physician would have an interest in Entity B that would not be excluded from the definition of ''ownership or investment interest'' for purposes of the physician self-referral law. For the physician to make referrals for designated health services to Entity B, the ownership or investment interest in Entity B would have to satisfy the requirements of an applicable exception. We explained in the FY 2009 IPPS final rule that it would pose a risk of program or patient abuse to permit a physician to own another entity that furnishes designated health services (other than the entity which employs the physician) through his or her retirement plan, because the physician could then use the retirement interest carve-out to skirt the prohibitions of the physician self-referral law.

Since we published the 2009 IPPS final rule, stakeholders have informed us that, in certain cases, employers seeking to offer retirement plans to physician employees may find it necessary or practical, for reasons of Federal law, State law, or taxation, to structure a retirement plan using a holding company. By way of example, assume a home health agency desires to sponsor a retirement plan for its employees and elects to establish such plan using a holding company whose primary asset will be the home health agency. To effectuate the retirement plan, the home health agency's assets are transferred to or purchased by the holding company, which then employs the physicians and other staff of the home health agency. The holding company sponsors the retirement plan for its employees, offering the employees (including physician employees) an interest in the holding company. Under our current regulations, the physician's interest in the holding company would not be considered an ownership or investment interest under § 411.354(b)(3)(i), because the physician is employed by the holding company, the holding company sponsors the retirement plan, and the physician's ownership interest in the holding company arises through the retirement plan sponsored by the holding company. However, because the retirement plan owns the holding company, and the holding company owns the home health agency, the physician has an indirect ownership or investment interest in the home health agency that would not be carved out under § 411.354(b)(3)(i) and may not satisfy the requirements of an applicable exception at § 411.356.

It is our understanding that a retirement plan structure involving ownership of a holding company and indirect ownership of a legally separate entity furnishing designated health services may be particularly advantageous or necessary in certain circumstances for the establishment of an employee stock ownership plan (ESOP). An ESOP is an individually designed stock bonus plan, which is qualified under Internal Revenue Code (IRC) section 401(a), or a stock bonus and a money purchase plan, both of which are qualified under IRC section 401(a), and which are designed to invest primarily in qualifying employer securities. It is our understanding that ESOPs must be structured to comply with certain safeguards under the Employee Retirement Income Security Act of 1974 (ERISA) (Pub. L. 93–406), including certain nondiscrimination rules and vesting rules that, among other things, do not allow an employee to receive the value of his or her employer stocks held through the retirement plan until at least 1 year after separation from the employer. Given the statutory and regulatory safeguards that exist for ESOPs, we believe that an interest in an entity arising through participation in an ESOP merits the same protection from the physician self-referral law's prohibitions as an interest in an entity that arises from a retirement plan offered by that entity to the physician through the physician's employment with the entity. We do not believe that excluding from the definition of ''ownership or investment interest'' an interest in an entity that arises through participation in an ESOP qualified under IRC section 401(a) poses a risk of program or patient abuse, and we are proposing at § 411.354(b)(3)(vii) to remove such interests from the definition of ''ownership or investment interest'' for purposes of section 1877 of the Act. To provide regulatory flexibility in structuring retirement plans, proposed § 411.354(b)(3)(vii) is not restricted to an interest in an entity that both employs the physician and sponsors the retirement plan.

To illustrate our proposal, assume that a holding company is owned by its employees, including physician employees, through an ESOP, and that the holding company owns a separate legal entity that furnishes designated health services (an ''entity'' for purposes of section 1877 of the Act). Under proposed § 411.354(b)(3)(vii), for purposes of the physician self-referral law, the physician's interest in the ESOP would not constitute an ownership or investment interest in the holding company or the legally separate entity the holding company owns. As with the current retirement interest carve-out at § 411.354(b)(3)(i), employer contributions to the ESOP on behalf of an employed physician would be considered part of the physician's overall compensation and would have to meet the requirements of an applicable exception for compensation arrangements at § 411.357.

We are seeking comments on whether the safeguards on ESOPs that are imposed by ERISA are sufficient for purposes of the physician self-referral to ensure that they do not pose a risk of program or patient abuse and, if not, what additional safeguards we should include to ensure that such interests do not pose a risk of program or patient abuse. To prevent the kind of abuses of retirement plans identified by the commenter on Phase II, we seek comment as to whether it is necessary to restrict the number or scope of entities owned by an ESOP that would not be considered an ownership or investment interest of its physician employees. It is our understanding that an ESOP is designed to invest primarily in ''qualifying employer securities,'' but the ESOP may also invest in other securities. Further, we seek comment whether the exclusion from the definition of ''ownership or investment interest'' should apply only to an interest in an entity arising from an interest in ''qualifying employer securities'' that are offered to a physician as part of an ESOP. We are also seeking comment on whether the proposed revision to § 411.354(b)(3)(vii) is necessary; that is, whether existing § 411.354(b)(3)(i) affords entities furnishing designated health services sufficient regulatory flexibility to structure nonabusive retirement plans, including ESOPs or other plans that involve holding companies.

5. Special Rules on Compensation Arrangements (§ 411.354(e))

In the CY 2008 PFS proposed rule (72 FR 38184 through 38186), we proposed an alternative method for satisfying certain requirements of some of the exceptions in §§ 411.355 through 411.357. We explained that, although we do not have the authority to waive violations of the physician self-referral law, we do have the authority under section 1877(b)(4) of the Act to implement an alternative method for satisfying the requirements of an exception. The proposed method would have required, among other things, that an entity self-disclose the facts and circumstances of the arrangement at issue and that CMS make a determination that the arrangement satisfied all but the ''procedural or 'form' requirements'' of an exception (72 FR 38185). We cited the signature requirement of the exception for personal service arrangements at § 411.357(d)(1) as an example of a procedural or ''form'' requirement, and explained that the alternative method would not be available for violations of requirements such as compensation that is fair market value, set in advance, and not determined in a manner that takes into account the volume or value of referrals.

In the FY 2009 IPPS final rule, we did not finalize the alternative method proposed in the CY 2008 PFS proposed rule. Instead, relying on our authority under section 1877(b)(4) of the Act, we finalized a rule for temporary noncompliance with signature requirements at § 411.353(g) (73 FR 48705 through 48709). As finalized in the FY 2009 IPPS final rule, § 411.353(g) applied only to the signature requirement of an applicable exception at § 411.357. We declined to extend the special rule for temporary noncompliance to any other procedural or ''form'' requirement of an exception (73 FR 48706) or to noncompliance arising from ''minor payment errors'' (73 FR 48703). The special rule at § 411.353(g) permitted an entity to submit a bill and receive payment for a designated health service if the compensation arrangement between the referring physician and the entity fully complied with the requirements of an applicable exception at § 411.357, except with respect to the signature requirement, and the parties obtained the required signatures within 90 days if the failure to obtain the signatures was inadvertent, or within 30 days if the failure to obtain the signatures was not inadvertent (73 FR 48706). Entities were allowed to use the special rule at § 411.353(g) only once every 3 years with respect to the same physician. We stated that we would evaluate our experience with the special rule at § 411.353(g) and that we may propose modifications, either more or less restrictive, at a later date (73 FR 48707). Subsequently, in the CY 2016 PFS final rule, we removed the distinction between failures to obtain missing signatures that were inadvertent and not inadvertent, thereby allowing all parties up to 90 days to obtain the missing signatures (80 FR 71333). As discussed in further detail in this section of the proposed rule, in the FY 2019 PFS final rule, we removed the provision limiting the use of the special rule at § 411.353(g) to once every 3 years with respect to the same physician (83 FR 59715 through 59717).

In the CY 2016 PFS final rule, we clarified that the writing requirement of various exceptions in § 411.357 can be satisfied with a collection of documents, including contemporaneous documents evidencing the course of conduct between the parties (80 FR 71314 through 71317).[5] A commenter requested that CMS permit a 60- or 90-day grace period for satisfying the writing requirement of an applicable exception, stating that such a grace period is needed for last minute arrangements between physicians and entities to which they refer patient for designated health services (80 FR 71316 through 71317). In response, we noted that the special rule at § 411.353(g) applied only to temporary noncompliance with the signature requirement of an applicable exception, and we declined to extend the special rule to the writing requirement of various exceptions at § 411.357. We stated our belief that a ''grace period'' for satisfying the writing requirement poses a risk of program or patient abuse; for example, if the rate of compensation is not documented before a physician provides services to an entity, the entity could adjust the rate of compensation during the proposed grace period in a manner that takes into account the volume or value of the physician's referrals (80 FR 71317). We added that an entity could not satisfy the ''set in advance'' requirement at the outset of an arrangement if the only documents stating the compensation term of an arrangement were generated after the arrangement began. Finally, we reminded parties that, even if an arrangement is not sufficiently documented at the outset, depending on the facts and circumstances, contemporaneous documents created during the course of an arrangement may allow parties to satisfy the writing requirement and the ''set in advance'' requirement for referrals made *after* the contemporaneous documents were created.

Section 50404 of the Bipartisan Budget Act of 2018 (Pub. L. 115–123, enacted February 9, 2018) added provisions to section 1877(h)(1) of the Act pertaining to the writing and signature requirements in certain compensation arrangement exceptions. As amended, section 1877(h)(1)(D) of the Act provides that the writing requirement in various compensation arrangement exceptions ''shall be satisfied by such means as determined by the Secretary,'' including by a collection of documents, including contemporaneous documents evidencing the course of conduct between the parties. Section 1877(h)(1)(E) of the Act created a statutory special rule for temporary noncompliance with signature requirements, providing that the signature requirement of an applicable compensation arrangement exception shall be satisfied if the arrangement otherwise complies with all the requirements of the exception and the parties obtain the required signatures no later than 90 consecutive calendar days immediately following the date on which the compensation arrangement became noncompliant. In the CY 2019 PFS final rule, we finalized at § 411.354(e) a special rule on compensation arrangements, which codified in our regulations the clarification of the writing requirement found at section 1877(h)(1)(D) of the Act (83 FR 59715 through 59717). In addition, we removed the 3-year limitation on the special rule on temporary noncompliance with signature requirements at § 411.353(g)(2) in order to align the regulatory provision at § 411.353(g) with section 1877(h)(1)(E) of the Act. We proposed, in the alternative, to delete § 411.353(g) in its entirety and to codify section 1877(h)(1)(E) of the Act in the newly created special rules on compensation arrangements at § 411.354(e). However, we declined to finalize the alternative proposal in the CY 2019 PFS final rule, because we believed it would be less disruptive to stakeholder compliance efforts to amend the already-existing § 411.353(g).

We have reconsidered our policy on temporary noncompliance with the signature and writing requirements of

[5] Our guidance on the writing requirement was subsequently codified in statute at section 1877(h)(1)(D) of the Act and incorporated into our regulations at § 411.354(e). See CY 2019 PFS final rule (83 FR 59715 through 59717).

various compensation arrangement exceptions. In our administration of the SRDP, we have reviewed numerous compensation arrangements that fully satisfied all the requirements of an applicable exception, including requirements pertaining to fair market value compensation and the volume or value of referrals, except for the writing or signature requirements. In many cases, there are short periods of noncompliance with the physician self-referral law at the outset of a compensation arrangement, because the parties begin performance under the arrangement before reducing the key terms and conditions of the arrangement to writing. As long as the arrangement otherwise meets all the requirements of an applicable exception, and the parties memorialize the arrangement in writing and sign the written documentation within 90 days, we do not believe that the arrangement poses a risk of program or patient abuse. Therefore, we believe that entities and physicians should be provided flexibility under our rules to satisfy the writing or signature requirement of an applicable exception within 90 calendar days of the inception of a compensation arrangement.

Relying on our authority at section 1877(h)(1)(D) of the Act, which grants the Secretary the authority to determine the means by which the writing requirement of a compensation arrangement exception may be satisfied, and section 1877(h)(1)(E) of the Act, which establishes a statutory rule for temporary noncompliance with signature requirements, we are proposing to create a special rule for noncompliance with the writing or signature requirement of an applicable compensation arrangement exception. Specifically, we are proposing to delete § 411.353(g) in its entirety, codify the statutory rule for noncompliance with signature requirements at section 1877(h)(1)(E) of the Act in a special rule on compensation arrangements at § 411.354(e)(3), and incorporate a special rule for noncompliance with the writing requirement into the new special rule at § 411.354(e)(3). Under this proposal, the writing requirement or the signature requirement would be deemed to be satisfied if: (1) The compensation arrangement satisfies all requirements of an applicable exception other than the writing or signature requirement(s); and (2) the parties obtain the required writing or signature(s) within 90 consecutive calendar days immediately after the date on which the arrangement failed to satisfy the requirement(s) of the applicable exception. We note that the writing and signature requirements would not be mutually exclusive under the proposal; that is, a party could rely on proposed § 411.354(e)(3) if an arrangement was neither in writing nor signed at the outset, provided both the required writing and signature(s) were obtained within 90 days and the arrangement otherwise satisfied all the requirements of an applicable exception. For arrangements that are 90 days or less, such as short term arrangements as permitted under the exception for fair market value compensation at § 411.357(l), if the parties never obtain the required writing or signature(s), the arrangement could never have complied with an exception in § 411.357 that includes a writing or signature requirement; therefore, the special rule at § 411.354(e)(3) is not available to protect such arrangements. However, depending on the facts and circumstances, the proposed exception for limited remuneration at § 411.357(z), which does not include a writing or signature requirement, if finalized, might be available to protect the short term arrangement.

We remind readers that, as we explained in the CY 2016 PFS final rule and subsequently codified at § 411.354(e)(2), a single formal written contract is not necessary to satisfy the writing requirement (80 FR 71314 through 71317). Depending on the facts and circumstances, the writing requirement can be satisfied by a collection of documents, including contemporaneous documents evidencing the course of conduct between the parties. In this context, parties may rely on the special rule at § 411.354(e)(3) like a safe harbor to be sure that they have met the writing or signature requirements of an applicable exception. The special rule would not be the only way to show compliance with the writing or signature requirements.

The proposal to permit parties up to 90 days to satisfy the writing requirement of an applicable exception does not amend, nor does it affect, the requirement under various exceptions in § 411.357 that compensation be set in advance, including the special rule on compensation that is considered to be set in advance at § 411.354(d)(1). For an arrangement to be protected by proposed § 411.354(e)(3), the amount of or formula for calculating the compensation must be set in advance and the arrangement must satisfy all other requirements of an applicable exception, other than the writing or signature requirements. Section 1877(h)(1)(D) of the Act provides the Secretary with the authority to determine the means by which the writing requirement of various compensation arrangement exceptions may be satisfied, but it does not provide the Secretary similar authority with respect to the set in advance requirement. Moreover, we believe the ''set in advance'' requirement is necessary to prevent the amount of compensation paid under an arrangement from fluctuating in a manner that takes into account the volume or value of a physician's referrals over the course of the arrangement, including the first 90 days.

While we are not proposing to amend the special rule on compensation that is considered to be set in advance at § 411.354(d)(1), we are taking this opportunity to reiterate that the special rule is merely a deeming provision (*see* Phase II, 69 FR 16070). That is, while compensation is considered to be set in advance under § 411.354(d)(1) if the compensation is ''set out in writing before the furnishing of items or services'' and the other requirements of § 411.354(d)(1) are met, in order to satisfy the ''set in advance'' requirement included in various exceptions in § 411.357, it is not necessary that the parties reduce the compensation to writing before the furnishing of items or services. For example, assume that the parties to an arrangement agree on the rate of compensation before the furnishing of items or services, but do not reduce the compensation rate to writing at that point in time. Assume further that the first payment under the arrangement is documented and that, under proposed § 411.354(e)(3), during the 90-day period after the items or services are initially furnished, the parties compile sufficient documentation of the arrangement to satisfy the writing requirement of an applicable exception. Finally, assume that the written documentation compiled during the 90-day period provides for a rate of compensation that is consistent with the documented amount of the first payment, that is, the rate of compensation did not change during the 90-day period. Under these specific circumstances, we would consider the compensation to be set in advance. More broadly speaking, records of a consistent rate of payment over the course of an arrangement, from the first payment to the last, typically support the inference that the rate of compensation was set in advance. To the extent that our preamble discussion in the CY 2016 PFS final rule suggested that the rate of compensation must be set out in writing before the furnishing of items or services in order to meet the

''set in advance'' requirement of an applicable exception, we are retracting that statement (80 FR 71317).

We also note that there are many ways in which the amount of or a formula for calculating the compensation under an arrangement can be documented before the furnishing of items or services. It is not necessary that the document stating the amount of or a formula for calculating the compensation, taken by itself, satisfies the writing requirement at § 411.354(e)(2); the document stating the amount of or a formula for calculating the compensation may be one document among many which, taken together, constitute a collection of documents sufficient to satisfy the writing requirement at § 411.354(e)(2). For example, depending on the facts and circumstances, informal communications via email or text, internal notes to file, similar payments between the parties from prior arrangements, generally applicable fee schedules, or other documents recording similar payments to or from other similarly situated physicians for similar items or services, may be sufficient to establish that the amount of or a formula for calculating the compensation was set in advance before the furnishing of items or services. Even if the amount of or a formula for calculating the compensation is not set in advance, depending on the facts and circumstances, the parties may be able to rely on the newly proposed exception for limited remuneration to a physician at § 411.357(z), if finalized. If proposed § 411.357(z) is finalized, and an entity initially pays a physician for services relying on the exception for limited remuneration to a physician, if the parties subsequently decide to continue the arrangement relying on an exception that requires the compensation to be set in advance, such as the exception for personal services arrangements at § 411.357(d)(1), depending on the facts and circumstances, the parties may be able to use documentation of the initial payments made while relying on § 411.357(z) to establish that the amount of or a formula for calculating the compensation was set in advance before the furnishing of services under the personal service arrangement.

Finally, we are taking this opportunity to clarify our longstanding policy that an electronic signature that is legally valid under Federal or State law is sufficient to satisfy the signature requirement of various exceptions in our regulations. We also note that the collection of writings that parties may rely on under § 411.354(e)(2) to satisfy the writing requirement of our exceptions can include documents and records that are stored electronically. We are soliciting comments on whether we should include specific regulation text at § 411.354(e) to reflect our policy on electronic signatures and documents.

6. Exceptions for Rental of Office Space and Rental of Equipment (§ 411.357(a) and (b))

Section 1877(e)(1) of the Act establishes an exception to the physician self-referral law's referral and billing prohibitions for certain arrangements involving the rental of office space or equipment. Among other things, sections 1877(e)(1)(A)(ii) and (e)(1)(B)(ii) of the Act require the office space or equipment to be used exclusively by the lessee when being used by the lessee. The exclusive use requirements are incorporated into our regulations at § 411.357(a)(3) and (b)(2).

In the 1998 proposed rule, we stated our belief that the exclusive use requirement in the statute was meant to prevent ''paper leases,'' where payment passes from a lessee to a lessor, even though the lessee is not actually using the office space or equipment (63 FR 1714). In Phase II, we further explained our interpretation of the exclusive use requirement (69 FR 16086). We stated that, after reviewing the statutory scheme, we believe that the purpose of the exclusive use requirement was to ensure that the rented office space or equipment cannot be shared with the lessor when it is being used or rented by the lessee (or any subsequent sublessee). In other words, a lessee (or sublessee) cannot ''rent'' office space or equipment that the lessor will be using concurrently with, or in lieu of, the lessee (or sublessee). We added that we were concerned that unscrupulous physicians or physicians groups might attempt to skirt the exclusive use requirement by establishing holding companies to act as lessors. To foreclose this possibility, we modified the exclusive use requirements at § 411.357(a)(3) and (b)(2), to stipulate that the rented office space or equipment may not be ''shared with or used by the lessor or any person or entity related to the lessor'' when the lessee is using the office space or equipment.

Disclosures to the SRDP have included several arrangements where multiple lessees use the same rented office space or equipment either contemporaneously or in close succession to one another, while the lessor is excluded from using the premises or equipment. At least one entity disclosed that it had invited a physician who was not the lessor into its office space to treat a mutual patient for the patient's convenience. The disclosing parties assumed that the arrangements violated the physician self-referral law, because, based on their understanding of the exceptions at § 411.357(a) and (b), the arrangements did not satisfy the exclusive use requirement of the applicable exception. As noted in the 1998 proposed rule and in Phase II, the purpose of the exclusive use rule is to prevent sham leases where a lessor ''rents'' space or equipment to a lessee, but continues to use the space or equipment during the time period ostensibly reserved for the lessee. We do not interpret sections 1877(e)(1)(A)(ii) and (B)(ii) of the Act to prevent multiple lessees from using the rented space or equipment at the same time, so long as the lessor is excluded, nor do we interpret sections 1877(e)(1)(A)(ii) and (B)(ii) of the Act to prohibit a lessee from inviting a party other than the lessor (or any person or entity related to the lessor) to use the office space or equipment rented by the lessee. Moreover, we do not believe it would pose a risk of program or patient abuse for multiple lessees (and their invitees) to use the space or equipment to the exclusion of the lessor, provided that the arrangements satisfy all requirements of the applicable exception for the rental of office space or equipment, and any financial relationships between the lessees (or their invitees) that implicate the physician self-referral law likewise satisfy the requirements of an applicable exception. Therefore, relying on the Secretary's authority under section 1877(b)(4) of the Act, we are proposing to clarify our longstanding policy that the lessor (or any person or entity related to the lessor) is the only party that must be excluded from using the space or equipment under § 411.357(a)(3) and 411.357(b)(2). Specifically, we are proposing to add the following clarification to the regulation text: For purposes of this exception, exclusive use means that the lessee (and any other lessees of the same office space or equipment) uses the office space or equipment to the exclusion of the lessor (or any person or entity related to the lessor). The lessor (or any person or entity related to the lessor) may not be an invitee of the lessee to use the office space or the equipment.

7. Exception for Physician Recruitment (§ 411.357(e))

Section 1877(e)(5) of the Act established an exception for remuneration provided by a hospital to a physician to induce the physician to relocate to the geographic area served by

the hospital in order to be a member of the hospital's medical staff. The exception at section 1877(e)(5) of the Act authorizes the Secretary to impose additional requirements on recruitment arrangements as needed to protect against program or patient abuse. The 1995 final rule incorporated the provisions of section 1877(e)(5) of the Act into our regulations at § 411.357(e). As finalized in the 1995 final rule, § 411.357(e) requires the recruitment arrangement to be in writing and signed by both parties, that is, the recruited physician and the hospital.

In Phase II, we substantially modified § 411.357(e). Relying on our authority under section 1877(b)(4) of the Act, we expanded the exception at § 411.357(e)(4) to address remuneration from a hospital (or a federally qualified health center (FQHC), which was added as a permissible recruiting entity under Phase II) to a physician who joins a physician practice. There, we established requirements for recruitment arrangements under which remuneration is provided by a hospital or FQHC indirectly to a physician through payments made to his or her physician practice as well as directly to the physician who joins a physician practice (69 FR 16094 through 16095). When payment is made to a physician indirectly through a physician practice that the recruited physician joins, the practice is permitted to retain actual costs incurred by the practice in recruiting the physician under § 411.357(e)(4)(ii), and, in the case of an income guarantee made by the hospital or FQHC to the recruited physician, the practice may also retain the actual additional incremental costs attributable to the recruited physician under § 411.357(e)(4)(iii). Under the Phase II regulation, if a recruited physician joined a physician practice, § 411.357(e)(4)(i) required the party to whom the payments are directly made (that is, the physician practice that the recruited physician joins) to sign the written recruitment agreement (69 FR 16139).

In Phase III, we responded to a commenter who requested clarification with respect to who must sign the writing documenting the physician recruitment arrangement (72 FR 51012). The commenter's concern was that § 411.357(e)(4)(i) could be interpreted to require that the recruiting entity (in the commenter's example, a hospital), the physician practice, and the recruited physician all had to sign one document. The commenter asserted that this would be unnecessary and would add to the transaction costs of the recruitment. The commenter suggested that we require a written agreement between the hospital and either the recruited physician or the physician practice to which the payments would be made or, in the alternative, that we should permit the hospital and the physician practice receiving the payments to sign a written recruitment agreement and require the recruited physician to sign a one-page acknowledgment agreeing to be bound by the terms and conditions set forth in that agreement. We responded that the exception for physician recruitment requires a writing that is signed by all parties, including the recruiting hospital (or FQHC or rural health clinic, which was added as a permissible recruiting entity under Phase III), the recruited physician, and the physician practice that the physician will be joining, if any, and explained that nothing in the regulations precluded execution of the agreement in counterparts.

We have reconsidered our position regarding the signature requirement at § 411.357(e)(4)(i). In the SRDP, we have seen arrangements in which a physician practice that hired a physician who was recruited by a hospital (or FQHC or rural health clinic) did not receive any financial benefit as a result of the hospital and physician's recruitment arrangement. Examples of such arrangements include arrangements under which: (1) The recruited physician joined a physician practice but the hospital paid the recruitment remuneration to the recruited physician directly; (2) remuneration was transferred from the hospital to the physician practice, but the practice passed all of the remuneration from the hospital to the recruited physician (that is, the practice served merely as an intermediary for the hospital's payments to the recruited physician and did not retain any actual costs for recruitment, actual additional incremental costs attributable to the recruited physician, or any other remuneration); and (3) the recruited physician joined the physician practice after the period of the income guarantee but before the physician's ''community service'' repayment obligation was completed. In each of the arrangements disclosed to the SRDP, the arrangement was determined by the disclosing party not to satisfy the requirements of the exception at § 411.357(e) solely because the physician practice that the recruited physician joined had not signed the writing evidencing the arrangement. We do not believe, however, that, under the circumstances described by parties disclosing to the SRDP, there exists a compensation arrangement between the physician practice and the hospital (or FQHC or rural health clinic) of the type against which the statute is intended to protect; that is, the type of financial self-interest that impacts a physician's medical decision making. Because the physician practice is not receiving a financial benefit from the recruitment arrangement, we do not believe it is necessary for the physician practice to also sign the writing documenting the recruitment arrangement between the recruited physician and the hospital (or FQHC or rural health clinic) in order to protect against program or patient abuse. We also believe that eliminating the signature requirement for a physician practice that receives no financial benefit under the recruitment arrangement would reduce undue burden without posing a risk of program and patient abuse. For these reasons, we are proposing to modify the signature requirement at § 411.357(e)(4)(i). We are proposing to require the physician practice to sign the writing documenting the recruitment arrangement, if the remuneration is provided indirectly to the physician through payments made to the physician practice and the physician practice does not pass directly through to the physician all of the remuneration from the hospital.

8. Exception for Remuneration Unrelated to the Provision of Designated Health Services (§ 411.357(g))

Under section 1877(e)(4) of the Act, remuneration provided by a hospital to a physician does not create a compensation arrangement for purposes of the physician self-referral law, if the remuneration does not relate to the provision of designated health services. The statutory exception is codified in our regulations at § 411.357(g). Our prior rulemaking regarding § 411.357(g) has been based in part on an interpretation of the legislative history of section 1877(e)(4) of the Act. In order to explain the changes we are currently proposing to § 411.357(g), it is necessary to examine the legislative history of section 1877(e)(4) of the Act and certain provisions that preceded it.

As originally enacted by OBRA 1989, the referral and billing prohibitions of the physician self-referral law applied only to clinical laboratory services. OBRA 1989 created three general exceptions for both ownership and compensation arrangements at sections 1877(b)(1) through (3) of the Act, and granted the Secretary the authority at section 1877(b)(4) of the Act to create additional exceptions. Section 42017(e) of OBRA 1990 (Pub. L. 101–508) redesignated section 1877(b)(4) as 1877(b)(5) of the Act, and added an exception at section 1877(b)(4) of the

Act for financial relationships with hospitals that are unrelated to the provision of clinical laboratory services. (To avoid confusion between the exception added by OBRA 1990 at section 1877(b)(4) of the Act and section 1877(b)(4) of the Act as it currently exists, the exception for financial relationships unrelated to the provision of clinical laboratory services enacted by OBRA 1990 is referred to herein as the ''OBRA 1990 exception.'') The OBRA 1990 exception applied to both ownership or investment interests and compensation arrangements, and excepted financial relationships between physicians (or immediate family members of physicians) and hospitals that did not relate to the provision of clinical laboratory services. OBRA 1993 eliminated the OBRA 1990 exception, but the Social Security Act Amendments of 1994 (Pub. L. 103–432) (SSA 1994) reinstated the exception through January 1, 1995.

In place of the OBRA 1990 exception, OBRA 1993 added a new exception at section 1877(e)(4) of the Act. Under section 1877(e)(4) of the Act, remuneration provided by a hospital to a physician that does not relate to the provision of designated health services is not considered a compensation arrangement for purposes of the referral and billing prohibitions. Although there are certain similarities between section 1877(e)(4) of the Act and the OBRA 1990 exception, the exception at section 1877(e)(4) of the Act is narrower than the OBRA 1990 exception in several important respects: (1) The OBRA 1990 exception excepts both ownership interests and compensation arrangements between hospitals and physicians, whereas section 1877(e)(4) of the Act applies only to compensation arrangements under which remuneration passes from the hospital to the physician; (2) the OBRA 1990 exception protects a broad range of financial relationships that are unrelated to the provision of clinical laboratory services, whereas section 1877(e)(4) of the Act has a narrower application, applying only to remuneration unrelated to the provision of designated health services; and (3) the OBRA 1990 exception applies to financial relationships between entities and physicians or their immediate family members, whereas section 1877(e)(4) of the Act applies only to compensation arrangements with physicians.

In the 1998 proposed rule, we proposed to revise our regulation at § 411.357(g) to reflect our interpretation of section 1877(e)(4) of the Act (63 FR 1702). (The prior regulation at § 411.357(g) was based on former sections 1877(b)(4) and (e)(4) of the Act as they were effective on January 1, 1992 (63 FR 1669).) We stated that, for remuneration from a hospital to a physician to be excepted under § 411.357(g), the remuneration must be ''completely unrelated'' to the furnishing of designated health services. We clarified that the remuneration could not in any direct or indirect way involve designated health services, and further that the exception would not apply in any situation involving remuneration that might have a nexus with the provision of, or referrals for, a designated health service (63 FR 1702). We further stated that the remuneration could in no way reflect the volume or value of a physician's referrals, and that payments to physicians that were ''inordinately high'' or above fair market value would be presumed to be related to the furnishing of designated health services. We provided the following examples of remuneration that might be completely unrelated to the furnishing of designated health services and excepted under § 411.357(g): (1) Fair market value rental payments made by a teaching hospital to a physician to rent his or her house in order to use the house as a residence for a visiting faculty member; and (2) compensation for teaching, general utilization review, or administrative services.

In Phase II, we finalized the exception at § 411.357(g) with modifications (69 FR 16093 through 16094). As finalized, in addition to requiring that the remuneration does not in any way take into account the volume or value of the physician's referrals, § 411.357(g) requires that the remuneration is wholly unrelated (that is, neither directly nor indirectly related) to the furnishing of designated health services. The regulation stipulates that remuneration relates to the furnishing of designated health services if it: (1) Is an item, service, or cost that could be allocated in whole or in part to Medicare or Medicaid under cost reporting principles; (2) is furnished, directly or indirectly, explicitly or implicitly, in a selective, targeted, preferential, or conditioned manner to medical staff or other persons in a position to make or influence referrals; or (3) otherwise takes into account the volume or value of referrals or other business generated by the referring physician. We stated that we incorporated cost reporting principles in the regulation in order to provide the industry with bright-line rules to determine whether remuneration is related to the furnishing of designated health services (69 FR 16093). At the same time, we retracted the statement from the 1998 proposed rule that general utilization review or administrative services might not be related to the furnishing of designated health services. We justified our narrow interpretation of section 1877(e)(4) of the Act on the legislative history of the exception, noting that, initially, under the original statute, the exception was necessary to insulate a hospital's relationships with physicians that were unrelated to the provision of clinical laboratory services, a very small element of a hospital's practice. We continued that, since 1995, however, all hospital services are designated health services and a narrower interpretation of the exception is required to prevent abuse (69 FR 16093). We have made no changes to § 411.357(g) since Phase II. Commenters on Phase II stated that the Congress intended hospitals to be able to provide any amount of remuneration to physicians, provided that the remuneration did not *directly* relate to designated health services. In Phase III, based on our interpretation of the legislative history at that time, we reaffirmed our narrow interpretation of section 1877(e)(4) of the Act (72 FR 51056).

Based on our review of the statutory history of the OBRA 1990 exception and section 1877(e)(4) of the Act, and comments we received on our CMS RFI, we are proposing certain modifications to the exception at § 411.357(g) to broaden the application of the exception. As a preliminary matter, we agree with the statement in Phase II that the exception at section 1877(e)(4) of the Act is significantly narrower than the OBRA 1990 exception. There are many financial relationships between hospitals and physicians that would be permissible under the OBRA 1990 exception because they do not relate, directly or indirectly, to the provision of clinical laboratory services. On the other hand, insofar as the exception at section 1877(e)(4) of the Act requires the remuneration to be unrelated to the provision of designated health services, and OBRA 1993 defines this term to include inpatient and outpatient services, the scope of protected compensation arrangements under section 1877(e)(4) of the Act is much narrower than that of the OBRA 1990 exception. Generally speaking, most financial relationships between hospitals and physicians relate to the furnishing of designated health services, in particular, inpatient or outpatient hospital services. That being said, we must also consider that OBRA 1993 did not merely strike the term ''clinical

laboratory services'' in the OBRA 1990 exception and substitute the term ''designated health services.'' Rather, OBRA 1993 eliminated the OBRA 1990 exception and created a new (albeit somewhat similar) exception at section 1877(e)(4) of the Act. In light of this statutory history, we believe that the most accurate interpretation of section 1877(e)(4) of the Act is not as a carryover of the 1990 OBRA exception into the significantly revised statutory regime established by OBRA 1993. Rather, we believe that section 1877(e)(4) of the Act should be interpreted as a new exception that was intentionally created by the Congress in OBRA 1993, the very same legislation in which the Congress expanded the referral and billing prohibition of the physician self-referral law to inpatient and outpatient hospital services. In creating a new exception for remuneration unrelated to the provision of designated health services *and* expanding the definition of ''designated health services'' to include inpatient and outpatient hospital services, we believe that the Congress intended the exception to apply to a narrow—but not empty—subset of compensation arrangements between hospitals and physicians.

According to commenters that responded to the CMS RFI, current § 411.357(g) has an extremely limited application. Several commenters stated that it is not clear what remuneration, if any, is permissible under the exception, if the exception does not apply to any item, cost, or service that could be allocated to Medicare or Medicaid under cost reporting principles, or to remuneration that is offered in any preferential or selective manner whatsoever. After reconsidering the matter, we agree with the commenters that the current exception is too restrictive.

To give appropriate meaning to the statutory exception at section 1877(e)(4) of the Act, we are proposing to delete the current provisions at § 411.357(g)(1) and (2) in their entirety and to remove the phrase ''directly or indirectly'' from the regulation text. In place of existing § 411.357(g)(1) and (2), we are proposing language that incorporates the concept of patient care services as the touchstone for determining when remuneration for an item or service is related to the provision of designated health services. In particular, we are proposing regulation text to clarify that remuneration from a hospital to a physician does not relate to the provision of designated health services if the remuneration is for items or services that are not related to patient care services. Section 1877(e)(4) of the Act specifically excepts remuneration unrelated to the *provision* of designated health services. For purposes of applying the exception at section § 411.357(g), we are interpreting section 1877(e)(4) of the Act to except remuneration unrelated to the act or process of providing designated health services, a concept which is not as all-encompassing as remuneration that is unrelated in any manner whatsoever to designated health services. We believe that patient care services provided by a physician, when the physician is acting in his or her capacity as a medical professional, are integrally related to the act or process of providing designated health services, regardless of whether such services are provided to patients of the hospital; thus, payment for such services relates to the provision of designated health services. Likewise, we believe that items that are used in the act or process of furnishing patient care services are integrally related to the provision of designated health services, and payments for such items relate to the provision of designated health services. On the other hand, we believe that remuneration from a hospital to a physician for services that are not patient care services or items that are not used in the act or process of providing designated health services does not relate to the *provision* of designated health services and would, therefore, not be prohibited under section 1877(e)(4) of the Act or our regulations at proposed § 411.357(g) (provided that the remuneration is not determined in any manner that takes into account the volume or value of the physician's referrals).

We believe that the concept of patient care services, as further specified in the proposed regulation text and as explained in this section of the proposed rule, provides a determinant and practicable principle for applying § 411.357(g) to compensation arrangements between hospitals and physicians. We note that the proposed regulation at § 411.357(g) retains the requirement that the remuneration is not determined in any manner that takes into account the volume or value of the physician's referrals. Remuneration that is determined in a manner that takes into account the volume or value of a physician's referrals clearly relates to the provision of designated health services, regardless of the nature of the item or service for which the physician receives remuneration. Thus, the proposed provisions at § 411.357(g)(2) and (g)(3), which are intended to clarify when remuneration does not relate to the provision of designated health services, do not apply to any remuneration that is determined in a manner that takes into account the volume or value of a physician's referrals.

We believe that remuneration from a hospital to a physician that pertains to the physician's patient care services is the paradigm of remuneration that relates to the provision of designated health services. Most obviously, when a physician provides patient care services to hospital patients, the physician's patient care services are directly correlated with the provision of designated health services. Thus, remuneration from the hospital to the physician for such services is clearly related to designated health services. However, there does not have to be a direct one-to-one correlation between a physician's services and the provision of designated health services in order for payments for the service to be related to the provision designated health services. For example, payment for emergency department call coverage relates to the furnishing of designated health services, even if the physician is not as a matter of fact called to the hospital to provide patient care services, because the hospital is paying the physician to be available to provide patient care services at the hospital. Similarly, medical director services typically include, among other things, establishing clinical pathways and overseeing the provision of designated health services in a hospital. It is our policy that payments for such services are related to the furnishing of designated health services for purposes of applying the exception at proposed § 411.357(g). We also believe that utilization review services are closely related to patient care services, and for this reason, we consider remuneration for such services to be related to the furnishing of designated health services.

In contrast to the services described above, we do not believe that the administrative services of a physician pertaining solely to the business operations of a hospital relate to patient care services. Thus, if a physician is a member of a governing board along with persons who are not licensed medical professionals, and the physician receives stipends or meals that are available to the other board members, it is our policy that this remuneration would not relate to the provision of designated health services under proposed § 411.357(g), provided the physician's compensation for the administrative services is not determined in a manner that takes into account the volume or value of his or

her referrals. In this instance, we believe that the dispositive factor in determining that a physician's services are not related to the provision of designated health services is that the services are also provided by persons who are not licensed medical professionals, and the physician is compensated on the same terms and conditions as the non-medical professionals. Insofar as services may be provided by persons who are not licensed medical professionals, we do not believe that they are patient care services. To provide clarity for stakeholders, we are proposing a general principle at § 411.357(g)(3) for determining when remuneration for a particular service, when provided by a physician, is related to the provision of designated health services. We believe that, if a service can be provided legally by a person who is not a licensed medical professional *and* the service is of the type that is typically provided by such persons, then payment for such a service is unrelated to the provision of designated health services and may be protected under proposed § 411.357(g), provided that it is not determined in a manner that takes into account the volume or value of the physician's referrals. We note in this context that ''licensed medical professional'' includes, but is not limited to, a licensed physician. That is, if a service can be provided legally by both a physician and a medical professional who is not a physician, such as a registered nurse, but the service cannot be provided by a person who is not a licensed medical professional, it is still considered to be a patient care service for purposes of § 411.357(g)(3). Thus, remuneration provided by a hospital to a physician for the service would not be excepted under proposed § 411.357(g), notwithstanding the fact that the service does not have to be performed by a *physician.*

With respect to remuneration from a hospital for items provided by a physician, typical examples of remuneration that is related to the provision of designated health services include rental of medical equipment and purchasing of medical devices from physicians. Because these items are used in the provision of patient care services, and the patient care services may be designated health services or be directly correlated with the provision of designated health services, remuneration for such items clearly relates to the provision of designated health services. We also believe that rental of office space where patient care services are provided, including patient services that are not necessarily designated health services, is remuneration related to the provision of designated health services. However, if a physician who joins another practice sells the furniture from his or her medical office to a hospital, and the hospital places the furniture in the hospital's facilities, as long as the payment is not determined in a manner that takes into account the physician's referrals, we do not believe that the remuneration is related to the provision of designated health services. Also, we continue to believe that, as first stated in the 1998 proposed rule, § 411.357(g) (including proposed § 411.357(g)) applies to rental payments made by a teaching hospital to a physician to rent his or her house in order to use the house as a residence for a visiting faculty member. To provide stakeholders with greater clarity, we are proposing to stipulate in regulation that remuneration provided in exchange for any item, supply, device, equipment, or office space that is used in the diagnosis or treatment of patients, or any technology that is used to communicate with patients regarding patient care services, is presumed to be related to the provision of designated health services for purposes of § 411.357(g).

We believe that proposed § 411.357(g)(2) and (3) provide clarity regarding when payments for items and services relate to the provision of designated health services, and also give the meaning to the statutory exception. We believe that the requirement pertaining to the volume or value of a physician's referrals at § 411.357(g)(1) will ensure that payments to a physician for items or services that are ostensibly not related to patient care services are not in fact disguised payments for the physician's referrals. We seek comments on our proposals, as well as other possible ways for distinguishing between remuneration that is related to the provision of designated health services and remuneration that is unrelated to the provision of designated health services. Specifically, we seek comment as to whether we should limit what we consider to be ''remuneration related to the provision of designated health services'' to remuneration paid explicitly for a physician's provision of designated health services to a hospital's patients.

9. Exception for Payments by a Physician (§ 411.357(i))

Section 1877(e)(8) of the Act excepts payments made by a physician to a laboratory in exchange for the provision of clinical laboratory services, or to an entity as compensation for other items or services if the items or services are furnished at a price that is consistent with fair market value. The 1995 final rule (60 FR 41929) incorporated the provisions of section 1877(e)(8) of the Act into our regulations at § 411.357(i). In the 1998 proposed rule, we proposed to interpret ''other items and services'' to mean any kind of item or service that a physician might purchase (that is, not limited to ''services'' for purposes of the Medicare program in § 400.202 of this Chapter), but not including clinical laboratory services or those items or services that are specifically excepted by another provision in §§ 411.355 through 411.357 (63 FR 1703). We stated that we did not believe that the Congress meant the exception for payments by a physician to protect financial relationships that were covered by more specific exceptions with specific requirements, such as the exceptions for rental arrangements at section 1877(e)(1) of the Act.

In Phase II, we responded to commenters who disagreed with our position that the exception for payments by a physician is not available for arrangements involving any items or services excepted by another exception (69 FR 16099). We reiterated the statutory interpretation from the 1998 proposed rule, explaining that the determination that items and services addressed by another exception should not be covered in this exception is consistent with the overall statutory scheme and purpose and is necessary to prevent the exception for payments by a physician from negating the statute (69 FR 16099; *see also* 72 FR 51057). As a result, we made no changes to the regulation at § 411.357(i) in Phase II. Thus, as finalized in Phase II, the exception for payments by a physician at § 411.357(i) stated that the exception could not be used for items or services that are specifically *excepted* by another exception in §§ 411.355 through 411.357, with a parenthetical clarifying that this included the exception for fair market value compensation at § 411.357(l). However, at that time, the exception for fair market value compensation applied only to the provision of items or services *by* physicians *to* entities; the exception did not apply to items or services provided by entities to physicians.

Following the publication of Phase II, commenters complained that neither § 411.357(i) nor § 411.357(l) were available to protect many legitimate arrangements wherein physicians purchased items and services from entities, because: (1) The exception for payments by a physician was limited to the purchase of items and services not

specifically excepted by another exception in §§ 411.355 through 411.357 (including § 411.357(l)); and (2) the exception for fair market value compensation did not apply to items or services provided by an entity to a physician (72 FR 51057). In response to the commenters, we expanded § 411.357(l) in Phase III to include both items and services furnished by physicians to entities *and* items and services furnished by entities to physicians (72 FR 51094 through 51095). However, Phase III did not modify the exception for payments by a physician,[6] including the parenthetical indicating that § 411.357(i) could not be used for items or services specifically excepted under § 411.357(l). We acknowledged that the expansion of the exception for fair market value compensation to items or services furnished by entities to physicians would require parties in some instances to rely on § 411.357(l) instead of § 411.357(i). We concluded, however, that upon further consideration, we believe that the required application of the fair market value compensation exception, which contains conditions not found in the less transparent exception for payments by a physician to a hospital, further reduces the risk of program abuse (72 FR 51057). We also emphasized in Phase III that the exception for payments by a physician could not be used to protect office space leases (72 FR 51044 through 51045). We explained that we did not believe that the lease of office space is an ''item or service'' and that parties seeking to protect arrangements for the rental of office space must rely on § 411.357(a) (72 FR 51059). In 2015, when we finalized the exception at § 411.357(y) for timeshare arrangements, we reaffirmed our position that the exception for payments by a physician is not available for arrangements involving the rental of office space (80 FR 71325 through 71327).

Commenters on the CMS RFI stated that our interpretation of the exception for payments by a physician, especially our determination that the exception is not available if any other exception would apply to an arrangement, unreasonably narrowed the scope of the statutory exception. Commenters also noted that compliance with other exceptions is generally more burdensome than compliance with the statutory exception for payments by a physician, and urged us to conform the language of the exception at § 411.357(i) to the statutory language at section 1877(e)(8) of the Act. We find the CMS RFI comments regarding the narrowing of the statutory exception persuasive and, as a result, have reconsidered our position regarding the availability of the exception for payments by a physician for certain compensation arrangements.

To explain the policies we set forth in this proposed rule regarding the availability of the exception at § 411.357(i), it is important to distinguish between the statutory exceptions found at section 1877(e) of the Act (codified at § 411.357(a) through § 411.357(i) of our regulations) and the regulatory exceptions (codified at § 411.357(j) *et seq.*) issued using the Secretary's authority under section 1877(b)(4) of the Act.[7] We continue to believe that the exception for payments by a physician at section 1877(e)(8) of the Act was not meant to apply to compensation arrangements that are specifically excepted by other *statutory* exceptions in section 1877 of the Act. Given the placement of the exception for payments by a physician as the final statutory exception at section 1877(e) of the Act, we believe that this exception functions as a catch-all to protect certain legitimate arrangements that are not covered by the exceptions at sections 1877(e)(1) through (7) of the Act. As a matter of statutory construction, the catch-all exception at section 1877(e)(8) of the Act does not supersede the previous exceptions. With respect to arrangements for the rental of office space or the rental of equipment, in particular, we note that the statutory exceptions for such arrangements at section 1877(e)(1) of the Act include requirements that are specific to rental arrangements, as well as general requirements that the arrangements are commercially reasonable, that rental charges are fair market value, and that compensation is not determined in a manner that takes into account the volume or value of referrals or other business generated between the parties. We do not believe that the Congress would have imposed these particularized requirements at section 1877(e)(1) of the Act, but also allowed parties to sidestep them by relying on the exception for payments by a physician to protect rental arrangements.

Although we maintain our policy with respect to the statutory exceptions, we no longer believe that the regulatory exceptions should limit the scope of the exception for payments by a physician. Thus, we are proposing to remove from § 411.357(i)(2) the reference to the regulatory exceptions, including the parenthetical referencing the exception for fair market value compensation. We are also proposing that the exception at § 411.357(i) would not be available to protect compensation arrangements specifically addressed by one of the statutory exceptions, codified in our regulations at § 411.357(a) through (h). Under the proposal, parties would generally be able to rely on the exception at § 411.357(i) to protect fair market value payments by a physician to an entity for items or services furnished by the entity, even if a regulatory exception at § 411.357(j) *et seq.* may be applicable. However, for the reasons noted previously, § 411.357(i) would not be applicable to arrangements for the rental of office space or equipment.[8] That is, we believe that, as a matter of statutory construction, the exception for payments by a physician is not available to protect any type of arrangement that is specifically addressed by another statutory exception at section 1877(e) of the Act, including arrangements for the rental of office space or the rental of equipment.

We are retracting our prior statements that office space is neither an ''item'' nor a ''service.'' We made these statements, in significant part, to emphasize that we do not believe that the exception for payments by a physician should be available to protect the type of arrangement for which the Congress established a specific exception in statute. In this proposed rule, we have more clearly explained this position and no longer believe it is

[6] In the September 5, 2007 **Federal Register**, the regulation text of the exception for payments by a physician was modified in error. Phase II stated that § 411.357(i) is limited to payments for items or services that are ''not specifically *excepted* by another provision in §§ 411.355 through 411.357'' (69 FR 16140). The September 5, 2007 **Federal Register** replaced ''excepted'' with ''addressed'' (72 FR 51094). The original language of the exception was restored in a correction notice to Phase III and published in the December 4, 2007 **Federal Register** (72 FR 68076).

[7] Section 1877(b)(5) of the Act directs the Secretary to establish a regulatory exception for electronic prescribing, but does not provide any statutory text or specific requirements for the exception. Pursuant to this authority, we established an exception for electronic prescribing items and services at § 411.357(v). Although § 411.357(v), unlike all the other exceptions at § 411.357(j) *et seq.,* was not issued using the Secretary's authority under section 1877(b)(4) of the Act, for purposes of our interpretation of the exception for payments by a physician, we treat § 411.357(v) as a regulatory exception. In particular, we interpret section 1877(b)(5) of the Act as a grant of authority for the Secretary to issue a regulatory exception; it is not itself a statutory exception, just as section 1877(b)(4) of the Act grants the Secretary authority to create exceptions, but is not an exception in its own right.

[8] Elsewhere in this proposed rule, we are proposing to extend § 411.357(l) to arrangements for the rental of office space, including rentals of less than 1 year, provided all the requirements of the proposed exception are satisfied.

necessary to preclude office space from the categories of ''items'' and ''services.'' (We note that we have not made prior similar statements regarding equipment.) As such, and because the exception at § 411.357(i) is unavailable to protect an arrangement for the rental of office space or equipment, parties seeking to protect an arrangement for the rental of office space or equipment must structure the arrangement to satisfy the requirements of § 411.357(a), § 411.357(b), § 411.357(l) (for direct compensation arrangements), or § 411.357(p) (for indirect compensation arrangements). We note that, under our proposal, § 411.357(i) may be available to protect payments by a physician for the lease or use of space that is *not* office space, such as storage space or residential real estate.

We are also proposing to remove from § 411.357(i)(2) the reference to exceptions in §§ 411.355 and 411.356. As noted previously, we believe that the exception at section 1877(e)(8) of the Act for payments by a physician functions in the statutory scheme as a catch-all, to apply to compensation arrangements for the furnishing of other items or services by entities that are not specifically addressed at sections 1877(e)(1) through (7) of the Act. Therefore, we no longer believe that the exception should be limited by the exceptions at sections 1877(b) and (c) of the Act or the regulatory exceptions codified in §§ 411.355 and 411.356.

Lastly, we would like to stress that the ''items or services'' furnished by the entity under the exception for payments by a physician may not include cash or cash equivalents. That is, the physician may not make in-kind ''payments'' to the entity in exchange for cash from the entity. We believe that cash provided by an entity to a physician poses a risk of program or patient abuse, and that the Congress would have included additional safeguards at section 1877(e)(8) of the Act if the exception were designed to cover such arrangements. At the same time, we note that, if a physician pays an entity $10 in cash for a gift card worth $10, we do not believe that this would constitute a financial relationship for purposes of the physician self-referral law. Likewise, in cases where a physician or an entity acts as a pure pass-through, taking money from one party and passing the *exact* same amount of money to another party, we do not believe that the pass-through arrangement is a financial relationship for purposes of the physician self-referral law.

10. Exception for Fair Market Value Compensation (§ 411.357(l))

In the 1998 proposed rule, we proposed an exception at § 411.357(l) for fair market value compensation (63 FR 1699). We noted that the statutory exceptions at section 1877(e) of the Act apply to specific categories of financial relationships and do not address many common and legitimate compensation arrangements between physicians and the entities to which they refer designated health services. The exception for fair market value compensation was proposed as an open-ended exception to protect certain compensation arrangements that may not be specifically addressed in the statutory exceptions. Among other things, we stated that the exception might be used to protect arrangements for the sublease of office space (63 FR 1714). We suggested that parties could use the exception for fair market value compensation if they had any doubts about whether they met the requirements of another exception in § 411.357.

In Phase I, we finalized § 411.357(l), stating that parties could use the exception, even if another exception potentially applied to an arrangement (66 FR 919). We explained our belief that the safeguards incorporated into the exception for fair market value compensation were sufficient to cover various compensation arrangements, including arrangements covered by other exceptions. In Phase II, we responded to commenters who requested that the exception at § 411.357(l) be made available to protect arrangements for the rental of office space, including arrangements where space is rented *by* entities *to* physicians (69 FR 16111). We declined to extend § 411.357(l) to arrangements for the rental of office space, and emphasized that § 411.357(l) applied only to payments *from* an entity *to* a physician for items and services furnished by the physician. We modified our policy in Phase III and extended the application of the exception at § 411.357(l) to payments *from* a physician *to* an entity for items or services provided by the entity, but continued to decline to make § 411.357(l) applicable to an arrangement for the rental of office space (72 FR 51059 through 51060). As noted previously, we explained that the rental of office space is not an ''item or service.'' We added that, because arrangements for the rental of office space had been subject to abuse, we believed that it could pose a risk of program or patient abuse to permit parties to protect such arrangements relying on § 411.357(l). In the CY 2016 PFS final rule, we reaffirmed our position that the exception for fair market value compensation does not apply to arrangements for the rental of office space (80 FR 71327).

We have reconsidered our policy regarding the application of § 411.357(l). Through our administration of the SRDP, we have seen legitimate, nonabusive arrangements for the rental of office space that could not satisfy the requirements of § 411.357(a) because the term of the arrangement was less than 1 year, and could not satisfy the requirements of § 411.357(y) because the arrangement conveyed a possessory leasehold interest in the office space. To provide flexibility to stakeholders to protect such nonabusive arrangements, we are proposing to make § 411.357(l) available to protect arrangements for the rental or lease of office space.

As discussed in many of our previous rulemakings and most recently in the CY 2017 PFS proposed rule (81 FR 46448 through 46453) and final rule (81 FR 80524 through 80534), we are concerned about potential abuse that may arise when rental charges for the lease of office space or equipment are determined using a formula based on: (1) A percentage of the revenue raised, earned, billed, collected, or otherwise attributable to the services performed or business generated in the office space (a ''percentage-based compensation formula''); or (2) per-unit of service rental charges, to the extent that such charges reflect services provided to patients referred by the lessor to the lessee (a ''per-click compensation formula''). We stated that arrangements based on percentage compensation or per-unit of service compensation formulas present a risk of program or patient abuse because they may incentivize overutilization and patient steering. To address this risk, in the FY 2009 IPPS final rule, we included in the exceptions for the rental of office space, the rental of equipment, fair market value compensation, and indirect compensation arrangements restrictions on percentage-based compensation and per-click compensation formulas when determining the rental charges for the lease of equipment. Because the exception at § 411.357(l), to date, has not been applicable to arrangements for the rental of office space, it does not include a prohibition on percentage-based compensation and per-click compensation formulas when determining the rental charges for the lease of office space. (The exceptions for the rental of office space and indirect compensation arrangements currently include the prohibitions as they relate to

the determination of rental charges for the lease of office space.) We remain concerned about the potential abuse related to percentage-based compensation and per-click compensation formulas for determining the rental charges of both office space and equipment. Therefore, we are proposing to incorporate into the exception at § 411.357(l) prohibitions on percentage-based compensation and per-unit of service compensation formulas with respect to the determination of rental charges for the lease of office space, similar to the restrictions found in § 411.357(a)(5)(ii) and § 411.357(p)(1)(ii).

Unlike the exception for the rental of office space at § 411.357(a), the exception for fair market value compensation does not require a 1-year term. Therefore, short-term arrangements for the rental of office space of less than 1 year would be permissible under the proposed exception. However, as with other compensation arrangements permitted under § 411.357(l), the parties would be permitted to enter into only one arrangement for the rental of the same office space during the course of a year. The parties would be able to renew the arrangement on the same terms and conditions any number of times, provided that the terms of the arrangement and the compensation for the same office space do not change. Although we believe that, in most cases, parties seeking to lease office space prefer leases with longer terms—for instance, to justify expenses spent on property improvements—as described by commenters, some parties, especially parties in rural areas, would prefer or find necessary the flexibility of a short-term rental of office space. Given the requirements of the exception for fair market value compensation, including the requirement that parties enter into only one arrangement for the leased office space over the course of a year, we do not believe that short-term arrangements for the rental of office space that satisfy all the requirements of § 411.357(l) pose a risk of program or patient abuse. We remind readers that, as explained in section II.D.9 of this proposed rule, the exception for payments by a physician at § 411.357(i) is not available to protect any leases of office space, including short-term leases.

Lastly, § 411.357(l)(6) requires that any services to be performed under the arrangement do not involve the counseling or promotion of a business arrangement or other activity that violates a Federal or State law. As explained in section II.D.1. of this rule, we are proposing to remove from our exceptions the requirements pertaining to the anti-kickback statute and Federal or State billing and claims submission rules. Although similar, at this time, we are not proposing to remove § 411.357(l)(6). However, we are soliciting comments on whether this requirement is necessary to protect against program or patient abuse or should be removed from the exception, and whether substitute safeguards such as those included in many of the statutory or regulatory exceptions to the physician self-referral law would be appropriate.

11. Electronic Health Records Items and Services (§ 411.357(w))

Relying on our authority at section 1877(b)(4) of the Act, on August 8, 2006, we published a final rule (the 2006 EHR final rule) that, among other things, finalized an exception at § 411.357(w) for certain arrangements involving the donation of interoperable EHR software or information technology and training services (the EHR exception) (71 FR 45140). The EHR exception was initially scheduled to expire on December 31, 2013. On December 27, 2013, we published a final rule (the 2013 EHR final rule) modifying the EHR exception by, among other things, extending the expiration date of the exception to December 31, 2021, excluding laboratory companies from the types of entities that may donate EHR items and services under the exception, and updating the provision under which EHR software is deemed interoperable (78 FR 78751).

Although we did not specifically request comments on the EHR exception in the CMS RFI, we received several comments on the exception. In addition, in its request for information, OIG requested comments on the anti-kickback statute EHR safe harbor at 42 CFR 1001.952(y), which is substantively similar to the EHR exception at § 411.357(w). After reviewing comments submitted on the EHR exception and safe harbor, as well as recent statutory and regulatory developments arising from the 21st Century Cures Act (Pub. L. 114–255 (December 13, 2016)) (Cures Act), we are proposing to update provisions in the EHR exception pertaining to interoperability (§ 411.357(w)(2)) and data lock-in (§ 411.357(w)(3)), clarify that donations of certain cybersecurity software and services are permitted under the EHR exception, remove the sunset provision, and modify the definitions of ''electronic health record'' and ''interoperable'' to ensure consistency with the Cures Act. We are also proposing to modify the 15 percent physician contribution requirement and to permit certain donations of replacement technology.

This proposed rule sets forth certain proposed changes to the EHR exception. The OIG is considering changes to the EHR safe harbor elsewhere in this issue of the **Federal Register**. We seek comment on our proposals and, as noted above, given the close nexus between our proposals and OIG's proposals, we encourage stakeholders to review and submit comments on both proposed rules. Despite the differences in the respective underlying statutes, we attempted to ensure as much consistency as possible between our proposed changes to the EHR exception and the policies that OIG is considering with respect to its safe harbor. Because of the close nexus between this proposed rule and OIG's proposed rule, we may consider comments submitted in response to OIG's proposed rule, even if we do not receive such comments on our proposals, and take additional actions when crafting our final rule.

a. Interoperability

The requirements at § 411.357(w)(2) and (3) require donated items and services to be interoperable and prohibit the donor (or someone on the donor's behalf) from taking action to limit the interoperability of the donated item or service. We are proposing changes that impact § 411.357(w)(2) and (3) based on the Cures Act and the Office of the National Coordinator for Health Information Technology (ONC), HHS Notice of Proposed Rulemaking, ''21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program'' (ONC NPRM), which proposes to implement key provisions in Title IV of the Cures Act.[9] Among other things, the ONC NPRM proposes conditions and maintenance of certification requirements for health IT developers under the ONC Health IT Certification Program (certification program) and reasonable and necessary activities that do not constitute information blocking for purposes of section 3022(a)(1) of the Public Health Service Act (PHSA). These proposed changes, if finalized, would affect the deeming provision pertaining to interoperability at § 411.357(w)(2) and provisions related to interoperability and data lock-in at § 411.357(w)(3).

[9] 84 FR 7424 (March 4, 2019).

(1) The ''Deeming Provision'' (§ 411.357(w)(2))

Section 411.357(w)(2) requires software donated under the EHR exception to be interoperable. The deeming provision at § 411.357(w)(2) provides certainty to parties seeking protection of the EHR exception by providing an optional method of ensuring that donated items or services meet the interoperability requirement at § 411.357(w)(2). Specifically, § 411.357(w)(2) provides that software is deemed to be interoperable if it is certified under ONC's certification program. In the 2013 EHR final rule, we modified the deeming provision to reflect developments in the ONC certification program and to track ONC's anticipated regulatory cycle. By relying on ONC's certification program and related updates of criteria and standards, we stated that the deeming provision would meet our objective of ensuring that software is certified to the current required standard of interoperability when it is donated (78 FR 78753). We are proposing to retain this general construct for the proposed updated EHR exception. However, we are proposing two textual clarifications to this provision. Our current regulation text specifies that the software is deemed to be interoperable if, on the date it is provided to the physician, it has been certified by a certifying body to an edition of the electronic health record certification criteria identified in the then-applicable version of 45 CFR part 170. We are proposing to modify this language to clarify that, on the date the software is provided, it ''is'' certified. In other words, the certification must be current as of the date of the donation, as opposed to the software having been certified at some point in the past but no longer maintaining certification on the date of the donation. We also propose to remove the reference to ''an edition'' of certification criteria to align with proposed changes to ONC's certification program. We solicit comments on these clarifications. As we describe in more detail below, however, we are proposing to update the definition of ''interoperable.'' Although the revised definition would not require a change to the text of paragraph (w)(2), the revision would impact the deeming provision, and we solicit comments regarding this update. We emphasize that any final revisions to the deeming provisions or the definition of ''interoperable'' would be prospective only. That is, donated software that met the definition of interoperable and satisfied the requirements of § 411.357(w) at the time the donation was made would not cease to be protected by the exception if these proposed changes are finalized.

(2) Information Blocking and Data Lock-in (§ 411.357(w)(3))

The current requirement at § 411.357(w)(3) prohibits the donor (or any person on the donor's behalf) from taking any action to limit or restrict the use, compatibility, or interoperability of the items or services with other electronic prescribing or EHR systems (including, but not limited to, health IT applications, products, or services). Beginning with the 2006 EHR final rule and reaffirmed in the 2013 EHR final rule, § 411.357(w)(3) has been designed to: (1) Prevent the misuse of the exception that results in data and referral lock-in; and (2) encourage the free exchange of data (in accordance with protections for privacy) (78 FR 78762). Since the publication of the final rules, significant legislative, regulatory, policy, and other Federal government action defined this problem further (now commonly referred to as ''information blocking'') and established penalties for certain types of individuals and entities that engage in information blocking. Most notably, the Cures Act added section 3022 of the PHSA, known as ''the information blocking provision,'' which defines conduct by health care providers, health IT developers of certified health IT, exchanges, and networks that constitutes information blocking. Section 3022(a)(1) of the PHSA defines ''information blocking'' in broad terms, while section 3022(a)(3) of the PHSA authorizes and charges the Secretary to identify reasonable and necessary activities that do not constitute information blocking. The ONC NPRM, which includes proposals to implement the statutory definition of information blocking at 45 CFR part 171, proposes to define certain terms related to the statutory definition of information blocking, and proposes seven exceptions to the information blocking definition.[10]

In this proposed rule, we are proposing modifications to § 411.357(w)(3) to recognize these significant updates since the 2013 EHR final rule. Specifically, we are proposing at § 411.357(w)(3) to prohibit the donor (or any person on the donor's behalf) from engaging in a practice constituting information blocking, as defined in section 3022 of the PHSA, in connection with the donated items or services. Should ONC finalize its proposals to implement section 3022 of the PHSA at 45 CFR part 171, we would incorporate such regulations into the requirement at § 411.357(w)(3) for purposes of the physician self-referral law if we finalize the proposals described in this proposed rule. In addition, proposed § 411.357(w)(3) provides that the donor (or any person on the donor's behalf) cannot engage in information blocking ''in connection with the donated items or services,'' in order to clarify that § 411.357(w)(3) prohibits *both* engaging in conduct constituting information blocking that affects the functions of the donated items or services *and* using the donated items or services as an instrument of information blocking.

We note that the current EHR exception requirements, while not using the term ''information blocking,'' already include concepts similar to those found in the Cures Act's prohibition on information blocking. For example, in our prior rulemaking, we were concerned about donors (or those on the donor's behalf) taking steps to limit the interoperability of donated software to lock in or steer referrals.[11] The modifications proposed here are not intended to change the underlying purpose of this requirement, but instead further our longstanding goal of preventing abusive arrangements that lead to information blocking and referral lock-in through modern understandings of those concepts established in the Cures Act.[12] We solicit comments on aligning the condition at § 411.357(w)(3) with the PHSA and the information blocking definition in proposed 45 CFR part 171, if finalized.

b. Cybersecurity

We are proposing to amend the EHR exception to clarify that the exception is available (and always has been available) to protect certain cybersecurity software and services,[13] and to more broadly protect the donation of software and services related to cybersecurity. Currently, the exception protects EHR software or information technology and training services necessary and used predominantly to create, maintain,

[10] 84 FR at 7602 through 7605.

[11] *See,* for example, *Implementation of the 21st Century Cures Act: Achieving the Promise of Health Information Technology Before the S. Comm. On Health, Education, Labor, & Pensions,* 115th Cong. 1 (2017) (statement of James Cannatti, Senior Counselor for Health Information Technology HHS OIG).

[12] We recognize that the ONC NPRM is not a final rule and is subject to change. However, we base our proposals on both the statutory language and the language in ONC's NPRM for purposes of soliciting public input on our proposals.

[13] For instance, a secure log-in or encrypted access mechanism included with an EHR system or EHR software suite would be cybersecurity features of the EHR that may be protected under the existing EHR exception.

transmit, or receive electronic health records. We are proposing to modify this language to include software that ''protects'' electronic health records, and to expressly include services related to cybersecurity.

In the 2006 EHR final rule, we emphasized the requirement that software, information technology and training services donated must be closely related to EHR and that the EHR functions must predominate (71 FR 54151). We stated that the core functionality of the technology must be the creation, maintenance, transmission, or receipt of individual patients' EHR, but, recognizing that EHR software is commonly integrated with other features, we also stated that arrangements in which the software package included other functionality related to the care and treatment of individual patients would be protected. Under our proposal, the same criteria would apply to cybersecurity software and services: The predominant purpose of the software or services must be cybersecurity associated with the EHR.

In section II.E.2. of this proposed rule, we also are proposing a new exception at proposed § 411.357(bb) specifically to protect arrangements involving the donation of cybersecurity technology and related services (the cybersecurity exception). As proposed, the cybersecurity exception is broader and includes fewer requirements than the EHR exception. Nonetheless, we are proposing to expand the EHR exception to expressly include certain cybersecurity software and services so that it is clear that an entity donating EHR software, and providing training and other related services, may also donate related cybersecurity software and services to protect the EHR. As detailed in section II.E.2.a. of this proposed rule, we are proposing a definition of ''cybersecurity'' at § 411.351 that would apply to both the EHR exception and the proposed cybersecurity exception at § 411.357(bb). A party seeking to protect an arrangement involving the donation of cybersecurity software and services only needs to comply with the requirements of one applicable exception. We solicit comments on this approach. In particular, with the addition of a stand-alone cybersecurity exception, we solicit comments on whether it is necessary to modify the EHR exception to expressly include cybersecurity.

c. The Sunset Provision

The EHR exception originally was scheduled to expire on December 31, 2013. In adopting this sunset provision, we acknowledged in the 2006 EHR final rule that the need for an exception for donations of EHR technology should diminish substantially over time as the use of such technology becomes a standard and expected part of medical practice. In the 2013 notice of proposed rulemaking for an amendment to the EHR exception, we acknowledged that, although EHR technology adoption had risen dramatically, use of such technology had not yet been universally adopted nationwide. Because continued EHR technology adoption remained an important goal of the Department, we solicited comments regarding an extension of the EHR exception. In response to those comments, in the 2013 EHR final rule, we extended the sunset date of the exception to December 31, 2021, a date that corresponds to the end of the EHR Medicaid incentives. We stated our continued belief that, as progress on this goal is achieved, the need for an exception for donations should continue to diminish over time. However, commenters on the CMS RFI and on OIG's request for information requested that we make the EHR exception and safe harbor permanent.

Although we acknowledge that widespread adoption of EHR technology, though not universal, largely has been achieved, we no longer believe that once this goal is achieved the need for an exception for arrangements involving the donation of such technology will diminish over time or completely disappear. Rather, our experience indicates that the continued availability of the EHR exception plays a part in achieving the Department's goal of promoting EHR technology adoption by providing certainty with respect to the cost of EHR items and services for recipients, by encouraging adoption by physicians who are new entrants into medical practice or have postponed adoption based on financial concerns regarding the ongoing costs of maintaining and supporting an EHR system, and by preserving the gains already made in the adoption of interoperable EHR technology. Therefore, we are proposing to eliminate the sunset provision at § 411.357(w)(13). In the alternative, we are considering an extension of the sunset date. We seek comment on whether we should select a later sunset date instead of making the exception permanent, and if so, what that date should be.

d. Definitions

We are proposing to modify the definitions of ''interoperable'' and ''electronic health record.'' In the 2006 EHR final rule, we finalized these definitions based on contemporaneous terminology, the emerging standards for EHR, and other resources cited by commenters at that time. The following proposed modifications to these definitions are largely based on terms and provisions in the Cures Act that update or supersede terminology we used in the 2006 EHR final rule.

The term ''electronic health record'' is currently defined at § 411.351 as a repository of consumer health status information in computer processable form used for clinical diagnosis and treatment for a broad array of clinical conditions. We are proposing the following modifications: Replace the term ''consumer health status information'' with ''electronic health information;'' replace the term ''computer processable form'' with ''is transmitted by or maintained in electronic media;'' and replace the phrase ''used for clinical diagnosis and treatment for a broad array of clinical conditions'' with ''relates to the past, present, or future health or condition of an individual or the provision of health care to an individual.'' We are proposing these modifications to this definition to reflect the term ''electronic health information'' that is used throughout the Cures Act and that is central to the definition of interoperability at section 3000(9) of the PHSA and the information blocking provisions at section 3022 of the PHSA. Additionally, the ONC NPRM proposes a definition of ''electronic health information.'' [14] We have based our proposed modifications, in part, on ONC's proposed definition of ''electronic health information'' to reflect more modern terminology used to describe the type of information that is part of an electronic health record. We solicit comments on this updated definition.

The term ''interoperable'' is defined at existing § 411.351 and means able to communicate and exchange data accurately, effectively, securely, and consistently with different information technology systems, software applications, and networks, in various settings; and exchange data such that the clinical or operational purposes and meaning of the data are preserved and unaltered. This definition of ''interoperable'' was based on 44 U.S.C. 3601(6) (pertaining to the management and promotion of electronic Government services) and several comments we received in response to the proposed rule that referenced

[14] 84 FR 7424, 7513 (Mar. 4, 2019).

emerging industry definitions and standards related to interoperability.[15]

We are proposing to update the definition of ''interoperable'' to align with the statutory definition of ''interoperability'' added by the Cures Act to section 3000(9) of the PHSA. Consistent with section 3000(9) of the PHSA, we are proposing to define ''interoperable'' to mean: (i) Able to securely exchange data with and use data from other health information technology without special effort on the part of the user; (ii) allows for complete access, exchange, and use of all electronically accessible health information for authorized use under applicable State or Federal law; and (iii) does not constitute information blocking as defined in section 3022 of the PHSA. Should ONC finalize its proposals to implement section 3022 of the PHSA at 45 CFR part 171, and if we finalize our proposed definition of ''interoperable,'' we would incorporate the final ONC regulations into the definition of ''interoperable'' at § 411.351 by referencing 45 CFR part 171 instead of section 3022 of the PHSA.

We believe the statutory definition of ''interoperability'' includes concepts similar to the existing definition of ''interoperable'' at § 411.351 (for example, the ability to securely exchange data across different systems or technology). Two new concepts in the statutory definition are included in the proposed modification: (1) Interoperable means the ability to exchange electronic health information without special effort on the part of the user and (2) interoperable expressly does not mean information blocking.[16] As a practical matter, we believe these two concepts are not substantively different from the existing definition and only reflect an updated understanding of interoperability and related terminology. We solicit comments on the proposed definition that would align the definition of ''interoperable'' with the statutory definition of ''interoperability.''

In the alternative, we are considering revising our regulations to eliminate the term ''interoperable'' and instead incorporate the term ''interoperability'' and define this term by reference to section 3000(9) of the PHSA and 45 CFR part 170 (if finalized). Under this alternative proposal, we would revise § 411.357(w)(2) to require that the software meets interoperability standards established under Title XXX of the PHSA and its implementing regulations. Software would be deemed to meet interoperability standards if, on the date it is provided to the physician, it is certified by a certifying body authorized by the National Coordinator for Health Information Technology to electronic health record certification criteria identified in the then-applicable version of 45 CFR part 170. We seek comment regarding whether using terminology identical to the PHSA and ONC regulations would facilitate compliance with the requirements of the EHR exception and reduce any regulatory burden resulting from the differences in the agencies' different terminology related to the singular concept of interoperability.

We emphasize that our proposed modifications of the definitions of ''electronic health record'' and ''interoperable'' are prospective only. Donations made prior to the effective date of any finalized revisions to these definitions are governed by the definitions that are in effect when the donations are made. We solicit comments on this proposal.

e. Additional Proposals and Considerations

(1) 15 Percent Recipient Contribution

In the 2006 EHR final rule, we agreed with a number of commenters who suggested that cost sharing is an appropriate method to address some of the fraud and abuse risks inherent in unlimited donations of technology. Accordingly, we incorporated a requirement into § 411.357(w) that the physician pays 15 percent of the donor's cost of the technology. We noted in the 2006 EHR final rule that the 15 percent cost sharing requirement is high enough to encourage prudent and robust EHR arrangements, without imposing a prohibitive financial burden on recipients. Moreover, we stated that this approach requires recipients to contribute toward the benefits they may experience from the adoption of interoperable EHR (for example, a decrease in practice expenses or access to incentive payments related to the adoption of health IT).

We received a number of comments in response to our RFI, and OIG received similar comments in response to its RFI, indicating that the 15 percent contribution has proven burdensome to some recipients and acts as a barrier to adoption of EHR technology. We understand that this burden may be particularly acute for small and rural practices that cannot afford the contribution. Other commenters suggested that applying the 15 percent requirement to upgrades and updates to EHR technology is restrictive and cumbersome and similarly acts as a barrier. We are considering and solicit comments on two alternatives to the existing requirement as outlined below; however, we are not proposing specific regulation text regarding the 15 percent contribution requirement at this time.

First, we are considering eliminating or reducing the percentage contribution required for small or rural physician organizations. In particular, we solicit comments on how we should define ''small or rural physician organization.'' We solicit comments on whether ''rural physician organization'' should be defined as a physician organization located in a rural area, as that term is defined at § 411.351, or defined in line with the definition of a rural provider at § 411.356(c)(1). We also solicit comments on other subsets of potential physician recipients for which the 15 percent contribution is a particular burden.

As an alternative, we are considering reducing or eliminating the 15 percent contribution requirement in the EHR exception for all physician recipients. We solicit comments regarding the impact this might have on the use and adoption of EHR technology, and any attendant risks of fraud and abuse. We are interested in specific examples of any prohibitive costs associated with the 15 percent contribution requirement, both for the initial donation of EHR technology, and subsequent upgrades and updates to the technology.

Regardless of whether we retain the 15 percent contribution requirement or reduce that contribution requirement for some or all physician recipients, we are considering modifying or eliminating the contribution requirement for updates to previously donated EHR software or technology. We solicit comments on this approach as well as what such a modification should entail. For example, we are considering requiring a contribution for the initial investment only, as well as any new modules, but not requiring a contribution for any update of the software already purchased. We solicit comments on these alternatives, or another similar alternative that would still involve some contribution but could reduce the uncertainty and administrative burden associated with assessing a contribution for each update.

(2) Replacement Technology

In the 2013 EHR final rule, we highlighted a commenter's assertion that the prohibition on donating equivalent technology currently included in the

[15] See 70 FR 59186 and 71 FR 45155 through 45156.

[16] Section 3000(9) of the PHSA; (42 U.S.C. 300jj(9)).

exception locks physician practices into a vendor, even if they are dissatisfied with the technology, because the recipient must choose between paying the full amount for a new system and continuing to pay 15 percent of the cost of the substandard system (78 FR 78766). The same commenter asserted that the cost differential between these two options is too high and effectively locks physician practices into EHR technology vendors. In the 2013 EHR final rule, we responded that we continue to believe that items and services are not necessary if the recipient already possesses the equivalent items or services. We noted that providing equivalent items and services confers independent value on the physician recipient and noted our expectation that physicians would not select or continue to use a substandard system if it posed a threat to patient safety.

We appreciate that advancements in EHR technology are continuous and rapid. According to commenters, in some situations replacement technology is appropriate but prohibitively expensive. We are proposing to allow donations of replacement EHR technology. We specifically seek comment as to the types of situations in which the donation of replacement technology would be appropriate. We further solicit comment as to how we might safeguard against situations where donors inappropriately offer, or physician recipients inappropriately solicit, unnecessary technology instead of upgrading their existing technology for appropriate reasons.

12. Exception for Assistance To Compensate a Nonphysician Practitioner (§ 411.357(x))

Section 1877(e)(5) of the Act sets forth an exception for remuneration provided by a hospital to a physician to induce the physician to relocate to the geographic area served by the hospital to be a member of the hospital's medical staff, subject to certain requirements. This exception is codified in our regulations at § 411.357(e). In Phase III, we declined a commenter's request to expand § 411.357(e) to cover the recruitment of nonphysician practitioners (NPPs) into a hospital's service area, including into an existing physician practice, stating that the exception for physician recruitment at § 411.357(e) applies only to payments made directly (or, in some circumstances, passed through) to a recruited physician (72 FR 51049). Recruitment payments made by a hospital directly to an NPP would not implicate the physician self-referral law, unless the NPP serves as a conduit for physician referrals or is an immediate family member of a referring physician. We further stated that payments made by a hospital to subsidize a physician practice's costs of recruiting and employing NPPs would create a compensation arrangement between the hospital and the physician practice for which no exception would apply, and that these kinds of subsidy arrangements pose a substantial risk of fraud and abuse. Following the publication of Phase III, we reconsidered our position. There have been significant changes in our health care delivery and payment systems, as well as projected shortages in the primary care workforce. To address this changed landscape, in the CY 2016 PFS final rule, we finalized a limited exception at § 411.357(x) for hospitals, FQHCs, and rural health clinics (RHCs) to provide remuneration to a physician to assist with the employment of an NPP (80 FR 71301 through 71311).

The exception at § 411.357(x) applies to remuneration provided by a hospital to a physician to compensate an NPP to provide patient care services. We have received several inquiries regarding the meaning of the term ''patient care services'' as it relates to an NPP. The inquiries generally concentrate on the requirement at § 411.357(x)(1)(v)(B) that the NPP has not, within 1 year of the commencement of his or her compensation arrangement with the physician, been employed or otherwise engaged to provide patient care services by a physician or a physician organization that has a medical practice site located in the geographic area served by the hospital. Often, prior to becoming an NPP, an individual may have been a registered nurse (or some other health care professional) and may have provided services to patients that are similar to the services provided by an NPP. For purposes of the exception at § 411.357(x), the question presented by stakeholders is whether the services provided by the individual before the individual became an NPP constitute ''patient care services.''

We realize that the definition of ''patient care services'' found at § 411.351 relates to tasks performed by a physician only. To clarify the meaning of ''patient care services'' for purposes of the exception for assistance to compensate an NPP, we are proposing to revise § 411.357(x) to change the references to ''patient care services'' to ''NPP patient care services'' and include a definition of the term ''NPP patient care services'' in the exception at § 411.357(x)(4)(i). We are proposing to define ''NPP patient care services'' to mean direct patient care services furnished by an NPP that address the medical needs of specific patients or any task performed by an NPP that promotes the care of patients of the physician or physician organization with which the NPP has a compensation arrangement. Under the proposed definition of ''NPP patient care services,'' services provided by an individual who is not an NPP (as the term is defined at § 411.357(x)(3)) at the time the services are provided, are not NPP patient care services for purposes of § 411.357(x). Thus, if an individual worked in the geographic area served by the hospital providing the assistance (for example, as a registered nurse) for some period immediately prior to the commencement of his or her compensation arrangement with the physician or physician organization in whose shoes the physician stands, but had not worked as an NPP in that area during that time period, the exception at § 411.357(x) would be available to protect remuneration from the hospital to the physician to compensate the NPP to provide NPP patient care services, provided that all of the requirements of the exception are satisfied. In this example, the registered nursing services would not be considered NPP patient care services when determining whether the arrangement satisfies the 1-year restriction at § 411.357(x)(1)(v).

In addition, we are proposing conforming changes to the term ''referral'' as defined at § 411.357(x)(4) for purposes of the exception. Specifically, we are proposing to revise § 411.357(x) to change references to ''referral'' when describing the actions of an NPP to ''NPP referral'' and revise § 411.357(x)(4) accordingly. We believe that it is unnecessary to have a general definition of ''referral'' at § 411.351 that is applicable throughout our regulations and a different definition of the same term that applies only for purposes of the exception at § 411.357(x). We are not proposing substantive changes to the definition itself; however, we are proposing to move the definition to § 411.357(x)(4)(ii) in order to accommodate the inclusion of the related definition of ''NPP patient care services'' within section § 411.357(x)(4).

We are also proposing a related change to § 411.357(x)(1)(v)(A). As currently drafted, § 411.357(x)(1)(v)(A) requires the NPP to not have practiced in the geographical area served by the hospital within 1 year of the commencement of the compensation arrangement with the physician. According to stakeholders that requested guidance on the scope of the exception, the word ''practiced'' may be

interpreted to include the provision of NPP patient care services (as we are proposing to define the term here) and other services, for example, services provided by a health care professional who is not an NPP at the time the services are furnished. To resolve any potential stakeholder confusion, we are proposing to replace the term ''practiced'' with ''furnished NPP patient care services.'' Under the proposal, a hospital would not run afoul of § 411.357(x)(1)(v)(A) if the hospital provided remuneration to a physician to compensate an NPP, and the individual receiving compensation from the physician furnished services in the hospital's geographic service area within 1 year of the commencement of his or her compensation arrangement with the physician, provided that the services furnished by the individual during the 1-year period were not NPP patient care services, as we are proposing to define the term at § 411.357(x)(4)(i).

In addition to the inquiries related to the meaning of the terms ''patient care services'' and ''practice,'' we are aware of stakeholder uncertainty regarding the timing of arrangements that may be permissible under § 411.357(x). Specifically, stakeholders have inquired whether an NPP must begin his or her compensation arrangement with the physician (or physician organization in whose shoes the physician stands) on or after the commencement of the compensation arrangement between the hospital, FQHC, or RHC and the physician. Stakeholders noted that the exception includes no explicit prohibition on an entity providing assistance to a physician to reimburse the physician for the compensation, signing bonus, or benefits paid to an NPP already employed or contracted by the physician prior to the date of the commencement of the physician's compensation arrangement with the hospital, FQHC, or RHC. As we stated when finalizing the exception at § 411.357(x), our underlying goal is to increase access to needed care (80 FR 71309). Permitting a hospital, FQHC, or RHC to simply reimburse a physician for overhead costs of current employees or contractors already serving patients in the geographic area served by the hospital, FQHC, or RHC does not support this goal. Nonetheless, as stakeholders pointed out, there is no express requirement regarding the timing of the compensation arrangement between the NPP and the physician (or physician organization in whose shoes the physician stands) in § 411.357(x). To ensure that compensation arrangements protected under the exception do not pose a risk of program or patient abuse, we are proposing to amend § 411.357(x)(1)(i) to expressly require that the compensation arrangement between the hospital, FQHC, or RHC and the physician commences before the physician (or the physician organization in whose shoes the physician stands under § 411.354(c)) enters into the compensation with the NPP. Put another way, the compensation arrangement between the NPP and the physician (or physician organization in whose shoes the physician stands) must commence on or after the commencement of the compensation arrangement between the hospital, FQHC, or RHC and the physician.

13. Updating and Eliminating an Out-of-Date References

a. Medicare+Choice (§ 411.355(c)(5))

Section 1877(b)(3) of the Act and § 411.355(c) of the physician self-referral regulations set forth exceptions for designated health services furnished by various organizations to enrollees of certain prepaid health plans. When the Medicare+Choice program was established in the Balanced Budget Act of 1997 (Pub. L. 105–33) (BBA), the Congress failed to update section 1877(b)(3) of the Act to except the designated health services furnished under Medicare+Choice coordinated care plans. Based on our belief that this was an oversight, in the June 26, 1998 interim final rule with comment period (Medicare Program; Establishment of the Medicare+Choice Program (63 FR 34968)), we revised § 411.355(c) to accommodate the creation of the Medicare+Choice program and, relying on the Secretary's authority to create new exceptions under section 1877(b)(4) of the Act, we included Medicare+Choice coordinated care plans in § 411.355(c)(5) of our regulations (63 FR 35033 through 35034). (We declined to include Medicare+Choice medical savings account plans and Medicare+Choice private fee-fee-for service plans due to the risk of patient abuse related to financial liability for premiums and cost sharing, which were not limited by the BBA.) We included Medicare+Choice coordinated care plans at § 411.355(c)(5), in part, to avoid contradiction with the BBA's establishment of provider-sponsored organization (PSO) plans as coordinated care plans. PSOs are defined in the BBA as entities that must be organized and operated by a provider (which may be a physician) or a group of affiliated health care providers (which may include physicians). The BBA requires that the providers have at least a majority financial interest in the entity and share a substantial financial risk for the provision of items and services. If such ownership was not excepted, the physician owners of PSOs would not be permitted to refer enrollees for designated health services furnished by the coordinated care plan (or its contractors and subcontractors). Subsequently, in 1999, the Congress amended section 1877(b)(3) of the Act to create a similar statutory exception for Medicare+Choice at section 1877(b)(3)(E) of the Act (Pub. L. 106–113).

Section 201 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108–173, enacted on December 8, 2003) (MMA) renamed the Medicare+Choice program as the Medicare Advantage program and provided that any statutory reference to ''Medicare+Choice'' was deemed to be a reference to the Medicare Advantage program. In reviewing our regulations for out-of-date references, including references to Medicare+Choice, as part of this proposed rulemaking, it came to our attention that the language of § 411.355(c)(5) may be inconsistent with other program regulations. Current § 411.355(c)(5) excepts designated health services furnished by an organization (or its subcontractors) to enrollees of a coordinated care plan (within the meaning of section 1851(a)(2)(A) of the Act) offered by an organization in accordance with a contract with CMS under section 1857 of the Act and Part 422 of Title 42, Chapter IV of the Code of Federal Regulations. For consistency with the MMA directive and to ensure the accuracy of our regulations, we are proposing to revise § 411.355(c)(5) to more accurately reference Medicare Advantage plans. Under this proposal, § 411.355(c)(5) would reference designated health services furnished by an organization (or its contractors or subcontractors) to enrollees of a coordinated care plan (within the meaning of section 1851(a)(2)(A) of the Act) offered by a Medicare Advantage organization in accordance with a contract with CMS under section 1857 of the Act and part 422 of this chapter. This proposal does not represent a change in our policy.

The Medicare Advantage program varies from the Medicare+Choice program in ways other than its name and has matured in the years since passage of the MMA. More than 20 years have passed since we determined to

protect designated health services furnished to enrollees of coordinated care plans and exclude medical savings account plans and private fee-fee-for service plans from the scope of § 411.355(c)(5). In light of this, we are seeking comments regarding whether § 411.355(c)(5) is broad enough to protect designated health services furnished to enrollees in the full range of Medicare Advantage plans that exist today and that do not pose a risk of program or patient abuse. Specifically, we are interested in commenters' views on which, if any, other Medicare Advantage plans we should include within the scope of § 411.355(c)(5).

b. Website

We are proposing to modernize the regulatory text by changing ''website'' to ''website'' throughout the physician self-referral regulations to conform to the spelling of the term in the Government Publishing Office's Style Manual and other current style guides.

E. Providing Flexibility for Nonabusive Business Practices

1. Limited Remuneration to a Physician (Proposed § 411.357(z))

In the 1998 proposed rule, we proposed an exception for *de minimis* compensation in the form of noncash items or services (63 FR 1699). In Phase I, using the Secretary's authority at section 1877(b)(4) of the Act, we finalized the proposal at § 411.357(k) and changed the name of the exception to nonmonetary compensation, noting that, although free or discounted items and services such as free samples of certain drugs, chemicals from a laboratory, or free coffee mugs or note pads from a hospital fall within the definition of ''compensation arrangement,'' we believe that such compensation is unlikely to cause overutilization, if held within reasonable limits (66 FR 920). The exception for nonmonetary compensation at § 411.357(k) permits an entity to provide compensation to a physician in the form of items or services (other than cash or cash equivalents) up to an aggregate amount of $300 per calendar year, adjusted annually for inflation and currently $416 per calendar year, provided that the compensation is not solicited by the physician and is not determined in any manner that takes into account the volume or value of referrals or other business generated by the referring physician. The exception does not require that the physician provide anything to the entity in return for the nonmonetary compensation, nor does it require that the arrangement be set forth in writing and signed by the parties.

We also recognized in Phase I that many of the incidental benefits that hospitals provide to medical staff members do not qualify for the exception at § 411.357(c) for *bona fide* employment relationships because most members of a hospital's medical staff are not hospital employees, nor would they qualify for the exception at § 411.357(l) for fair market value compensation because, to the extent that the medical staff membership is the only relationship between the hospital and the physician, there is no written arrangement between the parties to which these incidental benefits could be added. We acknowledged that many medical staff incidental benefits are customary industry practices that are intended to benefit the hospital and its patients; for example, free computer and internet access benefits the hospital and its patients by facilitating the maintenance of up-to-date, accurate medical records and the availability of cutting edge medical information (66 FR 921). To address this, using the Secretary's authority under section 1877(b)(4) of the Act, we finalized a second exception for noncash items or services provided to a physician. The exception at § 411.357(m) for medical staff incidental benefits permits a hospital to provide noncash items or services to members of its medical staff when the item or service is used on the hospital's campus and certain conditions are met, including that the compensation is reasonably related to the provision of (or designed to facilitate) the delivery of medical services at the hospital and the item or service is provided only during periods when the physician is making rounds or engaged in other services or activities that benefit the hospital or its patients (66 FR 921). In addition the compensation may not be offered in a manner that takes into account the volume or value of referrals or other business generated between the parties. Under the exception, permissible noncash compensation is limited on a per-instance basis, and the current limit is $35 per instance. Like the exception at § 411.357(k) for nonmonetary compensation, the exception at § 411.357(m) for medical staff incidental benefits does not impose any documentation or signature requirements.

Through our administration of the SRDP, we have been made aware of numerous nonabusive arrangements under which a limited amount of remuneration was paid by an entity to a physician in exchange for the physician's provision of items and services to the entity. In some instances, the arrangements were ongoing service arrangements under which services were furnished sporadically or for a low rate of compensation; in others, services were furnished during a short period of time and the arrangement did not continue past the service period. For example, one submission to the SRDP disclosed an arrangement with a physician for short-term medical director services while the hospital was finalizing the engagement of its new medical director following the unexpected resignation of its previous medical director. Despite the hospital's legitimate need for the services and compensation that was fair market value and not determined in any manner that took into account the volume or value of the referrals or other business generated by the physician, the arrangement could not satisfy all requirements of any applicable exception because the compensation was not set in advance of the provision of the services and was not reduced to writing and signed by the parties. Under arrangements such as this, insofar as the hospital paid the physician in cash, the exception at § 411.357(k) for nonmonetary compensation would not apply to the arrangement. Similarly, the exception at § 411.357(l) for fair market value compensation would not protect the payment if the arrangement was not documented in contemporaneous signed writings and the amount of or formula for calculating the compensation was not set in advance of provision of the items or services, even if the payment did not exceed fair market value for actual items or services provided and was not determined in a manner that takes into account the volume or value of referrals or other business generated by the physician.

After reviewing numerous arrangements in the SRDP, we believe that the provision of limited remuneration to a physician would not pose a risk of program or patient abuse, even in the absence of documentation regarding the arrangement and where the amount of or a formula for calculating the remuneration is not set in advance of the provision of items or services, if: (1) The arrangement is for items or services actually provided by the physician; (2) the amount of the remuneration to the physician is limited; (3) the arrangement furthers a legitimate business purpose of the parties and is on similar terms and conditions as like arrangements, regardless of whether it results in profit for either or both of the parties; (4) the

remuneration is not determined in any manner that takes into account the volume or value of referrals or other business generated by the physician; and (5) the remuneration does not exceed the fair market value for the items or services. Under these circumstances, we believe that, if held within reasonable limits, remuneration is unlikely to cause overutilization or similar harms to the Medicare program. Therefore, using the Secretary's authority under section 1877(b)(4) of the Act, we are proposing an exception for limited remuneration from an entity to a physician for items or services actually provided by the physician. We are proposing that the exception would apply only where the remuneration does not exceed an aggregate of $3,500 per calendar year, which would be adjusted for inflation in the same manner as the annual limit on nonmonetary compensation and the per-instance limit on medical staff incidental benefits; that is, adjusted to the nearest whole dollar by the increase in the Consumer Price Index—Urban All Items for the 12-month period ending the preceding September 30. Under the proposal, the remuneration may not be determined in any manner that takes into account the volume or value of referrals or other business generated by the physician or exceed fair market value for the items or services provided by the physician, and the compensation arrangement must be commercially reasonable. We believe that an annual aggregate limit of $3,500 is sufficient to cover the typical range of commercially reasonable arrangements for the provision of items and services that a physician might provide to an entity on an infrequent or short-term basis. The proposed exception would not be applicable to payments from an entity to a physician's immediate family member or to payments for items or services provided by the physician's immediate family member.

Given the low annual limit of the proposed exception and the other proposed safeguards of the exception, we believe that the exception for limited remuneration to a physician would not pose a risk of program or patient abuse. In contrast, when the remuneration a physician receives from an entity for items or services exceeds the aggregate annual limit of $3,500, as adjusted annually for inflation, we believe that the additional safeguards of other applicable exceptions are necessary to prevent program or patient abuse. For example, for long-term arrangements for items or services provided on a more routine or frequent basis, where the aggregate annual compensation exceeds $3,500, we believe that the requirement that compensation is set in advance before the provision of the items or services is necessary to ensure that various payments made over the term of the arrangement are not determined retrospectively to reward past referrals or encourage increased referrals from the physician. We note that the annual limit of $3,500 for the proposed exception is higher than the annual limit for the exception for nonmonetary compensation at § 411.357(k) because the exception for limited remuneration to a physician would protect a fair market value exchange of remuneration for items or services actually furnished by a physician, while the exception for nonmonetary compensation does not require a physician to provide actual items or services in exchange for the nonmonetary compensation. We seek public comment on whether the $3,500 limit is appropriate, too high, or too low to accommodate nonabusive compensation arrangements for the provision of items or services by a physician. We are also interested in comments regarding whether it is necessary to limit the applicability of the exception to services that are personally performed by the physician and items provided by the physician in order to further safeguard against program or patient abuse.

The proposed exception at § 411.357(z) for limited remuneration to a physician would apply to the furnishing of both items and services by a physician. Previously, we stated that we are retracting prior statements that office space is neither an ''item'' nor a ''service.'' Thus, for the reasons articulated in section II.D.10. of this proposed rule and the CY 2017 PFS proposed rule (81 FR 46448 through 46453) and final rule (81 FR 80524 through 80534), we are proposing to incorporate in proposed § 411.357(z) prohibitions on percentage-based and per-unit of service compensation to the extent the remuneration is for the use or lease of office space or equipment, similar to the provisions at existing § 411.357(p)(1)(ii) for indirect compensation arrangements and § 411.357(y)(6)(ii) for timeshare arrangements. Lastly, in keeping with our policy decision in this rule to decouple exceptions issued under our authority at section 1877(b)(4) of the Act from the anti-kickback statute, the proposed exception for limited remuneration to a physician does not include a requirement that the arrangement must not violate the anti-kickback statute or other Federal or State law or regulation governing billing or claims submission. However, we are soliciting comment regarding whether such a safeguard is necessary here in light of the absence of requirements for set in advance compensation and written documentation of the arrangement. We note that, if we do not finalize our proposal to remove the requirements related to the compliance with the anti-kickback statute and Federal and State laws and regulations governing billing or claims submission, we would include a requirement at proposed § 411.357(z) that the arrangement does not violate the anti-kickback statute or any Federal or State law or regulation governing billing or claims submission. Moreover, to the extent that remuneration implicates the anti-kickback statute, nothing in our proposals would affect the parties' obligation to comply with the anti-kickback statute, and compliance with the exception for limited remuneration to a physician, if finalized, would not consequentially result in compliance with the anti-kickback statute. As we stated in Phase I, section 1877 of the Act is limited in its application and does not address every abuse in the health care industry. The fact that particular referrals and claims are not prohibited by section 1877 of the Act does not mean that the arrangement is not abusive (66 FR 879).

In determining whether payments to a physician under the proposed exception for limited remuneration to a physician exceed the annual limit, we would not count compensation to a physician for items or services provided outside of the arrangement, if the items or services provided are protected under an exception in § 411.355 or the arrangement for the other items or services fully complies with the requirements of another exception in § 411.357. To illustrate, assume an entity has an established call coverage arrangement with a physician that fully satisfies the requirements of § 411.357(d)(1) or § 411.357(l). Assume further that the entity later engages the physician to provide supervision services on a sporadic basis during the same year but failed to document the arrangement in a writing signed by the parties. In determining whether the supervision arrangement satisfies the requirements of the proposed exception for limited remuneration to a physician, we would not count the compensation provided under the call coverage arrangement towards the aggregate $3,500 annual limit. However, if an entity has multiple undocumented, unsigned arrangements under which it provides compensation to a physician

for items or services provided by the physician, we would consider the parties to have a single compensation arrangement for various items and services, and the aggregate of all the compensation provided under the arrangement could not exceed $3,500 during the calendar year in order for the proposed exception to protect the remuneration to the physician. To illustrate, assume the entity in the previous example also engaged the physician to provide occasional EKG interpretations during the course of the year, and that the aggregate annual compensation for the supervision services and the EKG interpretation services *taken together* exceeded $3,500.[17] Assuming neither arrangement satisfied the requirements of any other applicable exception, the exception for limited remuneration to a physician would not protect either arrangement (which, as noted, we would treat as a single arrangement for multiple services) after the $3,500 limit was exceeded during the calendar year.

We note that the proposed exception for limited remuneration to a physician could be used in conjunction with other exceptions to protect an arrangement during the course of a calendar year in certain circumstances. To illustrate, assume that an entity engages a physician to provide call coverage services, and that the arrangement is not documented or the rate of compensation has not been set in advance at the time the services are first provided. Further, assume that, after the services are provided and payment is made, the parties agree to continue the arrangement on a going forward basis and agree to a rate of compensation. Assume also that the parties have no other arrangements between them. Depending on the facts and circumstances, the parties could rely on the proposed exception to protect the first payments up to the $3,500 annual limit, provided that the requirements of the proposed exception are satisfied. For the ongoing compensation arrangement, the parties could rely on another applicable exception, such as § 411.357(d)(1), to protect the arrangement once the compensation is set in advance and the other requirements of the exception are satisfied. (We remind readers that, under proposed § 411.354(e)(3), the parties would have up to 90 consecutive calendar days to document and sign the arrangement.)

We note that § 411.357(d)(1)(ii) requires that the personal service arrangement covers all the services provided by the physician (or an immediate family member of the physician) to the entity (or incorporate other arrangements by reference or cross-reference a master list of contracts) and § 411.357(l)(2) requires that parties enter into only one arrangement for the same services in a year. For purposes of § 411.357(d)(1)(ii), we would not require an arrangement for items or services that satisfies all of the requirements of the proposed exception for limited remuneration to a physician to be covered by a personal service arrangement protected under § 411.357(d) or listed in a master list of contracts. Likewise, with respect to the restriction in the exception for fair market value compensation at § 411.357(l)(2), we would not consider an arrangement for items or services that is protected under the proposed exception at § 411.357(z) to violate the prohibition on entering into an arrangement for the same items and services during a calendar year. We are seeking comments on whether the regulation text at § 411.357(d)(1)(ii) or § 411.357(l)(2) should be modified to explicitly state this policy.

2. Cybersecurity Technology and Related Services (Proposed § 411.357(bb))

Relying on our authority under section 1877(b)(4) of the Act, we are proposing an exception at § 411.357(bb) to protect arrangements involving the donation of certain cybersecurity technology and related services. We believe that the proposed exception will help improve the cybersecurity posture of the health care industry by removing a perceived barrier to donations to address the growing threat of cyberattacks that infiltrate data systems and corrupt or prevent access to health records and other information essential to the delivery of health care. The OIG is considering a similar safe harbor to the anti-kickback statute elsewhere in this issue of the **Federal Register**. Despite the differences in the respective underlying statutes, we attempted to ensure as much consistency as possible between our proposed exception and OIG's proposed safe harbor. Because of the close nexus between our proposed exception and the policies under consideration by OIG, we may consider comments submitted in response to OIG's proposals, even if we do not receive such comments on our proposals, and take additional actions when crafting our final rule.

In recent years, both CMS and OIG have received numerous comments and suggestions urging the creation of an exception and a safe harbor to protect donations of cybersecurity technology and related services.[18] The digitization of health care delivery and rules designed to increase interoperability and data sharing in the delivery of health care create numerous targets for cyberattacks. The health care industry and the technology used to deliver health care have been described as an interconnected ecosystem where the weakest link in the system can compromise the entire system.[19] Given the prevalence of electronic health record storage, as well as the processing and transit of health records and other critical protected health information (PHI) between and within the components of the health care ecosystem, the risks associated with cyberattacks originating with ''weak links'' are borne by every component of the system.

Although we did not specifically request comments on cybersecurity, numerous commenters on the CMS RFI requested that we create an exception to protect the donation of cybersecurity technology and related services. Likewise, in response to its request for information specifically related to cybersecurity, OIG received overwhelming support for a safe harbor to protect the donation of cybersecurity technology and related services. Many commenters on both requests for information outlined the increasing prevalence of cyberattacks and other threats. Commenters noted that cyberattacks pose a fundamental risk to the health care ecosystem and that data breaches result in high costs to the health care industry and may endanger patients. Moreover, disclosures of PHI through a data breach can result in identity fraud, among other things.

The Health Care Industry Cybersecurity (HCIC) Task Force, created by the Cybersecurity Information Sharing Act of 2015 (CISA),[20] was established in March 2016 and is comprised of government and private sector experts. The HCIC Task Force produced its HCIC Task Force

[17] As noted previously, compensation paid under the call coverage arrangement would not be included when determining whether the limit was exceeded, because the call coverage arrangement in this example fully complies with an applicable exception.

[18] *See, for example,* U.S. Department of Health and Human Services, Office of Inspector General, *Semiannual Report to Congress,* Apr. 1, 2018–Sept. 30, 2018, at 84.

[19] *See, for example,* Health Care Industry Cybersecurity Task Force, *Report on Improving Cybersecurity in the Health Care Industry,* June 2017 (HCIC Task Force Report), *available at https://www.phe.gov/preparedness/planning/cybertf/documents/report2017.pdf.*

[20] Public Law 114–113, 129 Stat. 2242.

Report in June 2017.[21] The HCIC Task Force recommended, among other things, that the Congress ''evaluate an amendment to [the physician self-referral law and the anti-kickback statute] specifically for cybersecurity software that would allow health care organizations the ability to assist physicians in the acquisition of this technology, through either donation or subsidy,'' and noted that the regulatory exception to the physician self-referral law for EHR items and services and the safe harbor for EHR items and services could serve as a template for a new statutory exception.[22]

Based on responses to OIG's request for information, we understand that the cost of cybersecurity technology and related services has increased dramatically, to the point where some providers and suppliers are unable to invest in and, therefore, have not invested in, adequate cybersecurity measures. Therefore, we believe that allowing entities that are willing to donate certain cybersecurity technology and related services, with appropriate safeguards, would greatly strengthen the entire health care ecosystem. Although donated technology and services may have value for the recipients of a donation insomuch as the recipient would be able to use its resources for needs other than cybersecurity expenses, we believe that a primary reason donors would provide cybersecurity technology and related services is to protect themselves from cyberattacks. As previously noted, the risks associated with a cyberattack on a single provider or supplier in an interconnected system are ultimately borne by every player in the system. Thus, an entity wishing to protect itself from cyberattacks has a vested interest in ensuring that the physicians with whom the entity shares data are also protected from cyberattacks, particularly where the connections allow the physicians to establish bidirectional interfaces with the entity, which inherently present higher risk than connections that permit physicians ''read-only'' access to the entity's data systems. We believe that certain cybersecurity donations would not pose a risk of program or patient abuse, provided that they satisfy all the requirements of the proposed exception, and that the exception we are proposing in this proposed rule, if finalized, would promote increased security for interconnected and interoperable health care IT systems without protecting potentially abusive arrangements.

We are proposing to protect nonmonetary remuneration in the form of certain types of cybersecurity technology and related services. We are proposing to include within the scope of covered technology any software or other type of IT, other than hardware. In section II.E.2.e. of this proposed rule, we are alternatively proposing to permit the donation of certain cybersecurity hardware under certain circumstances. In an effort to foster beneficial cybersecurity donation arrangements without permitting arrangements that pose a risk of program or patient abuse, the proposed exception at § 411.357(bb) would impose a number of requirements for cybersecurity donations, as set forth below. Notably, the proposed exception would require the donation to be necessary and used predominantly to implement, maintain, or reestablish cybersecurity.

a. Definitions

We are proposing to define the terms ''cybersecurity'' and ''technology.'' Because the definition of ''cybersecurity'' would also apply to our proposal to explicitly permit the donation of cybersecurity software and services under § 411.357(w), we are proposing to include the definition of ''cybersecurity'' in our regulations at § 411.351. The proposed definition of ''technology,'' on the other hand, would be applicable only to the proposed exception for the donation of cybersecurity technology and related services and, therefore, would be included in the regulation text at proposed § 411.357(bb)(2). We are proposing to define the term ''cybersecurity'' to mean the process of protecting information by preventing, detecting, and responding to cyberattacks and define the term ''technology'' to mean any software or other type of information technology other than hardware.

We intend to interpret ''cybersecurity'' broadly and our proposed definition is derived from the National Institute for Standards and Technology (NIST) Framework for Improving Critical Infrastructure,[23] a framework that does not apply specifically to the health care industry, but applies generally to any United States critical infrastructure. Our goal is to broadly define cybersecurity and avoid unintentionally limiting donations by relying on a narrow definition or a definition that might become obsolete over time. We solicit comment on this approach and whether a definition tailored to the health care industry would be more appropriate.

Our proposed definition of ''technology'' is similarly broad. We intend to be neutral with respect to the types of non-hardware cybersecurity technology to which the exception would be applicable. We intend for this exception to be broad enough to include cybersecurity software and other IT, such as an Application Programming Interface (API), which is neither software nor a service as those terms are generally used, that is available now and technology that may become available as the industry continues to develop. The definition of ''technology'' for purposes of the proposed exception excludes hardware. Although we recognize that effective cybersecurity may require hardware that meets certain standards (for example, encrypted endpoints or updated servers), we are concerned that donations of valuable, multifunctional hardware may pose a risk of program or patient abuse. We believe that donations of technology that may be used for purposes other than cybersecurity present a risk that the donation is being made to influence referrals. Hardware is usually multifunctional and, as a result, likely would not be necessary and used predominantly to implement, maintain, or reestablish effective cybersecurity. To illustrate this policy, the proposed exception would not protect a laptop computer or tablet used in the general course by a physician to enter patient visit information into an EHR and respond to emails. However, it would protect encryption software for the laptop computer or tablet. Our proposal is consistent with a similar exclusion of hardware in the EHR exception at § 411.357(w). (See 71 FR 45149 for a discussion of our rationale for excluding hardware from protection under the EHR exception.) We solicit comments on this approach.

We are considering two alternative proposals that would allow for the donation of certain cybersecurity hardware. Under the first alternative proposal, the exception at § 411.357(bb) would cover specific hardware that is necessary for cybersecurity, provided that the hardware is stand-alone (that is, is not integrated within multifunctional equipment) and serves only cybersecurity purposes (for example, a two-factor authentication dongle). We solicit comments on what types of hardware might qualify and whether we should protect them under the proposed exception. Under our second alternative

[21] HCIC Task Force Report, *available at https://www.phe.gov/preparedness/planning/cybertf/documents/report2017.pdf.*

[22] *Id.* at 27.

[23] Appendix B, Version 1.1 (April 16, 2018) *available at https://nvlpubs.nist.gov/nistpubs/CSWP/NIST.CSWP.04162018.pdf.*

proposal, we would permit entities to donate a broader range of cybersecurity technology, including hardware, provided that specified requirements are satisfied. We discuss the second alternative proposal in section II.E.2.e. of this proposed rule.

Finally, we note that the proposed exception only protects items and services that meet the definition of cybersecurity technology and related services. It does not extend to other types of cybersecurity measures outside of technology or services. For example, the proposed exception would not protect donations of installation, improvement, or repair of infrastructure related to physical safeguards, even if they could improve cybersecurity (for example, upgraded wiring or installing high security doors). Donations of infrastructure upgrades are extremely valuable and have multiple benefits in addition to cybersecurity, and, thus, pose an increased risk that one purpose of the donation is to pay for or influence a physician's referrals to the donor entity.

b. Conditions on Donation and Protected Donors

At § 411.357(bb)(1)(i), we are proposing to limit the applicability of the exception for cybersecurity technology and related services to donated technology or services that are necessary and predominantly used to implement, maintain, or reestablish cybersecurity. The goal of this condition is to ensure that donations are being made for the purposes of addressing legitimate cybersecurity needs of donors and recipients; that is, the core function of the donated technology or service must be to protect information by preventing, detecting, and responding to cyberattacks. Our intent is to protect a wide range of technology and services that are specifically donated for the purpose of, and are necessary for, ensuring that donors and recipients have cybersecurity.

As stated previously, we are taking a neutral position with respect to protected technology, including as to the types and versions of software that can receive protection. We do not distinguish between cloud-based software and software that must be installed locally. The types of technology potentially protected under the proposed exception include, but are not limited to, software that provides malware prevention, software security measures to protect endpoints that allow for network access control, business continuity software, data protection and encryption, and email traffic filtering. We believe these examples are indicative of the types of technology that are necessary and used predominantly for cybersecurity. We solicit comments on the proposed breadth of protected technology as well as whether we should expressly include (or exclude) other technology or categories of technology in the proposed exception.

Similarly, we are proposing to protect a broad range of services. Such services could include—

- Services associated with developing, installing, and updating cybersecurity software;
- Cybersecurity training services, such as training recipients on how to use the cybersecurity technology, how to prevent, detect, and respond to cyber threats, and how to troubleshoot problems with the cybersecurity technology (for example, ''help desk'' services specific to cybersecurity);
- Cybersecurity services for business continuity and data recovery services to ensure the recipient's operations can continue during and after a cybersecurity attack;
- ''Cybersecurity as a service'' models that rely on a third-party service provider to manage, monitor, or operate cybersecurity of a recipient;
- Services associated with performing a cybersecurity risk assessment or analysis, vulnerability analysis, or penetration test; or
- Services associated with sharing information about known cyber threats, and assisting recipients responding to threats or attacks on their systems.

We believe these types of services are indicative of the types of services that are necessary and used predominantly for cybersecurity. We solicit comments on the proposed breadth of protected services as well as whether we should expressly include (or exclude) other services or categories of services in the proposed exception. In all cases, the donation of services must be nonmonetary. For example, donating the time of a consultant to implement a cybersecurity program could be protected, but if an entity were to experience a cyberattack that involved ransomware, payment of the ransom amount for a recipient would not be protected.

We reiterate that, although technology or services may have multiple uses, the proposed exception would only protect donations of technology and services that are used predominantly to implement, maintain, and reestablish cybersecurity. As explained in the discussion of the definition of technology, we remain concerned that donations of valuable multi-use technology or services pose a risk of program or patient abuse. The proposed exception would not protect donations of technology or services that are otherwise used in the normal course of the recipient's business (for example, general help desk services related to use of a practice's IT). We solicit comment on this approach and whether this proposed limitation would prohibit the donation of cybersecurity technology and related services that are vital to improving the cybersecurity posture of the health care industry.

For the purposes of meeting the proposed requirement at § 411.357(bb)(1)(i) that the technology or services are necessary to implement, maintain, or reestablish cybersecurity, we are considering, and seek comment on, whether to deem certain arrangements to satisfy this requirement. (The deeming provision would not affect the requirement that the technology or services are used predominantly to implement, maintain, or reestablish cybersecurity. Parties would have to show on a case-by-case basis that this requirement is met.) Specifically, if we determine that a deeming provision is appropriate, we would deem donors and recipients to satisfy the requirement that the technology or services are necessary to implement, maintain, or reestablish cybersecurity if the parties demonstrate that the donation furthers a recipient's compliance with a written cybersecurity program that reasonably conforms to a widely-recognized cybersecurity framework or set of standards. Examples of such frameworks and sets of standards include those developed or endorsed by NIST, another American National Standards Institute-accredited standards body, or an international voluntary standards body such as the International Organization for Standardization. If finalized, the deeming provision would not require compliance with a specific framework or specific set of standards; rather, a deeming provision would merely provide an option for donors to demonstrate that the donation is necessary to implement, maintain, or reestablish cybersecurity. We believe that a deeming provision would provide some assurance to donors and recipients about how to demonstrate that donations are necessary to secure IT systems, devices, and patient data. We solicit comments on incorporating a deeming provision in § 411.357(bb)(1)(i), including comments on ways that parties could reliably demonstrate that a donation furthers a recipient's compliance with a written cybersecurity program that reasonably

conforms to a widely-recognized cybersecurity framework or set of standards. For example, we seek comments on whether parties could demonstrate that a donation meets the cybersecurity deeming provision through documentation, certifications, or other methods not proscribed by regulation, as well as what qualifies as a widely recognized cybersecurity framework or set of standards.

At proposed § 411.357(bb)(1)(ii), we would require that donors not condition the amount or nature of, or eligibility for, cybersecurity donations on referrals. In other words, we are proposing that a donor could not require, explicitly or implicitly, that a recipient either refer to the donor or recommend the donor's business as a condition of receiving a cybersecurity donation. We understand that the purpose of donating cybersecurity technology and related services is to guard against threats that come from interconnected systems, and we understand and expect that a donor would provide the cybersecurity technology and related services only to physicians that connect to its systems, which includes physicians that refer to the donor. However, this condition would restrict a donor from *conditioning* the donation on referrals or other business generated.[24]

Nothing in the proposed requirements of the exception is intended to require a donor to donate cybersecurity technology and related services to every physician that connects to its system. Donors would be able to select recipients in a variety of ways, provided that neither a recipient's eligibility, nor the amount or nature of the cybersecurity technology or related services donated, is determined in a manner that directly takes into account the volume or value of referrals or other business generated between the parties. For example, a donor could perform a risk assessment of a potential recipient (or require a potential recipient to provide the donor with a risk assessment) before determining whether to make a donation or the scope of a donation. If a donor is a hospital, the hospital might choose to limit donations to physicians who are on the hospital's medical staff. Or, the donor might select recipients based on the type of actual or proposed interface between them. For example, an entity may elect to provide a higher level of cybersecurity technology and services to a physician with whom it has a higher-risk, bi-directional read-write connection than the entity would provide to a physician with whom it has a read-only connection to a properly implemented, standards-based API that enables only the secure transmission of a copy of the patient's record to the physician. We solicit comments on this requirement.

In contrast to the similar requirement in the EHR exception at § 411.357(w)(6), the proposed exception for cybersecurity technology and related services does not include a list of selection criteria which, if met, would be deemed not to directly take into account the volume or value of referrals or other business generated by the physician. Our intent in proposing this exception is to remove obstacles to the adoption of cybersecurity in the health care industry in order to address the growing threat of cyberattacks. We are concerned that deeming provisions pertaining to the volume or value of referrals or other business generated may be interpreted as prescriptive requirements. It is our experience that deeming provisions may act as limits on the type or range of items or services that are deemed acceptable. Because we do not want to inhibit legitimate cybersecurity donations that may not fit squarely within an enumerated deeming provision, we are not proposing any deeming provisions pertaining to the requirement at proposed § 411.357(bb)(1)(ii). At the same time, we recognize that some parties may prefer the guidance and assurance offered by deeming provisions, even if the deeming provisions are only ''safe harbors'' and are not requirements of the exception. Therefore, we are soliciting comments on whether we should include deeming provisions in the exception for cybersecurity donations that are similar to the provisions at § 411.357(w)(6). We solicit comments on this approach and any other conditions or permitted conduct we should enumerate in this exception.

We do not propose to restrict the types of entities that may make cybersecurity donations under this exception. Although donating cybersecurity technology and related services would relieve a recipient of a cost that it otherwise would incur, the fraud and abuse risks associated with cybersecurity are different than donations of other valuable technology, such as EHR items and services.

Several commenters to OIG's request for information suggest that technology donations risk making referral sources beholden to the donors. Therefore, we are considering narrowing the scope of entities that may provide remuneration under the exception as we have done in other exceptions, such as the EHR exception. We solicit comments on whether particular types of entities should be excluded from donating cybersecurity technology and related services, and if so, why. Specifically, in past rulemakings we have distinguished between individuals and entities with direct and primary patient care relationships that have a central role in the health care delivery infrastructure, such as hospitals and physician practices, and suppliers of ancillary services, such as laboratories, and manufacturers or vendors that indirectly furnish items and services used in the care of patients. (For a discussion of our rationale in past rulemakings, see 78 FR 78757 through 78762.) We seek comments as to whether our historical concerns and other considerations regarding direct and indirect patient care apply in the context of cybersecurity donations.

c. Conditions for Recipients

In proposed § 411.357(bb)(1)(iii), we are proposing a requirement that neither a potential recipient, nor a potential recipient's practice (including employees or staff members), may make the receipt of cybersecurity technology and related services, or the amount or nature of the technology or services, a condition of continuing to do business with the donor. This requirement mirrors a requirement in the EHR exception at § 411.357(w)(5). We solicit comments on this proposed requirement.

We are not proposing to require a recipient contribution under the exception for cybersecurity technology and related services. As we explained previously, with this proposed exception, we seek to remove a barrier to donations that improve cybersecurity throughout the health care industry in response to the critical cybersecurity issues identified in the HCIC Task Force Report, by commenters to the CMS RFI and OIG request for information, and elsewhere. We are proposing to include only those requirements under the proposed exception that we believe are necessary to ensure that the arrangements do not pose a risk of program or patient abuse. In the case of cybersecurity technology and related services, we do not believe that requiring a minimum contribution to the cost by the recipient is necessary or, in some cases, practical. We recognize that the level of services for each recipient might vary, and might be higher or lower each year, each month, or even each week, resulting in the inability of certain physician practices, especially those in rural areas, to make the required contribution, which, in

[24] We note that, if a system is only as strong as its weakest link, then even a very low-referring physician's practice poses a cybersecurity risk.

turn, risks the overall cybersecurity of the health ecosystem of which the practices are a part. Similarly, donors may aggregate the cost of certain services across all recipients, such as cybersecurity patches and updates, on a regular basis, which may result in a contribution requirement becoming a barrier to widespread, low-cost improvements in cybersecurity because of the amount allocated to each recipient. Moreover, if physicians are not required to utilize resources to contribute to the cost of cybersecurity that benefits both the donor and the physician, they will instead have the flexibility to contribute to the overall cybersecurity of the health care system by using available resources for otherwise unprotected cybersecurity-related hardware that is core to their business, including updates or replacements for outdated legacy hardware that may pose a cybersecurity risk.

Importantly, although the proposed exception would not require a recipient to contribute to the cost of donated cybersecurity technology or related services, the exception would not prohibit donors from requiring such a contribution. Donors are free to require recipients to contribute to the cost, and such contributions would be excepted under proposed § 411.357(bb), provided that the arrangement satisfies all other requirements of the proposed exception, including the requirement at proposed § 411.357(bb)(ii) regarding determinations of the eligibility for or the amount or nature of the donated cybersecurity technology and related services. For example, if a donor gave a full suite of cybersecurity technology and related services at no cost to a high-referring practice but required a low-referring practice to contribute 20 percent of the cost, then the donor could violate the conditions at proposed § 411.357(bb)(1)(ii).

d. Written Documentation

At § 411.357(bb)(iv), we are proposing to require that the arrangement is documented in writing. Although we would not interpret this requirement to mean that every item of cybersecurity technology and every potential related cybersecurity service must be specified in the documentation evidencing the arrangement, we expect that written documentation of the arrangement would identify the recipient of the donation and include the following: A general description of the cybersecurity technology and related services provided to the recipient over the course of the arrangement, the timeframe of donations made under the arrangement, a reasonable estimate of the value of the donation(s), and, if applicable, any financial responsibility for the cost of the cybersecurity technology and related services that is shared by the recipient. We are not requiring the parties to document the arrangement in a signed contract, because we believe that this requirement may lead to inadvertent violation of the physician self-referral law, especially in situations where donors need to act quickly and decisively—prior to obtaining the signature of each physician who is considered a party to the arrangement—to provide needed cybersecurity technology or related services to recipients. However, we note that a written agreement between the parties that includes the identified elements would satisfy the proposed writing requirement at § 411.357(bb)(1)(iv). We solicit comments on whether we should specify in regulation which terms should be required to be in writing and, if so, whether they should be the terms discussed in this section II.E.2.d. or whether additional or different terms should be required. We also seek comment regarding whether we should require a signed writing between the parties to the arrangement.

e. Alternative Proposal for Inclusion of Cybersecurity Hardware Donations

We are also proposing and solicit comments on an alternative approach that would allow the donation of cybersecurity hardware, provided that an additional requirement is satisfied. Under this alternative proposal, a protected donation could also include cybersecurity hardware that a donor has determined is reasonably necessary based on cybersecurity risk assessments of its own organization and the potential recipient. We believe that this alternative proposal would provide donors and recipients the ability to provide most types of technology necessary to bolster cybersecurity without creating a risk of program or patient abuse because the hardware would be necessary to implement and maintain effective cybersecurity if it was identified in the cybersecurity risk assessments.

This alternative proposal builds on existing legal requirements and best practices related to information security generally and the health care industry more specifically. NIST Special Publication 800–30, which does not directly apply to the health care industry, but represents industry standards for information security practices, explains that the purpose of a risk assessment is to inform decision makers and support risk responses.[25]

According to NIST, a risk assessment does so by identifying: (i) Relevant threats to organizations or threats directed through organizations against other organizations; (ii) vulnerabilities both internal and external to organizations; (iii) impact ([that is], harm) to organizations that may occur given the potential for threats exploiting vulnerabilities; and (iv) likelihood that harm will occur. The end result is a determination of risk ([that is], typically a function of the degree of harm and likelihood of harm occurring). With respect to health care organizations, the HHS Office for Civil Rights has explained that conducting a risk analysis is the first step in identifying and implementing safeguards that comply with and carry out the standards and implementation specifications in the Health Information Technology for Economic and Clinical Health (HITECH) Act (Title XIII of the American Recovery and Reinvestment Act of 2009, Pub. L. 111–5). (For more information, see HHS Guidance on Risk Analysis at *https://www.hhs.gov/hipaa/for-professionals/security/guidance/guidance-risk-analysis/index.html?language=es.*) We believe that risk assessments are a key component to developing effective organization-wide risk management for information security and that, when conducted consistent with industry standards, would provide a reasonable basis for donors to identify risks and threats to their organizational information security that could be mitigated by donating cybersecurity hardware to physicians who connect with their IT systems. We expect that donations made in response to a risk or threat identified through a cybersecurity risk assessment would satisfy the core requirement of the proposed exception; that is, that the donated cybersecurity technology and related services are necessary to implement and maintain effective cybersecurity.

Under this alternative proposal, a donor must have a cybersecurity risk assessment that identifies the recipient as a risk to its cybersecurity. In addition, the recipient must have a cybersecurity risk assessment (which may be provided by the donor if all the requirements of proposed § 411.357(bb) are satisfied) that would provide a reasonable basis to determine that the donated cybersecurity hardware is needed to address a risk or threat identified by a

[25] NIST Special Publication 800–30 Revision 1, *Guide for Conducting Risk Assessments* (Sept. 2012), *available at https://nvlpubs.nist.gov/nistpubs/legacy/sp/nistspecialpublication800–30r1.pdf.*

risk assessment. Both risk assessments must be conducted in a manner consistent with industry standards. We are proposing to base our definition of ''risk assessment'' on NIST Special Publication 800–30 and we are soliciting comment on whether such a definition would be sufficient for purposes of our proposed exception and the alternative proposal to allow donations of hardware. We are also soliciting comment on whether we should include specific standards for cybersecurity risk assessments as independent requirements of the exception at § 411.357(bb) if we finalize this alternative proposal, and whether the requirement that any donated cybersecurity hardware must be necessary and used predominantly for cybersecurity obviates the need for requiring that the recipient has a cybersecurity risk assessment. Finally, we are interested in commenters' perspectives as to whether the requirement that both the donor and recipient have cybersecurity risk assessments: (1) Is necessary in light of other laws and regulations that require similar risk assessments; and (2) would inhibit donations of critical cybersecurity technology and related services by diverting resources to the procurement of such risk assessments that could otherwise be used to improve the cybersecurity of the parties to the arrangement or the health care ecosystem as a whole.

As described previously in this section II.E.2., the proposed exception for cybersecurity technology and related services would allow an entity to donate a cybersecurity risk assessment, provided that all of the requirements of the exception are satisfied. One goal of our proposed exception is to eliminate certain barriers to the donation of cybersecurity and related services, in order to increase the cybersecurity of all health care organizations and improve their cybersecurity practices. We believe that protecting the donation of cybersecurity hardware that is reasonably based on the risks or threats identified in a risk assessment (whether or not the risk assessment is donated by the donor) would lead to improved cybersecurity for all health care organizations, especially those organizations that cannot afford to retain dedicated in-house information security personnel or designate an IT staff member with cybersecurity as a collateral duty. We expect that risk assessment practices vary across the health care industry and may be dependent on the size and sophistication of the organization. We are interested in comments that describe the existing practices of potential donors and recipients with respect to the conducting of risk assessments that would provide a reasonable basis to determine that a donation of cybersecurity hardware is reasonable and necessary.

We are considering additional safeguards in the event we finalize this alternate proposal. For instance, we might limit the types of cybersecurity hardware permitted under the alternative proposal by defining ''hardware'' for purposes of § 411.357(bb). We are interested in comments that explain what types of hardware are necessary for effective cybersecurity. Even if we finalize this alternative proposal, multifunctional hardware still would be prohibited because it would not be necessary and predominantly used to implement and maintain effective cybersecurity, as required under proposed § 411.357(bb)(1)(i). We are also considering requiring a 15 percent financial contribution from the recipient, similar to the EHR exception at § 411.357(w)(4). We are interested in comments on this approach, whether a 15 percent financial contribution would be sufficient to ensure that the recipient would use the donated hardware to improve its cybersecurity posture as well as that of the donor, and whether a different financial contribution percentage would be more appropriate and why. We are proposing to exempt small and rural providers from the financial contribution requirement if we finalize this alternative proposal, and we are interested in comments on this approach.

Finally, we are soliciting comments regarding whether we should limit the amount or type of donated hardware by establishing a cap on the value of the donated hardware, either in lieu of or in conjunction with the 15 percent financial contribution.

III. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, 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. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 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 (ICRs):

A. ICRs Regarding Exceptions to the Physician Self-Referral Law Related to Compensation (§ 411.357)

We are proposing new exceptions for compensation arrangements that facilitate value-based health care delivery and payment in a value-based enterprise (§ 411.357(aa)). A value-based enterprise would be required to have a governing document that describes the enterprise and how its VBE participants intend to achieve the value-based purposes of that enterprise (see the proposed definition of ''value-based enterprise'' at § 411.351).

The proposed exception for value-based arrangements with meaningful downside financial risk to the physician at § 411.357(aa)(2) would require a description of the nature and extent of the physician's downside financial risk to be set forth in writing.

The proposed exception for value-based arrangements at § 411.357(aa)(3) would require the arrangement to be set forth in writing and signed by the parties. All proposed exceptions at § 411.357(aa) would require records of the methodology for determining and the actual amount of remuneration paid under the arrangement to be maintained for a period of at least 6 years. We have also proposed a new exception for cybersecurity technology and related services (§ 411.357(bb)), and arrangements under this new exception would have to be documented in writing. Finally, we have proposed streamlining the parties who must sign the writing in the exception for physician recruitment (§ 411.357(e)). The burden associated with writing and signature requirements would be the time and effort necessary to prepare written documents and obtain signatures of the parties. The burden associated with record retention requirements would be the time and effort necessary to compile and store the records.

While the writing, signature, and record retention requirements are

subject to the PRA, we believe the associated burden is exempt under 5 CFR 1320.3(b)(2). We believe that the time, effort, and financial resources necessary to comply with these requirements would be incurred by persons without federal regulation during the normal course of their activities. Specifically, we believe that, for normal business operations purposes, health care providers and suppliers document their financial arrangements with physicians and others and retain these documents in order to identify and be able to enforce the legal obligations of the parties. Therefore, we believe that the writing, signature and record retention requirements should be considered usual and customary business practices.

If you comment on these information collection and recordkeeping requirements, please do either of the following:

1. Submit your comments electronically as specified in the **ADDRESSES** section of this proposed rule; or

2. Submit your comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: CMS Desk Officer, CMS–1720–P, Fax: (202) 395–6974; or Email: *OIRA_submission@omb.eop.gov*

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 Statement (or Analysis) (RIA)

A. Statement of Need

This proposed rule aims to remove potential regulatory barriers to care coordination and value-based care created by the physician self-referral law. Currently, certain beneficial arrangements that would advance the transition to value-based care and the coordination of care among providers in both the Federal and commercial sectors may be impermissible under the physician self-referral law. Industry stakeholders have informed us that, because the consequences of noncompliance with the physician self-referral law are so dire, providers, suppliers, and physicians may be discouraged from entering into innovative arrangements that would improve quality outcomes, produce health system efficiencies, and lower costs (or slow their rate of growth). This proposed rule would address this issue by establishing three new exceptions that would protect certain arrangements for value-based activities between physicians and entities that furnish designated health services in a value-based enterprise. These exceptions would provide critically needed flexibility for physicians and entities to work together while protecting the integrity of the Medicare program. We believe this new flexibility will promote innovation throughout the health care system.

Commenters on the CMS RFI also told us that they currently invest sizeable resources to comply with the physician self-referral law's billing and claims submission prohibitions and thereby avoid its substantial penalties. Our proposals that do not directly address value-based arrangements seek to balance genuine program integrity concerns against this considerable burden. These proposals would reassess our regulations to ensure they appropriately reflect the scope of the statute's reach, establish exceptions for common nonabusive compensation arrangements between physicians and the entities to which they refer Medicare beneficiaries for designated health services, and provide critically necessary guidance for physicians and health care providers and suppliers whose financial relationships are governed by the physician self-referral law. We believe these reforms will greatly reduce burden by providing additional flexibility to enable parties to enter into nonabusive arrangements and by making physician self-referral law compliance more straightforward.

B. Overall Impact

We have examined the impact 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), the Congressional Review Act (5 U.S.C. 804(2)), and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017).

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). An RIA must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). This rule is considered to be economically significant. Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), the Office of Information and Regulatory Affairs designated this rule as a major rule, as defined by 5 U.S.C. 804(2).

The RFA requires agencies to analyze options for regulatory relief of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. For purposes of the RFA, most hospitals and most other providers and suppliers are considered small entities, either by nonprofit status or by having revenues of less than $7.5 million to $38.5 million in any 1 year. We anticipate that a large portion of affected entities are small based on these standards. The specific affected entities are discussed later in this section. Individuals and states are not included in the definition of a ''small entity.'' HHS considers a rule to have a significant impact on a substantial number of small entities if it has at least a three percent impact of revenue on at least five percent of small entities. We are not preparing an analysis for the RFA because we have determined, and the Secretary proposes to certify, that this proposed rule would not have a significant economic impact on a substantial number of small entities.

We determined that this proposed rule does not have a significant impact on small businesses because it would likely reduce, not increase, regulatory burden. This proposed rule would not require existing compliant financial relationships to be restructured. Instead, it would provide important new flexibility to enable parties to create new arrangements that advance the transformation to a value-based health care system and remove regulatory barriers to certain beneficial and nonabusive arrangements, such as the donation of cybersecurity technology and services. It would also reduce burden by clarifying certain key provisions found in current regulations. Also, although we expect entities to incur costs, these costs are estimated to be less than $1,000 per entity. These costs are unlikely to have an impact of three percent of revenue, and we expect they will be offset by savings resulting

from this rule. Overall, this proposed rule is accommodating to legitimate financial relationships while reducing regulatory burden and continuing to protect against program and patient abuse.

In addition, section 1102(b) of the Act requires us to prepare an RIA 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 for Medicare payment regulations and has fewer than 100 beds. The impact of this rule on small rural hospitals is minimal. In fact, several provisions of the rule benefit small rural hospitals by giving them more flexibility to maintain operations and participate in innovative arrangements that enhance care coordination and advance the transition to a value-based health care system. Therefore, we are not preparing an analysis for section 1102(b) of the Act because we have determined, and the Secretary certifies, that this proposed rule would not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 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 2019, that threshold is approximately $154 million. This rule imposes no mandates on state, local, or tribal governments, or on the private sector, and reduces regulatory burden on health care providers and suppliers.

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. Since this regulation does not impose any costs on state or local governments, the requirements of Executive Order 13132 are not applicable.

Executive Order 13771, titled Reducing Regulation and Controlling Regulatory Costs, was issued on January 30, 2017 and requires that the costs associated with significant new regulations ''shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations.'' This proposed rule, if finalized, is expected to be a deregulatory action. We seek comment on the economic impact of this proposed rule, including any potential increase or decrease in utilization, any potential effects due to behavioral changes, or any other potential cost savings or expenses to the Government as a result of this rule.

C. Anticipated Effects

This proposed rule would affect physicians and entities with which they have financial relationships that furnish designated health services payable by Medicare. The following items or services are DHS: (1) Clinical laboratory services; (2) physical therapy services; (3) occupational therapy services; (4) outpatient speech-language pathology services; (5) radiology and certain other imaging services; (6) radiation therapy services and supplies; (7) durable medical equipment and supplies; (8) parenteral and enteral nutrients, equipment, and supplies; (9) prosthetics, orthotics, and prosthetic devices and supplies; (10) home health services; (11) outpatient prescription drugs; and (12) inpatient and outpatient hospital services. We do not have data on the number of physicians and entities that furnish designated health services payable by Medicare that have financial relationships, but we believe a substantial fraction of Medicare-enrolled physicians, group practices, hospitals, clinical laboratories, and home health agencies are affected by the physician self-referral law. We anticipate that this proposed rule will have significant, ongoing benefits for the affected physicians and entities and the entire health care system.

To estimate the number of entities directly affected by this rule, we use Medicare enrollment data. According to this data, there were 2,039 single or multispecialty clinics or group practices, 3,139 clinical laboratories (billing independently), 2,043 outpatient physical therapy/speech pathology providers, 2,843 independent diagnostic testing facilities, 11,593 home health agencies, 6,123 inpatient hospitals, 4,233 rural health clinics, 180 comprehensive outpatient rehabilitation facilities, 8,289 federally qualified health centers, and 9,748 medical supply companies enrolled in Medicare in in 2017.[26] In addition, we estimate that 400 physician practices unassociated with single or multispecialty clinics or group practices will independently review and respond to the rule. We request public comment on the entities affected by the rule.

We anticipate that directly affected entities will review the rule upon finalization in order to determine whether to explore newly permissible value-based arrangements and to take advantage of burden-reducing clarifications provided by the rule. We estimate that all directly affected entities described above that would be eligible to use the proposed rules will review the rule. We estimate that reviewing the final rule will require an average of three hours of time each from the equivalent of a compliance officer and a lawyer.

To estimate the costs associated with this review, we use a 2018 wage rate of $34.86 for compliance officers and $69.34 for lawyers from the Bureau of Labor Statistics,[27] and we double those wages to account for overhead and benefits. As a result, we estimate total regulatory review costs of $31.7 million in the first year following finalization of the rule. We seek public comment on these assumptions.

In developing this proposed rule, we have taken great care to ensure that the safeguards against program and patient abuse in our proposed new exceptions impose the minimum burden possible while providing full protection against overutilization and other harms against which the physician self-referral law is designed to protect. For example, we believe a value-based enterprise would ordinarily develop a governing document that describes the value-based enterprise and how the VBE participants intend to achieve its value-based purpose(s), so our requirement would not impose any additional burden. We also believe that parties to an arrangement under which remuneration is paid already keep business records necessary for a variety of purposes, such as income tax filings, records of compliance with state laws (including fee splitting laws), and, for nonprofit entities, justification for tax-exempt status. Therefore, we do not believe the proposed requirement to maintain records of the methodology for determining and the actual amount of remuneration paid under a value-based arrangement for a period of at least 6 years imposes additional burden. In addition, we believe that physicians and entities routinely document their financial arrangements in writing as a common good business practice and so the arrangements can be enforced. For

[26] CMS Program Statistics, *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/CMSProgramStatistics/2017/2017_Providers.html.*

[27] U.S. Department of Labor, Bureau of Labor Statistics, May 2018 National Occupational Employment and Wage Estimates United States, *https://www.bls.gov/oes/2018/may/oes_nat.htm.*

example, we believe that an entity would ordinarily ensure that the details of a shared loss repayment agreement are documented in writing to ensure the arrangement can be enforced under state law. Similarly, we believe that entities that are working together to achieve a purpose would routinely monitor their operations to confirm that their plans are working as intended. We seek comments on these assumptions.

The new exceptions for arrangements that facilitate value-based health care delivery and payment have numerous benefits that would reduce costs and improve quality not only for Medicare and its beneficiaries but to patients and the health care system in general. For example, these new exceptions provide important new flexibility for physicians and entities to work together to improve patient care and reduce costs. This increased flexibility would provide new opportunities for the private sector to develop and implement cost-saving, quality-improving programs that might currently be impermissible. We anticipate that implementation of improvements and efficiencies such as care redesign protocols resulting from private sector innovation could have a beneficial effect on the care provided to Medicare beneficiaries and thereby result in savings for beneficiaries and the Trust Funds. We believe that these new exceptions would also increase participation in Innovation Center models because, unlike the fraud and abuse waivers that have been issued for certain Innovation Models, the exceptions would not expire and would not be narrowly designed to apply solely to one specific model. We anticipate that this increased participation would bolster the cost savings and quality improvements of Innovation Center models. We also believe that applying the new exceptions would make compliance more straightforward for physicians and entities participating in Innovation Center models, thus resulting in cost savings for these parties. In addition, we believe that the new exceptions for arrangements that facilitate value-based health care delivery and payment would ensure that the physician self-referral law continues to provide meaningful protection against overutilization and other harms, thus preventing increased Medicare expenditures and associated beneficiary liability. We lack data to quantify these effects and seek public comment on these impacts.

We believe that the clarifications and regulatory revisions of key terminology (specifically, the terms ''commercially reasonable'' and ''fair market value,'' the volume or value standard, and the other business generated standard) discussed in section II.B. of this proposed rule would have significant, ongoing benefits to all physicians and entities affected by the physician self-referral law. These terms are used throughout the physician self-referral regulations. Commenters on the CMS RFI indicated that additional guidance on these terms is necessary to reduce the complexity of structuring financial arrangements to comply with the physician self-referral law.

We anticipate that the proposed changes to decouple the physician self-referral law regulations from the anti-kickback statute and federal and state laws or regulations governing billing or claims submission would reduce burden by making compliance more straightforward for physicians and entities. We stress that the anti-kickback statute and billing laws remain in full force and effect, so those laws would continue to protect against program and patient abuse. We anticipate that our proposed changes to the definitions of ''designated health services,'' ''physician,'' and ''remuneration;'' the proposed ownership and investment interest provisions in § 411.354(b); and the proposed exception for remuneration unrelated to the provision of designated health services would reduce compliance burden by providing protection for nonabusive financial relationships. Our proposed changes for the exception for payments by a physician and the exception to fair market value would make these exceptions available to protect financial arrangements that must currently be protected by other exceptions that are more complicated and burdensome to meet. We anticipate that this added flexibility would provide substantial burden reduction through reduced compliance costs. We note that RFI commenters expressed concern about the need for regulatory change to reduce burden on many of these matters.

We have also proposed numerous other changes that while relatively minor, would reduce burden. For example, we believe that the modifications to the group practice rules provide useful clarification to physicians and group practices. We anticipate that even these minor changes would provide a beneficial effect on the burden to comply with the group practice rules. We anticipate that our proposed changes relating to isolated transactions, the period of disallowance, the special rules on compensation arrangements, the exceptions for rental of office space and rental of office equipment, the exception for physician recruitment, and the exception for assistance to compensate a nonphysician practitioner would also have a beneficial impact by reducing the existing burden on physicians and entities through the provision of additional guidance and clarifications. We lack data to quantify these effects and seek public comment on these impacts.

The American Hospital Association estimates compliance costs faced by hospitals.[28] They estimate $350,000 [29] in annual costs for an average hospital to comply with fraud and abuse regulations, which include the physician self-referral rules. To estimate aggregate fraud and abuse compliance costs, we multiply this figure by the number of Medicare enrolled hospitals, which implies $2.1 billion in total annual costs across these hospitals. Based on RFI comments, compliance with the physician self-referral regulations comprises a substantial fraction of these costs. Furthermore, we anticipate that clarifications provided in this rule will substantially reduce the complexity of compliance for affected entities, greatly reducing the burden that they face. As a result, we expect this rule will substantially reduce net fraud and abuse compliance burden for affected entities, although we lack data to quantify these estimates. If this rule reduces this burden for hospitals by 1.5 percent, this burden reduction will offset all first year costs of the rule and generate substantial net savings in subsequent years. We believe it is very likely that burden reduction at hospitals will exceed this level, and therefore tentatively believe that this rule will be considered a deregulatory action. We note that hospitals represent a fraction of entities affected by this rule, and burden is likely to decline substantially for other categories of entities affected by this rule. We seek public comment on the extent to which this rule will reduce compliance burden for hospitals and entities other than hospitals.

Our proposed modifications to the EHR exception are modest and would clarify that protection for certain cybersecurity technology is included as part of an electronic health records arrangement, update provisions regarding interoperability to align with newer CMS and ONC standards in a manner that is not expected to increase costs as a result of this rulemaking, and remove the sunset date. The EHR exception would continue to be available to physicians and entities other than laboratories. We would

[28] *https://www.aha.org/sites/default/files/regulatory-overload-report.pdf.*

[29] Note that the figure is adjusted for inflation between 2017 and 2018.

expect the same entities that are currently using the EHR exception to continue to use the exception. We anticipate that these proposed changes would result in an incremental reduction in compliance burden.

In section II.E. of this proposed rule, we discuss new exceptions for limited remuneration to a physician and cybersecurity technology. We anticipate that the new exception for limited remuneration to a physician would ease compliance burden because it would allow entities to compensate a physician for items or services provided by the physician without being subject to all the documentation and certain other requirements of existing exceptions to the physician self-referral law. We believe this new exception would also provide additional flexibility where these arrangements are not covered by an existing exception. We anticipate that the cybersecurity exception would be widely used by physicians, group practices, and hospitals. We believe this proposed exception would help to address the growing threat of cyberattacks that infiltrate data systems and corrupt or prevent access to health records and other information essential to the safe and effective delivery of health care. We lack data to quantify these effects and seek public comment on these impacts.

D. Alternatives Considered

We carefully considered the alternative of maintaining the status quo and not pursuing regulatory action. However, we believe that the transition to a value-based healthcare system is urgently needed due to unsustainable costs inherent in the current volume-based system. We believe this proposed rule would address the critical need for additional flexibility that is necessary to advance the transition to value-based care and improve the coordination of care among providers in both the Federal and commercial sectors.

We also considered proposing to limit the new exceptions for arrangements that facilitate value-based health care delivery and payment to CMS-sponsored models or establishing separate exceptions with different criteria for arrangements that exist outside CMS-sponsored models. However, we believe that in their current state, the physician self-referral regulations discourage the development and adoption of rewards that encourage change on a broad scale, across all patient populations and payor types, and over indefinite periods of time. In addition, we considered establishing an exception to protect care coordination activities performed outside of a value-based enterprise. We rejected this alternative due to program integrity concerns that could exist without the incentives and protections inherent in a value-based enterprise.

We considered including provisions in the proposed exceptions for value-based arrangements that would require compensation to be set in advance, fair market value, and not determined in any manner that takes into account the volume or value of a physician's referrals or the other business generated between the parties. We are concerned, however, that the inclusion of such requirements would conflict with our goal of dismantling and addressing regulatory barriers to value-based care transformation. We further believe that the disincentives for overutilization, stinting on patient care, and other harms the physician self-referral law was intended to address that are built into the proposed value-based definitions will operate in tandem with the requirements included in the proposed exceptions and be sufficient to protect against program and patient abuse. We are also considering whether to exclude laboratories and DMEPOS suppliers from the definition of VBE participant. It is not clear to us that laboratories and DMEPOS suppliers have the direct patient contacts that would justify their inclusion as parties working under a protected value-based arrangement to achieve the type of patient-centered care that is a core tenet of care coordination and a value-based health care system.

Through our own experience administering the physician self-referral law regulations and our thorough analysis of CMS RFI comments, we recognize the urgent and compelling public policy need for additional guidance on the physician self-referral law. In preparing this rule, we conducted an in-depth review of our existing regulations to identify those matters that might benefit from additional guidance. We have also taken great care to provide this guidance in the clearest, most straightforward manner possible. For example, we considered addressing the need for guidance on the applicability of the physician self-referral law to referrals for inpatient hospital services after admission through modifying the definition of ''referral'' rather than the definition of ''designated health services.'' We are concerned that modifying the definition of ''referral'' could have a broader effect and would not be as clear. We have also carefully weighed each proposal to ensure that it does not pose a risk of program or patient abuse. For example, we considered whether to protect donations of multi-use technology or services in the proposed cybersecurity exception but are concerned that they may pose a risk of program or patient abuse. We seek comments on these regulatory alternatives.

In accordance with the provisions of Executive Order 12866, this proposed rule was reviewed by the Office of Management and Budget.

List of Subjects in 42 CFR Part 411

Diseases, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR part 411 as set forth below:

PART 411—EXCLUSIONS FORM MEDICARE AND LIMITATIONS ON MEDICARE PAYMENT

■ 1. The authority citation for part 411 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395w–101 through 1395w–152, 1395hh, and 1395nn.

Subpart J—Financial Relationships Between Physicians and Entities Furnishing Designated Health Services

■ 2. Amend § 411.351 by—
■ a. Revising the introductory text;
■ b. Adding alphabetically definitions for ''Commercially reasonable'' and ''Cybersecurity'';
■ c. In the definition of ''Designated health services (DHS)'' by revising paragraph (2);
■ d. Removing the definition of ''Does not violate the anti-kickback statute'';
■ e. Revising the definition of ''Electronic health record'';
■ f. Revising the definition of ''Fair market value'';
■ g. Adding alphabetically a definition for ''General market value'';
■ h. Revising the definition of ''Interoperable'';
■ i. Adding alphabetically a definition for ''Isolated financial transaction'';
■ j. In the definition of ''List of CPT/HCPCS Codes'' by removing the term ''website'' and adding in its place the term '' website'';
■ k. In the definition of ''Locum tenens physician (or substitute physician)'' by removing the phrase ''is a physician'' and adding in its place the phrase ''means a physician'';
■ l. Revising the definition of ''Physician'';
■ m. In the definition of ''Referral'' by adding paragraph (4);
■ n. In the definition of ''Remuneration'' by revising paragraphs (2) introductory text and (3)(iii);
■ o. Adding alphabetically a definition for ''Target patient population'';

■ p. Revising the definition of ''Transaction''; and
■ q. Adding alphabetically definitions for ''Value-base activity'', ''Value-based arrangement'', ''Value-based enterprise (VBE)'', ''Value-based purpose'', and ''VBE participant''.

The revisions and additions read as follows:

§ 411.351 Definitions.

The definitions in this subpart apply only for purposes of section 1877 of the Act and this subpart. As used in this subpart, unless the context indicates otherwise:

* * * * *

Commercially reasonable means that the particular arrangement furthers a legitimate business purpose of the parties and is on similar terms and conditions as like arrangements. An arrangement may be commercially reasonable even if it does not result in profit for one or more of the parties.

* * * * *

Cybersecurity means the process of protecting information by preventing, detecting, and responding to cyberattacks.

Designated health services (DHS)

* * *

(2) Except as otherwise noted in this subpart, the term ''designated health services'' or DHS means only DHS payable, in whole or in part, by Medicare. DHS do not include services that are reimbursed by Medicare as part of a composite rate (for example, SNF Part A payments or ASC services identified at § 416.164(a)), except to the extent that services listed in paragraphs (1)(i) through (x) of this definition are themselves payable through a composite rate (for example, all services provided as home health services or inpatient and outpatient hospital services are DHS). For services furnished to inpatients by a hospital, a service is not a designated health service payable, in whole or in part, by Medicare if the furnishing of the service does not affect the amount of Medicare's payment to the hospital under the Acute Care Hospital Inpatient Prospective Payment System (IPPS).

* * * * *

Electronic health record means a repository that includes electronic health information that—

(1) Is transmitted by or maintained in electronic media; and

(2) Relates to the past, present, or future health or condition of an individual or the provision of health care to an individual.

* * * * *

Fair market value means—

(1) *General.* The value in an arm's-length transaction, with like parties and under like circumstances, of like assets or services, consistent with the general market value of the subject transaction.

(2) *Rental of equipment.* With respect to the rental of equipment, the value in an arm's-length transaction, with like parties and under like circumstances, of rental property for general commercial purposes (not taking into account its intended use), consistent with the general market value of the subject transaction.

(3) *Rental of office space.* With respect to the rental of office space, the value in an arm's-length transaction, with like parties and under like circumstances, of rental property for general commercial purposes (not taking into account its intended use), without adjustment to reflect the additional value the prospective lessee or lessor would attribute to the proximity or convenience to the lessor where the lessor is a potential source of patient referrals to the lessee, and consistent with the general market value of the subject transaction.

General market value means—

(1) *General.* The price that assets or services would bring as the result of *bona fide* bargaining between the buyer and seller in the subject transaction on the date of acquisition of the assets or at the time the parties enter into the service arrangement.

(2) *Rental of equipment or office space.* The price that rental property would bring as the result of *bona fide* bargaining between the lessor and the lessee in the subject transaction at the time the parties enter into the rental arrangement.

* * * * *

Interoperable means—

(1) Able to securely exchange data with and use data from other health information technology without special effort on the part of the user;

(2) Allows for complete access, exchange, and use of all electronically accessible health information for authorized use under applicable State or Federal law; and

(3) Does not constitute information blocking as defined in section 3022 of the Public Health Service Act.

Isolated financial transaction—(1) Isolated financial transaction means a transaction involving a single payment between two or more persons or a transaction that involves integrally related installment payments, provided that—

(i) The total aggregate payment is fixed before the first payment is made and does not take into account the volume or value of referrals or other business generated by the physician; and

(ii) The payments are immediately negotiable, guaranteed by a third party, secured by a negotiable promissory note, or subject to a similar mechanism to ensure payment even in the event of default by the purchaser or obligated party.

(2) An isolated financial transaction includes a one-time sale of property or a practice, or similar one-time transaction, but does not include a single payment for multiple or repeated services (such as a payment for services previously provided but not yet compensated).

* * * * *

Physician has the meaning set forth in section 1861(r) of the Act. A physician and the professional corporation of which he or she is a sole owner are the same for purposes of this subpart.

* * * * *

Referral * * *

(4) A referral is not an item or service for purposes of section 1877 of the Act and this subpart.

* * * * *

Remuneration * * *

(2) The furnishing of items, devices, or supplies that are, in fact, used solely for one or more of the following purposes:

* * * * *

(3) * * *

(iii) The amount of the payment is set in advance, does not exceed fair market value, and is not determined in any manner that takes into account the volume or value of any referrals.

* * * * *

Target patient population means an identified patient population selected by a value-based enterprise or its VBE participants based on legitimate and verifiable criteria that—

(1) Are set out in writing in advance of the commencement of the value-based arrangement; and

(2) Further the value-based enterprise's value-based purpose(s).

Transaction means an instance or process of two or more persons or entities doing business.

Value-based activity—(1) Means any of the following activities, provided that the activity is reasonably designed to achieve at least one value-based purpose of the value-based enterprise:

(i) The provision of an item or service;

(ii) The taking of an action; or

(iii) The refraining from taking an action.

(2) The making of a referral is not a value-based activity.

Value-based arrangement means an arrangement for the provision of at least one value-based activity for a target patient population between or among—

(1) The value-based enterprise and one or more of its VBE participants; or

(2) VBE participants in the same value-based enterprise.

Value-based enterprise (VBE) means two or more VBE participants—

(1) Collaborating to achieve at least one value-based purpose;

(2) Each of which is a party to a value-based arrangement with the other or at least one other VBE participant in the value-based enterprise;

(3) That have an accountable body or person responsible for financial and operational oversight of the value-based enterprise; and

(4) That have a governing document that describes the value-based enterprise and how the VBE participants intend to achieve its value-based purpose(s).

Value-based purpose means—

(1) Coordinating and managing the care of a target patient population;

(2) Improving the quality of care for a target patient population;

(3) Appropriately reducing the costs to, or growth in expenditures of, payors without reducing the quality of care for a target patient population; or

(4) Transitioning from health care delivery and payment mechanisms based on the volume of items and services provided to mechanisms based on the quality of care and control of costs of care for a target patient population.

VBE participant means an individual or entity that engages in at least one value-based activity as part of a value-based enterprise.

■ 3. Section 411.352 is amended by revising paragraph (i) to read as follows:

§ 411.352 Group practice.

* * * * *

(i) *Special rules for profit shares and productivity bonuses*—(1) *Overall profits.* (i) Notwithstanding paragraph (g) of this section, a physician in the group practice may be paid a share of overall profits of the group that is indirectly related to the volume or value of the physician's referrals.

(ii) Overall profits means the profits derived from all the designated health services of any component of the group that consists of at least five physicians, which may include all physicians in the group. If there are fewer than five physicians in the group, overall profits means the profits derived from all the designated health services of the group.

(iii) Overall profits must be divided in a reasonable and verifiable manner. The share of overall profits will be deemed not to relate directly to the volume or value of referrals if one of the following conditions is met:

(A) Overall profits are divided *per capita* (for example, per member of the group or per physician in the group).

(B) Overall profits derived from designated health services are distributed based on the distribution of the group's revenues attributed to services that are not designated health services and would not be considered designated health services if they were payable by Medicare.

(C) Revenues derived from designated health services constitute less than 5 percent of the group's total revenues, and the portion of those revenues distributed to each physician in the group constitutes 5 percent or less of his or her total compensation from the group.

(2) *Productivity bonuses.* (i) Notwithstanding paragraph (g) of this section, a physician in the group may be paid a productivity bonus based on services that he or she has personally performed, or services ''incident to'' such personally performed services, that is indirectly related to the volume or value of the physician's referrals (except that the bonus may directly relate to the volume or value of referrals by the physician if the referrals are for services ''incident to'' the physician's personally performed services).

(ii) A productivity bonus must be calculated in a reasonable and verifiable manner. A productivity bonus will be deemed not to relate directly to the volume or value of referrals if one of the following conditions is met:

(A) The productivity bonus is based on the physician's total patient encounters or the relative value units (RVUs) personally performed by the physician. (The methodology for establishing RVUs is set forth in § 414.22 of this chapter.)

(B) The services on which the productivity bonus is based are not designated health services and would not be considered designated health services if they were payable by Medicare.

(C) Revenues derived from designated health services are less than 5 percent of the group's total revenues, and the portion of those revenues distributed to each physician in the group constitutes 5 percent or less of his or her total compensation from the group.

(3) *Value-based enterprise participation.* Profits from designated health services that are directly attributable to a physician's participation in a value-based enterprise, as defined in § 411.351, are distributed to the participating physician.

(4) *Supporting documentation.* Supporting documentation verifying the method used to calculate the profit share or productivity bonus under paragraphs (i)(1), (2), and (3) of this section, and the resulting amount of compensation, must be made available to the Secretary upon request.

■ 4. Section 411.353 is amended—

■ a. By revising paragraph (c)(1);

■ b. In paragraph (f)(1)(i) by removing the semicolon and adding in its place ''; and'';

■ c. In paragraph (f)(1)(ii) by removing ''; and'' and adding in its place a period;

■ d. By removing paragraphs (f)(1)(iii) and (g).

The revision reads as follows:

§ 411.353 Prohibition on certain referrals by physicians and limitations on billing.

* * * * *

(c) * * *

(1) Except as provided in paragraph (e) of this section, no Medicare payment may be made for a designated health service that is furnished pursuant to a prohibited referral.

* * * * *

■ 5. Section 411.354 is amended—

■ a. In paragraph (b)(3)(iv) by removing ''or'' at the end of the paragraph;

■ b. In paragraph (b)(3)(v) by removing the period at the end of the paragraph and adding in its place a semicolon;

■ c. By adding paragraphs (b)(3)(vi) and (vii);

■ d. By revising paragraph (c)(2)(ii);

■ e. By adding paragraph (c)(4);

■ f. By revising paragraphs (d)(2) through (4);

■ g. By adding paragraphs (d)(5) and (6); and

■ h. Adding paragraph (e)(3).

The additions and revisions read as follows:

§ 411.354 Financial relationship, compensation, and ownership or investment interest.

* * * * *

(b) * * *

(3) * * *

(vi) A titular ownership or investment interest that excludes the ability or right to receive the financial benefits of ownership or investment, including, but not limited to, the distribution of profits, dividends, proceeds of sale, or similar returns on investment; or

(vii) An interest in an entity that arises from an employee stock ownership plan (ESOP) that is qualified under Internal Revenue Code section 401(a).

(c) * * *

(2) * * *

(ii) The referring physician (or immediate family member) receives aggregate compensation from the person or entity in the chain with which the

physician (or immediate family member) has a direct financial relationship that takes into account the volume or value of referrals or other business generated by the referring physician for the entity furnishing the DHS, regardless of whether the individual unit of compensation satisfies the special rules on unit-based compensation under paragraphs (d)(2) or (d)(3) of this section. If the financial relationship between the physician (or immediate family member) and the person or entity in the chain with which the referring physician (or immediate family member) has a direct financial relationship is an ownership or investment interest, the determination whether the aggregate compensation takes into account the volume or value of referrals or other business generated by the referring physician for the entity furnishing the DHS will be measured by the nonownership or noninvestment interest closest to the referring physician (or immediate family member). (For example, if a referring physician has an ownership interest in company A, which owns company B, which has a compensation arrangement with company C, which has a compensation arrangement with entity D that furnishes DHS, we would look to the aggregate compensation between company B and company C for purposes of this paragraph (c)(2)(ii));

* * * * *

(4) *Exceptions applicable to indirect compensation arrangements*—(i) *General.* Except as provided in this paragraph (c)(4) of this section, only the exceptions at §§ 411.355 and 411.357(p) are applicable to indirect compensation arrangements.

(ii) *Special rule for indirect compensation arrangements involving value-based arrangements.* When an unbroken chain described in paragraph (c)(2)(i) of this section includes a value-based arrangement (as defined in § 411.351) to which the physician (or the physician organization in whose shoes the physician stands under this paragraph) is a direct party, only the exceptions at §§ 411.355, 411.357(p), and 411.357(aa) are applicable to the indirect compensation arrangement.

(d) * * *

(2) Unit-based compensation (including time-based or per-unit of service-based compensation) is deemed not to take into account the volume or value of referrals if the compensation is fair market value for items or services actually provided and does not vary during the course of the compensation arrangement in any manner that takes into account referrals.

(3) Unit-based compensation (including time-based or per-unit of service-based compensation) is deemed not to take into account other business generated between the parties or other business generated by the referring physician if the compensation is fair market value for items or services actually provided and does not vary during the course of the compensation arrangement in any manner that takes into account referrals or other business generated by the referring physician, including private pay health care business (except for services personally performed by the physician, which are not considered ''other business generated'' by the physician).

(4) If a physician's compensation under a *bona fide* employment relationship, personal service arrangement, or managed care contract is conditioned on the physician's referrals to a particular provider, practitioner, or supplier, all of the following conditions must be met.

(i) The compensation, or a formula for determining the compensation, is set in advance for the duration of the arrangement. Any changes to the compensation (or the formula for determining the compensation) must be made prospectively.

(ii) The compensation is consistent with the fair market value of the physician's services.

(iii) The compensation arrangement otherwise complies with an applicable exception at §§ 411.355 or 411.357.

(iv) The compensation arrangement complies with both of the following conditions:

(A) The requirement to make referrals to a particular provider, practitioner, or supplier is set out in writing and signed by the parties.

(B) The requirement to make referrals to a particular provider, practitioner, or supplier does not apply if the patient expresses a preference for a different provider, practitioner, or supplier; the patient's insurer determines the provider, practitioner, or supplier; or the referral is not in the patient's best medical interests in the physician's judgment.

(v) The required referrals relate solely to the physician's services covered by the scope of the employment, personal service arrangement, or managed care contract, and the referral requirement is reasonably necessary to effectuate the legitimate business purposes of the compensation arrangement. In no event may the physician be required to make referrals that relate to services that are not provided by the physician under the scope of his or her employment, personal service arrangement, or managed care contract.

(5)(i) Compensation from an entity furnishing designated health services to a physician (or immediate family member of the physician) takes into account the volume or value of referrals only if—

(A) The formula used to calculate the physician's (or immediate family member's) compensation includes the physician's referrals to the entity as a variable, resulting in an increase or decrease in the physician's (or immediate family member's) compensation that positively correlates with the number or value of the physician's referrals to the entity; or

(B) There is a predetermined, direct correlation between the physician's prior referrals to the entity and the prospective rate of compensation to be paid over the entire duration of the arrangement for which the compensation is determined.

(ii) Compensation from an entity furnishing designated health services to a physician (or immediate family member of the physician) takes into account the volume or value of other business generated only if—

(A) The formula used to calculate the physician's (or immediate family member's) compensation includes other business generated by the physician for the entity as a variable, resulting in an increase or decrease in the physician's (or immediate family member's) compensation that positively correlates with the physician's generation of other business for the entity; or

(B) There is a predetermined, direct correlation between the other business previously generated by the physician for the entity and the prospective rate of compensation to be paid over the entire duration of the arrangement for which the compensation is determined.

(iii) For purposes of applying this paragraph (d)(5), a positive correlation between two variables exists when one variable decreases as the other variable decreases, or one variable increases as the other variable increases.

(iv) This paragraph (d)(5) applies only to section 1877 of the Act.

(6)(i) Compensation from a physician (or immediate family member of the physician) to an entity furnishing designated health services takes into account the volume or value of referrals only if—

(A) The formula used to calculate the entity's compensation includes the physician's referrals to the entity as a variable, resulting in an increase or decrease in the entity's compensation that negatively correlates with the

number or value of the physician's referrals to the entity; or

(B) There is a predetermined, direct correlation between the physician's prior referrals to the entity and the prospective rate of compensation to be paid over the entire duration of the arrangement for which the compensation is determined.

(ii) Compensation from a physician (or immediate family member of the physician) to an entity furnishing designated health services takes into account the volume or value of other business generated only if—

(A) The formula used to calculate the entity's compensation includes other business generated by the physician for the entity as a variable, resulting in an increase or decrease in the entity's compensation that negatively correlates with the physician's generation of other business for the entity; or

(B) There is a predetermined, direct correlation between the other business previously generated by the physician for the entity and the prospective rate of compensation to be paid over the entire duration of the arrangement for which the compensation is determined.

(iii) For purposes of applying this paragraph (d)(6), a negative correlation between two variables exists when one variable increases as the other variable decreases, or when one variable decreases as the other variable increases.

(iv) This paragraph (d)(6) applies only to section 1877 of the Act.

(e) * * *

(3) *Special rule on writing and signature requirements.* In the case of any requirement in this subpart for a compensation arrangement to be in writing and signed by the parties, the writing requirement or the signature requirement is satisfied if—

(i) The compensation arrangement between the entity and the referring physician fully complies with an applicable exception in this subpart except with respect to the writing or signature requirement of the exception; and

(ii) The parties obtain the required writing(s) or signature(s) within 90 consecutive calendar days immediately following the date on which the compensation arrangement became noncompliant with the requirements of the applicable exception.

■ 6. Section 411.355 is amended by—

■ a. Removing and reserving paragraph (b)(4)(v);

■ b. Revising paragraphs (c)(5) and (e)(1)(ii)(C);

■ c. Adding paragraph (e)(1)(ii)(D);

■ d. Removing paragraph (e)(1)(iv), removing and reserving paragraphs (f)(3) and (4), (g)(2) and (3), (h)(2) and (3), and (i)(2), and removing paragraphs (i)(3) and (j)(1)(iv).

The revisions and addition read as follows:

§ 411.355 General exceptions to the referral prohibition related to both ownership/investment and compensation.

* * * * *

(c) * * *

(5) A coordinated care plan (within the meaning of section 1851(a)(2)(A) of the Act) offered by a Medicare Advantage organization in accordance with a contract with CMS under section 1857 of the Act and part 422 of this chapter.

(e) * * *

(1) * * *

(ii) * * *

(C) The total compensation paid by each academic medical center component is not determined in any manner that takes into account the volume or value of referrals or other business generated by the referring physician within the academic medical center.

(D) If any compensation paid to the referring physician is conditioned on the physician's referrals to a particular provider, practitioner, or supplier, the arrangement satisfies the requirements of § 411.354(d)(4).

* * * * *

■ 7. Section 411.357 is amended—

■ a. By revising paragraphs (a)(3), (a)(5)(i), (b)(2), (b)(4)(i), and (c)(2)(ii);

■ b. By adding paragraph (c)(5);

■ c. By revising paragraph (d)(1)(v);

■ d. By adding paragraph (d)(1)(viii);

■ e. By revising paragraph (d)(2) introductory text;

■ f. By adding paragraph (d)(2)(iv);

■ g. By revising paragraphs (e)(1)(iii) and (e)(4)(i) and (v);

■ h. By removing paragraph (e)(4)(vii);

■ i By revising paragraphs (e)(6)(i), (f)(1) and (3), (g), and (h)(5);

■ j. By adding paragraph (h)(7);

■ k. By revising paragraph (i)(2);

■ l. Adding paragraph (i)(3);

■ m. By removing paragraph (j)(3);

■ n. By removing paragraph (k)(1)(iii);

■ o. In paragraph (k)(2), by removing the term ''website'' and adding in its place the term ''website'';

■ p. By revising paragraphs (l) and (m)(1);

■ q. In paragraphs (m)(2), (3), and (5) by removing the term '' website'' and adding in its place the term '' website'';

■ r. By removing and reserving paragraph (m)(7);

■ s. By revising paragraph (n);

■ t. By removing paragraph (p)(3);

■ u. By revising paragraph (r)(2)(iv);

■ v. By removing paragraph (r)(2)(x);

■ w. By removing paragraph (s)(5);

■ x. By removing paragraph (t)(3)(iv);

■ y. By removing paragraph (u)(3);

■ z. By revising paragraphs (w) introductory text, (w)(2) and (3), and (w)(6) introductory text.

■ aa By removing paragraphs (w)(11) through (13);

■ bb. By revising paragraphs (x)(1) and (4);

■ cc. In paragraph (x)(7)(ii) introductory text by removing the phrase ''patient care services'' is adding in its place the phrase ''NPP patient care services'';

■ dd. In paragraph (x)(7)(ii)(A) by removing the phrase ''patient care services'' and adding in its place the phrase ''NPP patient care services'';

■ ee. By revising paragraph (y)(6)(i);

■ ff. By removing and reserving paragraph (y)(8); and

■ gg. By adding paragraphs (z), (aa), and (bb).

The revisions and additions read as follows:

§ 411.357 Exceptions to the referral prohibition related to compensation arrangements.

(a) * * *

(3) The space rented or leased does not exceed that which is reasonable and necessary for the legitimate business purposes of the lease arrangement and is used exclusively by the lessee when being used by the lessee (and is not shared with or used by the lessor or any person or entity related to the lessor), except that the lessee may make payments for the use of space consisting of common areas if the payments do not exceed the lessee's pro rata share of expenses for the space based upon the ratio of the space used exclusively by the lessee to the total amount of space (other than common areas) occupied by all persons using the common areas. For purposes of this paragraph (a), exclusive use means that the lessee (and any other lessees of the same office space) uses the office space to the exclusion of the lessor (or any person or entity related to the lessor). The lessor (or any person or entity related to the lessor) may not be an invitee of the lessee to use the office space.

* * * * *

(5) * * *

(i) In any manner that takes into account the volume or value of referrals or other business generated between the parties; or

* * * * *

(b) * * *

(2) The equipment leased does not exceed that which is reasonable and necessary for the legitimate business purposes of the lease arrangement and is used exclusively by the lessee when

being used by the lessee (and is not shared with or used by the lessor or any person or entity related to the lessor). For purposes of this paragraph (b), exclusive use means that the lessee (and any other lessees of the same equipment) uses the equipment to the exclusion of the lessor (or any person or entity related to the lessor). The lessor (or any person or entity related to the lessor) may not be an invitee of the lessee to use the equipment.

* * * * *

(4) * * *

(i) In any manner that takes into account the volume or value of referrals or other business generated between the parties; or

* * * * *

(c) * * *

(2) * * *

(ii) Except as provided in paragraph (c)(4) of this section, is not determined in any manner that takes into account the volume or value of referrals by the referring physician.

* * * * *

(5) If remuneration to the physician is conditioned on the physician's referrals to a particular provider, practitioner, or supplier, the arrangement satisfies the requirements of § 411.354(d)(4).

(d) * * *

(1) * * *

(v) The compensation to be paid over the term of each arrangement is set in advance, does not exceed fair market value, and, except in the case of a physician incentive plan (as defined in § 411.351), is not determined in any manner that takes into account the volume or value of referrals or other business generated between the parties.

* * * * *

(viii) If remuneration to the physician is conditioned on the physician's referrals to a particular provider, practitioner, or supplier, the arrangement satisfies the requirements of § 411.354(d)(4).

(2) *Physician incentive plan exception.* In the case of a physician incentive plan (as defined at § 411.351) between a physician and an entity (or downstream contractor), the compensation may be determined in any manner (through a withhold, capitation, bonus, or otherwise) that takes into account the volume or value of referrals or other business generated between the parties, if the plan meets the following requirements:

* * * * *

(iv) If remuneration to the physician is conditioned on the physician's referrals to a particular provider, practitioner, or supplier, the arrangement satisfies the requirements of § 411.354(d)(4).

(e) * * *

(1) * * *

(iii) The amount of remuneration under the arrangement is not determined in any manner that takes into account the volume or value of actual or anticipated referrals by the physician or other business generated between the parties; and

* * * * *

(4) * * *

(i) The writing in paragraph (e)(1) of this section is also signed by the physician practice if the remuneration is provided indirectly to the physician through payments made to the physician practice and the physician practice does not pass directly through to the physician all of the remuneration from the hospital.

* * * * *

(v) The remuneration from the hospital under the arrangement is not determined in any manner that takes into account the volume or value of actual or anticipated referrals by the recruited physician or the physician practice (or any physician affiliated with the physician practice) receiving the direct payments from the hospital.

* * * * *

(6) * * *

(i) This paragraph (e) applies to remuneration provided by a federally qualified health center or a rural health clinic in the same manner as it applies to remuneration provided by a hospital.

* * * * *

(f) * * *

(1) The amount of remuneration under the isolated financial transaction is—

(i) Consistent with the fair market value of the isolated financial transaction; and

(ii) Not determined in any manner that takes into account the volume or value of referrals by the referring physician or other business generated between the parties.

* * * * *

(3) There are no additional transactions between the parties for 6 months after the isolated financial transaction, except for transactions that are specifically excepted under the other provisions in §§ 411.355 through 411.357 and except for commercially reasonable post-closing adjustments that do not take into account the volume or value of referrals or other business generated by the referring physician.

(g) *Remuneration unrelated to the provision of designated health services.* Remuneration provided by a hospital to a physician if the remuneration does not relate to the provision of designated health services. Remuneration does not relate to the provision of designated health services if—

(1) The remuneration is not determined in any manner that takes into account the volume or value of the physician's referrals; and

(2) The remuneration is for an item or service that is not related to the provision of patient care services.

(3) For purposes of this this paragraph (g):

(i) Items that are related to the provision of patient care services include, but are not limited to, any item, supply, device, equipment, or space that is used in the diagnosis or treatment of patients and any technology that is used to communicate with patients regarding patient care services.

(ii) A service is deemed to be not related to the provision of patient care services if the service could be provided by a person who is not a licensed medical professional.

(h) * * *

(5) The compensation paid over the term of the agreement is consistent with fair market value, and the compensation per unit of service is fixed in advance and is not determined in any manner that takes into account the volume or value of referrals or other business generated between the parties.

* * * * *

(7) If remuneration to the physician is conditioned on the physician's referrals to a particular provider, practitioner, or supplier, the arrangement satisfies the requirements of § 411.354(d)(4).

(i) * * *

(2) To an entity as compensation for any other items or services—

(i) That are furnished at a price that is consistent with fair market value; and

(ii) To which the exceptions in paragraphs (a) through (h) of this section are not applicable.

(3) For purposes of this paragraph (i), ''services'' means services of any kind (not merely those defined as ''services'' for purposes of the Medicare program in § 400.202 of this chapter).

* * * * *

(l) *Fair market value compensation.* Compensation resulting from an arrangement between an entity and a physician (or an immediate family member) or any group of physicians (regardless of whether the group meets the definition of a group practice set forth in § 411.352) for the provision of items or services or for the use of office space or equipment, if the arrangement meets the following conditions:

(1) The arrangement is in writing, signed by the parties, and covers only

identifiable items, services, office space, or equipment, all of which are specified in writing.

(2) The writing specifies the timeframe for the arrangement, which can be for any period of time and contain a termination clause, provided that the parties enter into only one arrangement for the same items, services, office space, or equipment during the course of a year. An arrangement may be renewed any number of times if the terms of the arrangement and the compensation for the same items, services, office space, or equipment do not change.

(3) The writing specifies the compensation that will be provided under the arrangement. The compensation must be set in advance, consistent with fair market value, and not determined in any manner that takes into account the volume or value of referrals or other business generated by the referring physician. Compensation for the rental of office space or equipment may not be determined using a formula based on—

(i) A percentage of the revenue raised, earned, billed, collected, or otherwise attributable to the services performed or business generated in the office space or to the services performed on or business generated through the use of the equipment; or

(ii) Per-unit of service rental charges, to the extent that such charges reflect services provided to patients referred by the lessor to the lessee.

(4) The arrangement is commercially reasonable (taking into account the nature and scope of the transaction).

(5) [Reserved]

(6) The services to be performed under the arrangement do not involve the counseling or promotion of a business arrangement or other activity that violates a Federal or State law.

(7) The arrangement satisfies the requirements of § 411.354(d)(4) in the case of—

(i) Remuneration to the physician that is conditioned on the physician's referrals to a particular provider, practitioner, or supplier; or

(ii) Remuneration paid to the group of physicians that is conditioned on one of the group's physician's referrals to a particular provider, practitioner, or supplier.

(m) * * *

(1) The compensation is offered to all members of the medical staff practicing in the same specialty (but not necessarily accepted by every member to whom it is offered) and is not offered in any manner that takes into account the volume or value of referrals or other business generated between the parties.

* * * * *

(n) *Risk-sharing arrangements.* Compensation pursuant to a risk-sharing arrangement (including, but not limited to, withholds, bonuses, and risk pools) between a MCO or an IPA and a physician (either directly or indirectly through a subcontractor) for services provided to enrollees of a health plan. For purposes of this paragraph (n), ''health plan'' and ''enrollees'' have the meanings set forth in § 1001.952(l) of this title.

* * * * *

(r) * * *

(2) * * *

(iv) The hospital, federally qualified health center, or rural health clinic does not determine the amount of the payment in any manner that takes into account the volume or value of referrals by the physician or other business generated between the parties.

* * * * *

(w) *Electronic health records items and services.* Nonmonetary remuneration (consisting of items and services in the form of software or information technology and training services, including certain cybersecurity software and services) necessary and used predominantly to create, maintain, transmit, receive, or protect electronic health records, if all of the following conditions are met:

* * * * *

(2) The software is interoperable (as defined in § 411.351) at the time it is provided to the physician. For purposes of this paragraph (w), software is deemed to be interoperable if, on the date it is provided to the physician, it is certified by a certifying body authorized by the National Coordinator for Health Information Technology to electronic health record certification criteria identified in the then-applicable version of 45 CFR part 170.

(3) The donor (or any person on the donor's behalf) does not engage in a practice constituting information blocking, as defined in section 3022 of the Public Health Service Act, in connection with the donated items or services.

* * * * *

(6) Neither the eligibility of a physician for the items or services, nor the amount or nature of the items or services, is determined in any manner that directly takes into account the volume or value of referrals or other business generated between the parties. For purposes of this paragraph (w), the determination is deemed not to directly take into account the volume or value of referrals or other business generated between the parties if any one of the following conditions is met:

* * * * *

(x) * * *

(1) Remuneration provided by a hospital to a physician to compensate a nonphysician practitioner to provide NPP patient care services, if all of the following conditions are met:

(i) The arrangement—

(A) Is set out in writing and signed by the hospital, the physician, and the nonphysician practitioner; and

(B) Commences before the physician (or the physician organization in whose shoes the physician stands under § 411.354(c)) enters into the compensation arrangement described in paragraph (x)(1)(vi)(A) of this section.

(ii) The arrangement is not conditioned on—

(A) The physician's referrals to the hospital; or

(B) The nonphysician practitioner's NPP referrals to the hospital.

(iii) The remuneration from the hospital—

(A) Does not exceed 50 percent of the actual compensation, signing bonus, and benefits paid by the physician to the nonphysician practitioner during a period not to exceed the first 2 consecutive years of the compensation arrangement between the nonphysician practitioner and the physician (or the physician organization in whose shoes the physician stands); and

(B) Is not determined in any manner that takes into account the volume or value of actual or anticipated—

(*1*) Referrals by the physician (or any physician in the physician's practice) or other business generated between the parties; or

(*2*) NPP referrals by the nonphysician practitioner (or any nonphysician practitioner in the physician's practice) or other business generated between the parties.

(iv) The compensation, signing bonus, and benefits paid to the nonphysician practitioner by the physician does not exceed fair market value for the NPP patient care services furnished by the nonphysician practitioner to patients of the physician's practice.

(v) The nonphysician practitioner has not, within 1 year of the commencement of his or her compensation arrangement with the physician (or the physician organization in whose shoes the physician stands under § 411.354(c))—

(A) Furnished NPP patient care services in the geographic area served by the hospital; or

(B) Been employed or otherwise engaged to provide NPP patient care

services by a physician or a physician organization that has a medical practice site located in the geographic area served by the hospital, regardless of whether the nonphysician practitioner furnished NPP patient care services at the medical practice site located in the geographic area served by the hospital.

(vi)(A) The nonphysician practitioner has a compensation arrangement directly with the physician or the physician organization in whose shoes the physician stands under § 411.354(c); and

(B) Substantially all of the NPP patient care services that the nonphysician practitioner furnishes to patients of the physician's practice are primary care services or mental health care services.

(vii) The physician does not impose practice restrictions on the nonphysician practitioner that unreasonably restrict the nonphysician practitioner's ability to provide NPP patient care services in the geographic area served by the hospital.

* * * * *

(4) For purposes of this paragraph (x), the following terms have the meanings indicated.

(i) ''NPP patient care services'' means direct patient care services furnished by a nonphysician practitioner that address the medical needs of specific patients or any task performed by a nonphysician practitioner that promotes the care of patients of the physician or physician organization with which the nonphysician practitioner has a compensation arrangement.

(ii) ''NPP referral'' means a request by a nonphysician practitioner that includes the provision of any designated health service for which payment may be made under Medicare, the establishment of any plan of care by a nonphysician practitioner that includes the provision of such a designated health service, or the certifying or recertifying of the need for such a designated health service, but does not include any designated health service personally performed or provided by the nonphysician practitioner.

* * * * *

(y) * * *

(6) * * *

(i) In any manner that takes into account the volume or value of referrals or other business generated between the parties; or

* * * * *

(z) *Limited remuneration to a physician*—(1) Remuneration from an entity to a physician for the provision of items or services provided by the physician to the entity that does not exceed an aggregate of $3,500 per calendar year, as adjusted for inflation in accordance with paragraph (z)(2) of this section, if all of the following conditions are satisfied:

(i) The compensation is not determined in any manner that takes into account the volume or value of referrals or other business generated by the physician.

(ii) The compensation does not exceed the fair market value of the items or services.

(iii) The arrangement is commercially reasonable.

(iv) Compensation for the lease of office space or equipment is not determined using a formula based on—

(A) A percentage of the revenue raised, earned, billed, collected, or otherwise attributable to the services performed or business generated in the office space or to the services performed on or business generated through the use of the equipment; or

(B) Per-unit of service rental charges, to the extent that such charges reflect services provided to patients referred by the lessor to the lessee.

(v) Compensation for the use of premises, equipment, personnel, items, supplies, or services is not determined using a formula based on—

(A) A percentage of the revenue raised, earned, billed, collected, or otherwise attributable to the services provided while using the premises, equipment, personnel, items, supplies, or services covered by the arrangement; or

(B) Per-unit of service fees that are not time-based, to the extent that such fees reflect services provided to patients referred by the party granting permission to use the premises, equipment, personnel, items, supplies, or services covered by the arrangement to the party to which the permission is granted.

(2) The annual remuneration limit in this paragraph (z) is adjusted each calendar year to the nearest whole dollar by the increase in the Consumer Price Index—Urban All Items (CPI–U) for the 12-month period ending the preceding September 30. CMS displays after September 30 each year both the increase in the CPI–U for the 12-month period and the new remuneration limit on the physician self-referral website at *http://www.cms.hhs.gov/PhysicianSelfReferral/10_CPI–U_Updates.asp.*

(aa) *Arrangements that facilitate value-based health care delivery and payment*—(1) *Full financial risk*—Remuneration paid under a value-based arrangement, as defined in § 411.351, if the following conditions are met:

(i) The value-based enterprise is at full financial risk (or is contractually obligated to be at full financial risk within the 6 months following the commencement of the value-based arrangement) during the entire duration of the value-based arrangement.

(ii) The remuneration is for or results from value-based activities undertaken by the recipient of the remuneration for patients in the target patient population.

(iii) The remuneration is not an inducement to reduce or limit medically necessary items or services to any patient.

(iv) The remuneration is not conditioned on referrals of patients who are not part of the target patient population or business not covered under the value-based arrangement.

(v) If remuneration paid to the physician is conditioned on the physician's referrals to a particular provider, practitioner, or supplier, the value-based arrangement satisfies the requirements of § 411.354(d)(4)(iv).

(vi) Records of the methodology for determining and the actual amount of remuneration paid under the value-based arrangement must be maintained for a period of at least 6 years and made available to the Secretary upon request.

(vii) For purposes of this paragraph (aa), ''full financial risk'' means that the value-based enterprise is financially responsible on a prospective basis for the cost of all patient care items and services covered by the applicable payor for each patient in the target patient population for a specified period of time. For purposes of this paragraph (aa), ''prospective basis'' means that the value-based enterprise has assumed financial responsibility for the cost of all patient care items and services covered by the applicable payor prior to providing patient care items and services to patients in the target patient population.

(2) *Value-based arrangements with meaningful downside financial risk to the physician*—Remuneration paid under a value-based arrangement, as defined in § 411.351, if the following conditions are met:

(i) The physician is at meaningful downside financial risk for failure to achieve the value-based purpose(s) of the value-based enterprise during the entire duration of the value-based arrangement.

(ii) A description of the nature and extent of the physician's downside financial risk is set forth in writing.

(iii) The methodology used to determine the amount of the remuneration is set in advance of the undertaking of value-based activities for which the remuneration is paid.

(iv) The remuneration is for or results from value-based activities undertaken by the recipient of the remuneration for patients in the target patient population.

(v) The remuneration is not an inducement to reduce or limit medically necessary items or services to any patient.

(vi) The remuneration is not conditioned on referrals of patients who are not part of the target patient population or business not covered under the value-based arrangement.

(vii) If remuneration paid to the physician is conditioned on the physician's referrals to a particular provider, practitioner, or supplier, the value-based arrangement satisfies the requirements of § 411.354(d)(4)(iv).

(viii) Records of the methodology for determining and the actual amount of remuneration paid under the value-based arrangement must be maintained for a period of at least 6 years and made available to the Secretary upon request.

(ix) For purposes of this paragraph (aa), ''meaningful downside financial risk'' means that the physician—

(A) Is responsible to pay the entity no less than 25 percent of the value of the remuneration the physician receives under the value-based arrangement; or

(B) Is financially responsible to the entity on a prospective basis for the cost of all or a defined set of patient care items and services covered by the applicable payor for each patient in the target patient population for a specified period of time.

(3) *Value-based arrangements*—Remuneration paid under a value-based arrangement, as defined in § 411.351, if the following conditions are met:

(i) The arrangement is set forth in writing and signed by the parties. The writing includes a description of—

(A) The value-based activities to be undertaken under the arrangement;

(B) How the value-based activities are expected to further the value-based purpose(s) of the value-based enterprise;

(C) The target patient population for the arrangement;

(D) The type or nature of the remuneration;

(E) The methodology used to determine the remuneration; and

(F) The performance or quality standards against which the recipient will be measured, if any.

(ii) The performance or quality standards against which the recipient will be measured, if any, are objective and measurable, and any changes to the performance or quality standards must be made prospectively and set forth in writing.

(iii) The methodology used to determine the amount of the remuneration is set in advance of the undertaking of value-based activities for which the remuneration is paid.

(iv) The remuneration is for or results from value-based activities undertaken by the recipient of the remuneration for patients in the target patient population.

(v) The remuneration is not an inducement to reduce or limit medically necessary items or services to any patient.

(vi) The remuneration is not conditioned on referrals of patients who are not part of the target patient population or business not covered under the value-based arrangement.

(vii) If the remuneration paid to the physician is conditioned on the physician's referrals to a particular provider, practitioner, or supplier, the value-based arrangement satisfies the requirements of § 411.354(d)(4)(iv).

(viii) Records of the methodology for determining and the actual amount of remuneration paid under the value-based arrangement must be maintained for a period of at least 6 years and made available to the Secretary upon request.

(bb) *Cybersecurity technology and related services.* (1) Nonmonetary remuneration (consisting of certain types of technology and services), if all of the following conditions are met:

(i) The technology and services are necessary and used predominantly to implement, maintain, or reestablish cybersecurity.

(ii) Neither the eligibility of a physician for the technology or services, nor the amount or nature of the technology or services, is determined in any manner that directly takes into account the volume or value of referrals or other business generated between the parties.

(iii) Neither the physician nor the physician's practice (including employees and staff members) makes the receipt of technology or services, or the amount or nature of the technology or services, a condition of doing business with the donor.

(iv) The arrangement is documented in writing.

(2) For purposes of this paragraph (bb), ''technology'' means any software or other types of information technology other than hardware.

§ 411.362 [Amended]

■ 8. Section 411.362 is amended in paragraphs (b)(3)(ii)(C), (c)(2)(iv), (c)(2)(v), and (c)(5) introductory text by removing the term ''website'' each time it appears and adding in its place the term ''website''.

§ 411.372 [Amended]

■ 9. Section 411.372 is amended in paragraph (a) by removing the term ''website'' and adding in its place the term ''website''.

§ 411.384 [Amended]

■ 10. Section 411.384 is amended in paragraph (b) by removing the term ''website'' and adding in its place the term ''website''.

Dated: September 26, 2019.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

Dated: September 27, 2019.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

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Part III

The President

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Presidential Documents

Title 3—

The President

Executive Order 13894 of October 14, 2019

Blocking Property and Suspending Entry of Certain Persons Contributing to the Situation in Syria

By the authority vested in me as President by the Constitution and the laws of the United States of America, including the International Emergency Economic Powers Act (50 U.S.C. 1701 *et seq.*) (IEEPA), the National Emergencies Act (50 U.S.C. 1601 *et seq.*) (NEA), section 212(f) of the Immigration and Nationality Act of 1952 (8 U.S.C. 1182(f)), and section 301 of title 3, United States Code,

I, DONALD J. TRUMP, President of the United States of America, find that the situation in and in relation to Syria, and in particular the recent actions by the Government of Turkey to conduct a military offensive into northeast Syria, undermines the campaign to defeat the Islamic State of Iraq and Syria, or ISIS, endangers civilians, and further threatens to undermine the peace, security, and stability in the region, and thereby constitutes an unusual and extraordinary threat to the national security and foreign policy of the United States. I hereby declare a national emergency to deal with that threat. I hereby determine and order:

Section 1. (a) All property and interests in property that are in the United States, that hereafter come within the United States, or that are or hereafter come within the possession or control of any United States person of the following persons are blocked and may not be transferred, paid, exported, withdrawn, or otherwise dealt in:

(i) any person determined by the Secretary of the Treasury, in consultation with the Secretary of State:

(A) to be responsible for or complicit in, or to have directly or indirectly engaged in, or attempted to engage in, any of the following in or in relation to Syria:

(1) actions or policies that further threaten the peace, security, stability, or territorial integrity of Syria; or

(2) the commission of serious human rights abuse;

(B) to be a current or former official of the Government of Turkey;

(C) to be any subdivision, agency, or instrumentality of the Government of Turkey;

(D) to operate in such sectors of the Turkish economy as may be determined by the Secretary of the Treasury, in consultation with the Secretary of State;

(E) to have materially assisted, sponsored, or provided financial, material, or technological support for, or goods or services to or in support of, any person whose property and interests in property are blocked pursuant to this order; or

(F) to be owned or controlled by, or to have acted or purported to act for or on behalf of, directly or indirectly, any person whose property and interests in property are blocked pursuant to this order.

(b) The prohibitions in subsection (a) of this section apply except to the extent provided by statutes, or in regulations, orders, directives, or licenses that may be issued pursuant to this order, and notwithstanding any contract entered into or any license or permit granted before the date of this order.

Sec. 2. (a) The Secretary of State, in consultation with the Secretary of the Treasury and other officials of the U.S. Government as appropriate, is hereby authorized to impose on a foreign person any of the sanctions described in subsections (b) and (c) of this section, upon determining that the person, on or after the date of this order:

(i) is responsible for or complicit in, has directly or indirectly engaged in, or attempted to engage in, or financed, any of the following:

(A) the obstruction, disruption, or prevention of a ceasefire in northern Syria;

(B) the intimidation or prevention of displaced persons from voluntarily returning to their places of residence in Syria;

(C) the forcible repatriation of persons or refugees to Syria; or

(D) the obstruction, disruption, or prevention of efforts to promote a political solution to the conflict in Syria, including:

(1) the convening and conduct of a credible and inclusive Syrian-led constitutional process under the auspices of the United Nations (UN);
(2) the preparation for and conduct of UN-supervised elections, pursuant to the new constitution, that are free and fair and to the highest international standards of transparency and accountability; or
(3) the development of a new Syrian government that is representative and reflects the will of the Syrian people;

(ii) is an adult family member of a person designated under subsection (a)(i) of this section; or

(iii) is responsible for or complicit in, or has directly or indirectly engaged in, or attempted to engage in, the expropriation of property, including real property, for personal gain or political purposes in Syria.

(b) When the Secretary of State, in accordance with the terms of subsection (a) of this section, has determined that a person meets any of the criteria described in that subsection and has selected one or more of the sanctions set forth below to impose on that person, the heads of relevant departments and agencies, in consultation with the Secretary of State, as appropriate, shall ensure that the following actions are taken where necessary to implement the sanctions selected by the Secretary of State:

(i) agencies shall not procure, or enter into a contract for the procurement of, any goods or services from the sanctioned person; or

(ii) the Secretary of State shall direct the denial of a visa to, and the Secretary of Homeland Security shall exclude from the United States, any alien that the Secretary of State determines is a corporate officer or principal of, or a shareholder with a controlling interest in, a sanctioned person.

(c) When the Secretary of State, in accordance with the terms of subsection (a) of this section, has determined that a person meets any of the criteria described in that subsection and has selected one or more of the sanctions set forth below to impose on that person, the Secretary of the Treasury, in consultation with the Secretary of State, shall take the following actions where necessary to implement the sanctions selected by the Secretary of State:

(i) prohibit any United States financial institution that is a U.S. person from making loans or providing credits to the sanctioned person totaling more than $10,000,000 in any 12-month period, unless such person is engaged in activities to relieve human suffering and the loans or credits are provided for such activities;

(ii) prohibit any transactions in foreign exchange that are subject to the jurisdiction of the United States and in which the sanctioned person has any interest;

(iii) prohibit any transfers of credit or payments between banking institutions or by, through, or to any banking institution, to the extent that

such transfers or payments are subject to the jurisdiction of the United States and involve any interest of the sanctioned person;

(iv) block all property and interests in property that are in the United States, that hereafter come within the United States, or that are or hereafter come within the possession or control of any United States person of the sanctioned person, and provide that such property and interests in property may not be transferred, paid, exported, withdrawn, or otherwise dealt in;

(v) prohibit any United States person from investing in or purchasing significant amounts of equity or debt instruments of the sanctioned person;

(vi) restrict or prohibit imports of goods, technology, or services, directly or indirectly, into the United States from the sanctioned person; or

(vii) impose on the principal executive officer or officers, or persons performing similar functions and with similar authorities, of the sanctioned person the sanctions described in subsections (c)(i)–(c)(vi) of this section, as selected by the Secretary of State.

(d) The prohibitions in subsections (b) and (c) of this section apply except to the extent provided by statutes, or in regulations, orders, directives, or licenses that may be issued pursuant to this order, and notwithstanding any contract entered into or any license or permit granted before the date of this order.

Sec. 3. (a) The Secretary of the Treasury, in consultation with the Secretary of State, is hereby authorized to impose on a foreign financial institution the sanctions described in subsection (b) of this section upon determining that the foreign financial institution knowingly conducted or facilitated any significant financial transaction for or on behalf of any person whose property and interests in property are blocked pursuant to section 1 of this order.

(b) With respect to any foreign financial institution determined by the Secretary of the Treasury, in accordance with this section, to meet the criteria set forth in subsection (a) of this section, the Secretary of the Treasury may prohibit the opening, and prohibit or impose strict conditions on the maintaining, in the United States of a correspondent account or a payable-through account by such foreign financial institution.

(c) The prohibitions in subsection (b) of this section apply except to the extent provided by statutes, or in regulations, orders, directives, or licenses that may be issued pursuant to this order, and notwithstanding any contract entered into or any license or permit granted before the date of this order.

Sec. 4. The unrestricted immigrant and nonimmigrant entry into the United States of aliens determined to meet one or more of the criteria in subsection 1(a) or 2(a) of this order, or aliens for which the sanctions under subsection 2(b)(ii) have been selected, would be detrimental to the interests of the United States, and the entry of such persons into the United States, as immigrants or nonimmigrants, is hereby suspended, except where the Secretary of State determines that the entry of the person into the United States would not be contrary to the interests of the United States, including when the Secretary so determines, based on a recommendation of the Attorney General, that the person's entry would further important United States law enforcement objectives. In exercising this responsibility, the Secretary of State shall consult the Secretary of Homeland Security on matters related to admissibility or inadmissibility within the authority of the Secretary of Homeland Security. Such persons shall be treated in the same manner as persons covered by section 1 of Proclamation 8693 of July 24, 2011 (Suspension of Entry of Aliens Subject to United Nations Security Council Travel Bans and International Emergency Economic Powers Act Sanctions). The Secretary of State shall have the responsibility for implementing this section pursuant to such conditions and procedures as the Secretary has established or may establish pursuant to Proclamation 8693.

Sec. 5. I hereby determine that the making of donations of the types of articles specified in section 203(b)(2) of IEEPA (50 U.S.C. 1702(b)(2)) by, to, or for the benefit of any person whose property and interests in property are blocked pursuant to section 1 of this order would seriously impair my ability to deal with the national emergency declared in this order, and I hereby prohibit such donations as provided by section 1 of this order.

Sec. 6. The prohibitions in sections 1 and 2 of this order include:

(a) the making of any contribution or provision of funds, goods, or services by, to, or for the benefit of any person whose property and interests in property are blocked pursuant to this order; and

(b) the receipt of any contribution or provision of funds, goods, or services from any such person.

Sec. 7. (a) Any transaction that evades or avoids, has the purpose of evading or avoiding, causes a violation of, or attempts to violate any of the prohibitions set forth in this order is prohibited.

(b) Any conspiracy formed to violate any of the prohibitions set forth in this order is prohibited.

Sec. 8. For the purposes of this order:

(a) The term ''entity'' means a partnership, association, trust, joint venture, corporation, group, subgroup, or other organization;

(b) the term ''foreign financial institution'' means any foreign entity that is engaged in the business of accepting deposits, making, granting, transferring, holding, or brokering loans or credits, or purchasing or selling foreign exchange, securities, commodity futures or options, or procuring purchasers and sellers thereof, as principal or agent. The term includes depository institutions, banks, savings banks, money service businesses, trust companies, securities brokers and dealers, commodity futures and options brokers and dealers, forward contract and foreign exchange merchants, securities and commodities exchanges, clearing corporations, investment companies, employee benefit plans, dealers in precious metals, stones, or jewels, and holding companies, affiliates, or subsidiaries of any of the foregoing. The term does not include the international financial institutions identified in 22 U.S.C. 262r(c)(2), the International Fund for Agricultural Development, the North American Development Bank, or any other international financial institution so notified by the Secretary of the Treasury;

(c) the term ''knowingly,'' with respect to conduct, a circumstance, or a result, means that a person has actual knowledge, or should have known, of the conduct, the circumstance, or the result;

(d) the term ''person'' means an individual or entity;

(e) the term ''United States person'' or ''U.S. person'' means any United States citizen, permanent resident alien, entity organized under the laws of the United States or any jurisdiction within the United States (including foreign branches), or any person in the United States; and

(f) the term ''Government of Turkey'' means the Government of Turkey, any political subdivision, agency, or instrumentality thereof, or any person owned or controlled by or acting for or on behalf of the Government of Turkey.

Sec. 9. For those persons whose property and interests in property are blocked pursuant to this order who might have a constitutional presence in the United States, I find that because of the ability to transfer funds or other assets instantaneously, prior notice to such persons of measures to be taken pursuant to this order would render those measures ineffectual. I therefore determine that for these measures to be effective in addressing the national emergency declared in this order, there need be no prior notice of a listing or determination made pursuant to this order.

Sec. 10. The Secretary of the Treasury, in consultation with the Secretary of State, is hereby authorized to take such actions, including the promulgation

of rules and regulations, and to employ all powers granted to the President by IEEPA as may be necessary to carry out the purposes of this order. The Secretary of the Treasury may, consistent with applicable law, redelegate any of these functions within the Department of the Treasury. All departments and agencies of the United States shall take all appropriate measures within their authority to implement this order.

Sec. 11. The Secretary of the Treasury, in consultation with the Secretary of State, is hereby authorized to submit the recurring and final reports to the Congress on the national emergency declared in this order, consistent with section 401(c) of the NEA (50 U.S.C. 1641(c)), and section 204(c) of IEEPA (50 U.S.C. 1703(c)).

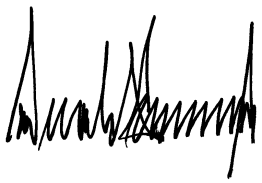
Sec. 12. (a) Nothing in this order shall be construed to impair or otherwise affect:

(i) the authority granted by law to an executive department or agency, or the head thereof; or

(ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(b) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(c) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.



THE WHITE HOUSE,
October 14, 2019.

[FR Doc. 2019–22849
Filed 10–16–19; 11:15 am]
Billing code 3295–F0–P

Presidential Documents

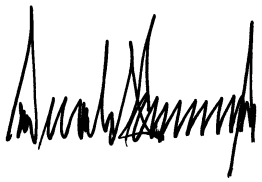
Notice of October 15, 2019

Continuation of the National Emergency With Respect to Significant Narcotics Traffickers Centered in Colombia

On October 21, 1995, by Executive Order 12978, the President declared a national emergency with respect to significant narcotics traffickers centered in Colombia pursuant to the International Emergency Economic Powers Act (50 U.S.C. 1701–1706) to deal with the unusual and extraordinary threat to the national security, foreign policy, and economy of the United States constituted by the actions of significant narcotics traffickers centered in Colombia and the extreme level of violence, corruption, and harm such actions cause in the United States and abroad.

The actions of significant narcotics traffickers centered in Colombia continue to threaten the national security, foreign policy, and economy of the United States and cause an extreme level of violence, corruption, and harm in the United States and abroad. For this reason, the national emergency declared in Executive Order 12978 of October 21, 1995, and the measures adopted pursuant thereto to deal with that emergency, must continue in effect beyond October 21, 2019. Therefore, in accordance with section 202(d) of the National Emergencies Act (50 U.S.C. 1622(d)), I am continuing for 1 year the national emergency with respect to significant narcotics traffickers centered in Colombia declared in Executive Order 12978.

This notice shall be published in the *Federal Register* and transmitted to the Congress.



THE WHITE HOUSE,
October 15, 2019.

[FR Doc. 2019–22852
Filed 10–16–19; 11:15 am]
Billing code 3295–F0–P

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